DRAFT REPORT TO THE MINISTER FOR HEALTH AND AGED CARE

Investigation of breaches found during IOGTR monitoring in Tasmania
and risk assessment advice from GMAC
Date: 29 March 2001

MONSANTO AUSTRALIA LTD past canola trial sites in Tasmania

1. Overview

1.1 This is a draft report to the Minister for Health and Aged Care concerning Monsanto Australia Ltd (Monsanto) non-compliance with recommendations advised by the Genetic Manipulation Advisory Committee (GMAC) in respect of field trials involving genetically modified organisms (GMOs) in Tasmania.

1.2 Investigation reports are confidential because they may contain information provided to the Interim Office of the Gene Technology Regulator (IOGTR) in confidence and/or personal information relating to third parties.

1.3 This draft report will now be provided to the Genetic Manipulation Advisory Committee (GMAC) for final comment. It will also be provided to the Australian Government Solicitor (AGS) for final clearance. It will be provided to Monsanto Australia for comment on matters of fact. A draft will then be prepared. The draft will be provided to the Minister, and to States and Territories (through the Commonwealth/State Consultative Group on Gene Technology) for comment and advice.

1.4 Following receipt of any advice from States and Territories, the report will be finalised. Once the report is finalised, a summary of the IOGTR's investigation, the non-compliance identified and follow up actions taken, will be published in the IOGTR Quarterly Report and the GMAC Annual Report in accordance with standard procedures for the public notification of such incidents of non-compliance.

2. The current system of administrative controls over GMOs

2.1 Prior to the commencement of the Gene Technology Act 2000, Australia does not currently have a system of legislative controls in place to regulate dealings with GMOs. Rather, it relies on a system of voluntary compliance whereby:

2.1.1 Companies, research organisations and other entities dealing with GMOs choose to submit information about a GMO to GMAC;

2.1.2 GMAC assesses the biosafety risks (being risks to the environment and/or risks to human health and safety) associated with the GMO;

2.1.3 GMAC provides recommendations to the company, research organisation or other entity about any biosafety risks and how those risks should be managed; and

2.1.4 The organisation, research institute or other entity voluntarily implements and complies with those recommendations.

2.2 The voluntary administrative system is overseen by the IOGTR, which provides secretariat services to GMAC. The IOGTR is also responsible for developing and implementing the national regulatory system that will replace the administrative arrangements from 21 June 2001.

2.3 Despite being a voluntary system, the IOGTR relies on a number of mechanisms for identifying non-compliance (consistent with other regulatory schemes):

2.3.1 Self-reporting by entities dealing with GMOs as required under the GMAC Guidelines for the Deliberate Release of Genetically Modified Organisms;

2.3.2 Notification of possible breaches by third parties; and

2.3.3 Independent monitoring undertaken by the IOGTR and other experts in accordance with the IOGTR's monitoring strategy.

2.4 The IOGTR's monitoring strategy was implemented in 2000. Under the strategy, the IOGTR has undertaken to carry out random inspections of 20% of the current field trials involving GMOs in a calendar year. The crucial period for monitoring of each field trial considered by GMAC is when there is the highest risk to the environment or to human health and safety, for example when crops are planted, are flowering or at harvest. To meet the 20% target over 12 months a minimum of 5% of current trials must be inspected each quarter.

2.5 Each monitoring visit is tailored to the GMAC recommendations made in respect of a specific trial. A monitoring visit may involve, for example:

2.5.1 interviews with the company personnel, the owner of the property or other personnel involved in the trial or post trial monitoring;

2.5.2 observation of activities, and the property, for objective evidence of compliance including independent measurement of buffer zones, calculation

of isolation distances, identification of closely related weeds/species within buffer zones and isolation distances, and monitoring of waste disposal methods may all be undertaken by the independent monitors; and

2.5.3 recording findings, either by photographing, video or audio recording, making sketches, making copies of relevant records, or taking samples for testing.

2.6 Further information on the monitoring program is set out in the IOGTR's Information Bulletin No. 2.

3. Conduct of Monitoring Visits in January – March 2001

3.1 In the quarter January-March 2001, the Monitoring and Surveillance Unit, IOGTR, concentrated its efforts on examining compliance with GMAC recommendations in respect of GM canola field trial sites. GM canola has been grown as a summer trial in the milder parts of Australia. Canola is likely to flower and set seed during the January – March quarter. This represents the period of greatest risk of gene flow.

3.2 In January 2001, the Monitoring and Surveillance Unit, IOGTR, contracted an expert in canola and weed identification to assist with monitoring visits.

3.3 A monitoring team was assembled to conduct monitoring visits for the period between 13 and 14 February 2001. The team comprised an IOGTR monitoring officer and an expert on canola and brassicaceous weed species.

3.4 The IOGTR conducted monitoring visits to all past trial sites in Tasmania during the period between 20 and 23 February. Each team comprised an IOGTR monitoring officer and an expert on canola and brassicaceous weed species.

3.5 Monitoring of Monsanto Australia sites was conducted in five shires in Tasmania.

3.6 The IOGTR has no legislative underpinning for the conduct of investigations into an entity's voluntary compliance with recommendations made by GMAC to manage risks associated with GMOs. Pending the establishment of the new regulatory system, the IOGTR has, therefore, limited capacity to access documents or premises, or to investigate matters unless the entity concerned chooses to provide this access. Similarly, the IOGTR has no legislative capacity to enforce compliance with GMAC recommendations or to enforce compliance with risk management plans.

4. Summary of this report

4.1 In summary, as a result of monitoring of GM canola sites conducted by Monsanto Australia Ltd in Tasmania, the IOGTR found that 3 of the 8 sites visited did not comply with GMAC advice regarding destruction of volunteers at past canola sites before flowering occurred.

4.2 As set out in Part 3 of this report, the IOGTR conducted routine monitoring of two Monsanto genetically modified (GM) canola sites in Tasmania. This monitoring took place on 13 February 2001. One of the sites was for a current Monsanto GM canola trial site. The second was a past trial site. Monsanto was notified of the pending IOGTR monitoring visit, including the specific sites to be visited.

4.3 At the time of monitoring the Monsanto sites, IOGTR also conducted monitoring of Aventis CropScience and GlaxoSmithKline sites. As a result, an investigation also commenced into Aventis compliance, which is subject to a separate report to the Minister for Health and Aged Care.

4.4 Of the two sites inspected on 13 February 2001, the monitoring team did not identify any non–compliance issues at either site.

4.5 On 16 February, the IOGTR decided to extend monitoring to encompass all past canola trial sites in Tasmania. Monsanto was notified on 19 February 2001 that the IOGTR intended to inspect all past GM canola trial sites in Tasmania to monitor compliance with GMAC recommendations for post-trial monitoring. A monitoring team visited six additional sites on 20 and 21 February 2001.

4.6 Of the six additional Monsanto sites visited, three sites were found to be non-compliant with GMAC recommendations:

4.6.1 one site had a low number of volunteer canola plants flowering (two plants);

4.6.2 one site had less than 100 canola volunteers flowering or with pod formation; and

4.6.3 one site was found to have what is estimated to be over 1000 canola volunteers at various stages of growth up to seed pod development.

4.7 The presence of flowering canola volunteers on the trial sites is contrary to GMAC recommendations for the post-trial monitoring of the sites. GMAC requires that volunteers be controlled before flowering to prevent the risk of pollen escape and gene flow. Volunteer canola should also be controlled before reaching seed development stage to prevent the continued persistence of the genetically modified organism (GMO) in the environment.

4.8 In the morning of 21 February 2001, the Director of the Monitoring and Surveillance Unit, IOGTR, provided advice to the Head of the IOGTR on the non-compliance issues identified at Monsanto sites. The Head, IOGTR notified the Office of the

Minister for Health and Aged Care of the non-compliance issue, as well as senior departmental officials. The IOGTR wrote to Monsanto seeking immediate remedial action at the non-compliant sites (refer Attachment A). The IOGTR also briefed the General Manager, Food, Agriculture and Fisheries, Tasmanian Department of Primary Industry and Environment (by telephone and in writing, refer Attachment B). On 22 February, the IOGTR briefed relevant Commonwealth agencies, States and Territories (through the Commonwealth-State Consultative Group (CSCG) on Gene Technology) and sought advice from GMAC.

4.9 The IOGTR also convened an urgent meeting with the company, Monsanto Australia, to be held on Friday 23 February 2001. The meeting was attended by IOGTR representatives, as well as a representative from the Office of Minister for Health and Aged Care, the Australian Government Solicitor, the Chair of GMAC and the Tasmanian Department of Primary Industry, Water and Environment. The purpose of the meeting was to provide an opportunity for the Commonwealth and Tasmania to express the significant disappointment and dissatisfaction of government with the non-compliance, and to obtain information from Monsanto directly.

4.10 On 22 February, Monsanto advised that remedial action had been taken at all three sites where the IOGTR identified non-compliance.

4.11 Over the period 22 February to 16 March, GMAC assessed the risks associated with the presence of flowering volunteers at the three sites in Tasmania and the Monsanto advice on remedial actions. GMAC concluded that the non-compliance represented negligible risk of gene flow or continued dissemination in the environment. GMAC advised that gene flow risks are negligible as there are limited numbers of recipient plants and a low likelihood of viable hybrids being produced. The risk of continued dissemination in the environment is negligible as management actions can be put in place to mitigate such dissemination. However, GMAC considered that the results of the monitoring visit clearly showed that Monsanto Australia had failed to maintain appropriate levels of control over the trial sites in question. GMAC further concluded that:

4.11.1 the remedial action identified by the IOGTR to Monsanto (in correspondence of 21 February 2001) represented the most appropriate immediate response to the non-compliance;

4.11.2 in the light of Monsanto's subsequent advice (dated 22 February 2001) that cultivation had been used to treat the volunteers at one site there remained a negligible risk of gene flow or continued dissemination of the GMO in the environment, but that this could be managed through further remedial action;

4.11.3 the further remedial action should include:

- extension of the post-trial monitoring period for a further three years at all non-compliant sites;

- the monitoring and removal for weedy relatives within the vicinity of all non-compliant sites;
- increased frequency of company monitoring of past sites – 1 monthly at periods of risk (ie. after rain); and
- increased independent monitoring of sites by the IOGTR. Further inspections of the trial sites were conducted on 13 March 2001.

4.11.4 In addition, the IOGTR will commission an independent gene flow study of related weeds around the non-compliant sites to verify whether any gene flow has occurred.

4.12 On 13 March 2001, the IOGTR sent a monitoring team to Tasmania for a three day period during which the three Monsanto GM canola sites previously identified as non-compliant on 20-23 February 2001 were revisited to check the progress of remedial action. Two of the three sites still contained flowering volunteers although these were in very low numbers (one and two flowering plants respectively).

4.13 In addition to the risk management mechanisms now being implemented on the advice of GMAC, the IOGTR has asked GMAC to consider how the continued lack of demonstrated capacity to manage trials in accordance with GMAC recommendations impacts on GMAC's assessments of risks associated with applications for trials involving GM canola which are currently under consideration by GMAC. The IOGTR has asked GMAC to include advice on this issue in any recommendations made by GMAC in the future.

4.14 A further teleconference, to keep CSCG informed of progress with the investigation was held on 14 March 2001. The investigation was also discussed at the 20 March 2001 meeting of CSCG where a GMAC member was also made available to answer any questions (by telephone).

4.15 A copy of this draft report will be provided to the Minister for Health and Aged Care, for information. This draft of the report will, at the same time, be provided to:

4.15.1 Monsanto Australia. Monsanto will be invited to provide any initial comments on matters of fact immediately. A further period of five working days will be allowed for comment by the company on the draft report (refer below);

4.15.2 The Genetic Manipulation Advisory Committee, for comment especially in relation to the report's representation of the Committee's risk assessment. GMAC has provided comments on earlier drafts, which have been incorporated into this version; and

4.15.3 The Australian Government Solicitor for advice on the appropriate release of information contained in the report.

4.16 A draft report will then be provided to the Minister for Health and Aged Care, as well as to CSCG (together with any advice on confidentiality provided by the AGS). Comments from CSCG will be invited. These comments will inform the final report to the Minister for Health and Aged Care.

5. Chronology of key steps relevant to the breach identification and investigation

1 February 2001	Monsanto representatives notified of IOGTR inspections scheduled to begin on Wednesday, 7 February 2001.
5 February 2001	The contracted expert notified the IOGTR that the contracted expert was no longer able to accompany IOGTR staff to Tasmania as scheduled. Attempts commenced to secure an alternative expert under the contract.
6 February 2001	As the timeframe precluded securing the service of an alternative expert, given the short notice, IOGTR staff contacted Monsanto to postpone inspections until the following week.
8 February 2001	Monsanto representatives were contacted with a revised schedule of visits to begin on Tuesday, 13 February 2001.
13 February 2001	IOGTR monitoring team (comprising an official from IOGTR and an expert on canola and brassicaceous weed species) began inspections of Monsanto sites. Two sites were inspected. One site was a current trial conducted under tents and the other site was a past canola site. No cases of non–compliance were identified by the monitoring team at either site.
14 and 15 February 2001	The monitoring team continued monitoring visits in respect of trial sites relating to other (ie. not Monsanto) companies.
19 February 2001	IOGTR notified Monsanto that monitoring of compliance with GMAC recommendations was being extended and that all past canola sites in Tasmania would be inspected from Tuesday, 20 February 2001. Six further sites (all past canola sites) were to be visited by IOGTR monitoring teams (comprising an IOGTR staff member and an expert in canola/weed identification) over two days (20 to 21 February 2001).

20 and 21 February 2001	The IOGTR monitoring team conducted monitoring visits of the further six sites. The team identified issues of non–compliance at three of the six Monsanto sites visited. Large numbers of flowering canola volunteers were present at one of the sites. Small numbers of flowering volunteers were present at the other two sites.
21 February 2001	On the morning of 21 February 2001, Director of the Monitoring and Surveillance Unit, IOGTR, contacted the Head, IOGTR, in Perth and advised that non-compliance problems had been identified in respect of Monsanto sites through the monitoring on 20 February 2001. The Head, IOGTR, advised the Office of the Minister for Health and Aged Care, and senior Departmental officials, accordingly. A minute was sent to the Minister for Health and Aged Care, outlining the non-compliance problem and outlining the actions being taken by the IOGTR to investigate the non-compliance. The Head, IOGTR, wrote to Monsanto Australia seeking immediate remedial action at the three sites and seeking a response as to why the non-compliance had occurred (Attachment A). The Head, IOGTR, contacted the General Manager, Food Agriculture and Fisheries, Tasmanian Department of Primary Industries, Water and Environment (DPIWE) and provided briefing on the non-compliance found at sites in Tasmania. In addition, a letter detailing the nature of the non-compliance was faxed on the same day to the Tasmanian DPIWE (refer Attachment B).
22 February 2001	The IOGTR held a teleconference with GMAC members to discuss the extent of the non-compliance identified and to seek risk assessment advice in relation to human health and the environment. Advice was sought from GMAC on remedial action necessary (beyond the immediate work requested of Monsanto Australia in the IOGTR's letter of 21 February 2001). GMAC members advised that they considered the risks to be negligible but advised that further action should be taken to ensure that even the negligible risks were not realised. The IOGTR held a meeting with key Commonwealth agencies (Department of Agriculture, Fisheries and Forestry, Department of Prime Minister and Cabinet, Department of Industry, Science

and Resources and Environment Australia) to brief them on the nature of the non-compliance, the immediate remedial action taken and the further recommendations proposed by GMAC to minimise risks. The agencies agreed the action taken by the IOGTR and GMAC was appropriate.

The IOGTR convened a telephone conference with the Commonwealth-State Consultative Group on Gene Technology to brief States and Territories on the nature of the non-compliance, the immediate remedial action taken and the further recommendations proposed by GMAC to minimise risks. The IOGTR advised all jurisdictions of advice from AGS that, in the absence of legislative underpinning for the monitoring of compliance with GMAC recommendations, procedural fairness dictated that information relating to the investigation should be held confidentially until such time as the investigation was complete and the company had been given the opportunity to comment on matters of fact contained in the report. All jurisdictions agreed to keep the information confidential. Advice was sought from all jurisdictions about additional measures that should be taken. All jurisdictions agreed with the actions taken by the IOGTR to date and the process of investigation being employed.

Monsanto Australia responded to IOGTR's letter of 21 February 2001 indicating the remedial action taken at the sites found to be non-compliant (Attachment C).

23 February 2001

A meeting was held with Monsanto Australia to discuss the non-compliance and GMAC's proposed further recommendations for minimising risks. IOGTR staff, a Tasmanian DPIWE representative, the Chair of GMAC, an Australian Government Solicitor representative and an adviser to the Minister for Health and Aged Care were in attendance. Monsanto agreed with the IOGTR's approach and the proposed remedial action.

Further advice was sought from GMAC members by e-mail on scientific risks associated with specific sites in Tasmania and the general risk assessment and risk management actions to be taken across all sites.

A canola/weed expert used by the IOGTR for the monitoring in Tasmania provided further advice on observations made at various sites in Tasmania.

	The IOGTR sought further advice from the canola/weed expert involved in the monitoring visits on 13 and 14 February 2001.
26 February 2001	IOGTR officials involved in monitoring in Tasmania met with the Head, IOGTR, to provide a detailed briefing on the monitoring visits conducted the previous week (monitoring of Monsanto sites was completed on 21 February, however the monitoring exercise overall, which was broader than Monsanto sites, did not conclude until 23 February 2001). IOGTR officials involved in the monitoring visits in Tasmania began developing comprehensive site reports on observations at each of the 6 Monsanto past sites visited over the period 20 to 21 February 2001.
27 February 2001	IOGTR officials continued the development of comprehensive site reports and began drafting the investigation report on the non-compliance in Tasmania.
28 February 2001	The Tasmanian Minister for Primary Industries, Water and Environment released some information on the non-compliance to the media. One of the canola/weed experts contracted by the IOGTR for the monitoring in Tasmania provided further advice on observations made at various sites in Tasmania.
1 March 2001	Further information was requested of Monsanto in relation to crops grown on the past canola sites.
2 March 2001	GMAC Release Subcommittee met to consider the breach and develop risk assessment advice. A draft of the investigation report was provided to the Head, IOGTR, for consideration. IOGTR initiated further discussions with experts that assisted with the IOGTR monitoring in Tasmania on the levels of risks in relation to observations at various sites. Monsanto provided information to the IOGTR in relation to crops grown on past canola sites.
5 March 2001	The Head, IOGTR provided comments on the draft investigation report, seeking further advice from GMAC about the deliberations of GMAC Release Sub-committee on 2 March

	2001, and advice provided by IOGTR monitoring experts on 2 March 2001. The Head, IOGTR also instigated further site monitoring for the week of 12 March 2001. Further information was requested from Monsanto as a result of the deliberations of GMAC Release Sub-committee meeting of 2 March 2001.
6 March 2001	Further GMAC advice sought on the issue of bees being introduced to the sites at the time when the trials were being conducted. GMAC members confirmed previous advice on the issue that risks were negligible. Additional information was sought from Monsanto to inform the investigation report. IOGTR had discussions with the Australia New Zealand Food Authority to confirm that honey derived from genetically modified crops is not considered genetically modified food.
7 March 2001	Monsanto provided written advice on the introduction of bees to trial sites.
8 March 2001	Further confirmatory advice sought from GMAC on risks related to crops grown on past canola sites. A draft of the investigation report provided to GMAC for comments.
9 March 2001	Monsanto provided further information to inform the investigation report as requested on 5 March following the GMAC meeting. Monsanto was advised that the IOGTR would conduct follow-up monitoring of sites identified as non-compliant to commence on Tuesday, 13 March 2001. Monsanto were advised that three sites would be visited. The team comprised two IOGTR staff members.
13 March 2001	The three non-compliant sites were re-visited by the IOGTR monitoring team. The monitoring team identified non-compliance issues at two sites. The first site contained one mature volunteer and the second site two flowering volunteers.

16 March 2001	IOGTR officials involved in monitoring in Tasmania met with the Head, IOGTR, to provide a detailed briefing on the follow-up monitoring visits. The IOGTR officials involved in the monitoring visits began developing comprehensive site reports on observations at each of the three Monsanto sites visited on 13 March 2001.
20 March 2001	Further discussion of the breaches with States and Territories at the meeting of the CSCG. All States and Territories, excluding Tasmania, expressed support for the investigation and its conduct by the IOGTR.

6. Background - GMAC recommendations for Monsanto's canola sites

6.1 The non-compliant sites which are the subject of this breach investigation relate to trials conducted under Planned Release (PR) 77X and PR77X(2).

6.2 Canola plants trialed in PR77X and PR77X(2) were genetically modified to confer tolerance to the herbicide glyphosate (the active ingredient of the Roundup®) by the introduction of the *CP4 EPSPS* gene (which codes for the enzyme 5-enolpyruvylshikimate-3-phosphate synthase) from the soil bacterium *Agrobacterium* strain CP4. These plants were also modified to confer tolerance to the herbicide glyphosate by the introduction of the *gox* gene (which codes for the enzyme glyphosate oxidoreductase) from the soil bacterium *Ochromobactrum anthropii* strain LBAA (formerly *Achromobacter* sp.). These proteins are found naturally in common soil microorganisms, and together they confer tolerance to glyphosate, the active ingredient of the herbicide Roundup®.

6.3 As set out in Part 9 of this report, GMAC is responsible for assessing risks posed by proposed dealings with GMOs (including proposed field trials) and for providing advice to proponents on how any risks can be appropriately managed.

6.4 The relevant GMAC recommendations, in relation to the Monsanto sites investigated by the IOGTR, are contained in advice issued to the company by GMAC in relation to:

6.4.1 planned release proposal PR77X - GMAC advice was issued on 24 March 1998; and

6.4.2 planned release proposal PR77X(2) – GMAC advice was issued on 25 March 1999.

6.5 In addition to a range of recommendations regarding the growing of crops, GMAC made the following recommendations regarding post-trial monitoring of all field trials of canola undertaken as part of these proposals:

6.5.1 PR77X – 'The field will be planted in the following year to cereal crop and in the year after that to a crop other than canola. GMAC advises that, as for PR-77, the sites should be monitored for the emergence of volunteer canola plants for the three years following the trial, and that any volunteer plants should be destroyed by cultivation or appropriate herbicide treatment.'

6.5.2 PR77X(2) – 'The field will be planted in the following year to a cereal crop and in the year after that to a crop other than canola. Over the three years following the trial the sites will be monitored for the emergence of volunteer canola plants, which will be destroyed by cultivation or appropriate herbicide treatment.'

6.6 The purpose of GMAC recommendations is to:

6.6.1 minimise dissemination of the GMO and its genetic material;

6.6.2 minimise persistence of the GMO into the environment (ie. it is GMAC's intention that, by the end of the three year post trial monitoring, volunteers will have been controlled to the extent that the GMO is no longer present at the trial site); and

6.6.3 ensure that full control of the GMO is maintained by the proponent.

7. Details of non-compliant sites: Outcomes of the IOGTR monitoring visits of Monsanto sites on 13 February 2001.

7.1 Of the two sites monitored by the IOGTR on 13 February 2001, the monitoring team did not identify any non–compliance issues.

8. Details of non-compliant sites: Outcomes of the IOGTR monitoring visits of Monsanto sites on 20 and 21 February 2001.

8.1 Of the five sites monitored by the IOGTR on 20 February 2001, the monitoring team identified that three trial sites (that are subject to GMAC post-trial monitoring recommendations) did not comply with GMAC recommendations. The single site visited on 21 February did not present non-compliance problems.

8.2 The monitoring teams have prepared a detailed report on this monitoring exercise. Following is a summary of the results of monitoring at the three non-compliant sites:

8.2.1 PR77X(2)/16 and PR77X(2)/17

This site had a number of volunteers at the pre-flowering stage. Two volunteers were found to be flowering. (Sites 16 and 17 are adjacent to each other on the same property).

8.2.2 PR77X/15

This site had been sown to poppies which had been harvested prior to the monitoring visit. It is estimated that over 1000 canola volunteers were observed on the site in the flowering stage and/or with seed pods developing.

8.2.3 PR77X(2)/34

This site was sown to potatoes (unharvested at the time inspection) and poppies (which had been harvested at the time of inspection). Within the site, a number of canola volunteers were found. Approximately 30 volunteers were estimated to be flowering within the site.

9. Risk Assessment – contextual overview

9.1 As set out in Part 2 of this report, Australia has had a voluntary system of controls over dealings with GMOs in place for the past 25 years. All field trials conducted in Australia to date have been conducted under this voluntary system.

9.2 Before a field trial involving a GMO can proceed, the proponent of the trial seeks GMAC's advice on the risks to the environment, and to human health, associated with the conduct of the trial. GMAC makes recommendations about conditions that should be complied with by the proponent to manage any identified risks. If GMAC believes that the risks cannot be appropriately managed, GMAC recommends that the trial not proceed.

9.3 GMAC is a non-statutory expert Committee responsible for overseeing the development and use of novel genetic manipulation techniques in Australia.

9.4 GMAC reviews such work and provides advice to the institutions conducting the work on the management of potential hazards, including those associated with the release of GMOs into the environment, to the community or the environment. GMAC also provides advice to the Minister for Health and Aged Care and to other government regulatory bodies.

9.5 The membership of GMAC includes a wide range of expertise in fields that are relevant to risk assessment of genetic manipulation work, including experts in the fields of molecular biology, ecology, plant genetics, microbial genetics, animal genetics, virology, entomology and biosafety engineering.

9.6 The recommendations set out in Part 6 of this report are the sub-set of the recommendations made by GMAC for the conduct of the GM canola trials in Tasmania, as relevant to this investigation.

9.7 GMAC has provided advice to the IOGTR on the assessment and management of risks associated with the presence of volunteer GM canola plants identified by the IOGTR monitoring teams at sites used by Monsanto Australia for the trial of GM canola under trials PR77X and PR77X(2).

9.8 Parts 10, 11, 12 and 13 of this report set out a summary of GMAC's assessment of the risks associated with the non-compliance at sites as set out in Parts 7 and 8 of this report. The risks include gene flow (Part 10 refers), antibiotic resistance (Part 11 refers), transport off-site (Part 12 refers) and persistence in the environment (Part 13 refers). GMAC's assessment of the non-compliance risks is an adjunct to the Committee's risk assessment carried out prior to the commencement of these trials in 1998/99.

9.9 GMAC has advised that the Committee will include the non-compliance identified in this report as a standing item on GMAC Release Sub-committee agendas, to ensure that the Committee's assessment of risks is iterative, and remains informed as new information becomes available.

10. GMAC Risk Assessment - Gene Flow

10.1 Gene flow to weedy relatives

10.1.1 A risk associated with the conduct of field trials with genetically modified (GM) canola is gene flow to weedy relatives that are sexually compatible with canola and capable of forming interspecific hybrids. GMAC advice for the conduct of GM canola trials is that removing related species of weeds from within 50m of the GM canola when it is flowering significantly reduces out-crossing to weedy relatives. The table provided at Attachment D details the sexual compatibility of weedy relative species with canola. The species that GMAC considers to pose a risk of outcrossing with canola are listed in columns I, II and III of the table at Attachment D.

10.1.2 The IOGTR monitoring team observed small numbers of the weedy relative *Raphanus raphanistrum* (commonly referred to as wild radish) at two of the three non–compliant sites.

10.1.3 A summary of the incidence of weedy relatives (considered by GMAC to be capable of crossing with canola, observed by the monitoring team at the sites of concern) is provided in Table 1 below.

Table 1
Monsanto GM canola sites of concern in Tasmania – incidence of weedy relatives

Trial	Site ID	# of canola flowering and/or mature seed observed	# flowering *R. raphanistrum* observed	# *B. rapa* observed	Other weedy relatives observed
PR-77X	Sites 16 &17**	2	1 (separated)[1]	0	0
PR-77X	Site 15	>1000	0	0	0
PR-77X(2)	Site 34	30	14	0	0

1: Weedy relatives were on the contra-site from the flowering canola volunteers and separated by over 200m.
**: Sites 16 and 17 are immediately adjacent to each other.

10.1.4 GMAC considers that the presence of weedy relatives at these sites is limited as:

- The peak season for weedy relatives is the autumn-winter period rather than summer (unless under irrigation); and
- Selection of sites by the company includes seeking areas where there are low numbers of weedy relatives in the vicinity.

10.2 Gene flow to wild radish

10.2.1 Reports of crossing between canola and wild radish (*R. raphanistrum)* in Australia indicate that the rate is very low. Rieger *et al.* (2001)[1] reported that the outcrossing rate from canola to wild radish is 1 in 26 million. Because the rate of hybrid development is so low, and very few sites of concern contained wild radish in significant numbers, GMAC considers the risk of successful gene transfer from canola to wild radish at these sites to be negligible. In the event that a gene transfer did occur, the environmental impact would be minimal because the gene conferring resistance to the herbicide glufosinate-ammonium would not give the plant a selective advantage as this herbicide is not used for the control of these weeds. However, to ensure that even this negligible risk is not realised, a number of measures were recommended by GMAC (as set out under 15. Risk Management).

[1]Rieger MA, Potter TD, Preston C and Powles SB (2001) Hybridisation between Brassica napus L. and Raphanus raphanistrum L. under agronomic field conditions. *Theoretical and Applied Genetics* (in press).

10.3 Gene flow: *Brassica rapa*

10.3.1 *Brassica rapa* is a close relative of canola (*B. napus*). No *B. rapa* plants (sometimes referred to as wild turnip) were found by the IOGTR monitoring teams. While there was no evidence of a problem, GMAC considered the risks associated because crossing between canola and *Brassica rapa* is likely where both are present. The peer reviewed literature shows numerous examples of crossing between canola and *B. rapa* under controlled conditions such as hand pollination. In-field studies are limited but a peer reviewed paper by Bing *et.al* (1996) records fertile hybrids developing at a rate of 0.8% when the plants are co-cultivated[2]. GMAC advised that the risks in this case are considered to be negligible because no *B. rapa* plants were observed on or near sites where flowering canola volunteers were present.

10.3.2 Despite the risks being negligible, GMAC recommended further control measures to ensure that this negligible risk is not realised (as set out under 15. Risk Management).

10.4 Gene flow: other weedy relatives

10.4.1 Other weedy relatives that have the potential to cross pollinate with canola at shown in columns I, II and III of the table at Attachment D. The likelihood of crossing decreases as the table is viewed from left to right. No other weedy relatives were observed at the sites by the monitoring teams.

10.4.2 Despite the risks being negligible, GMAC recommended further control measures to ensure that this negligible risk associated with weedy relatives is not realised (as set out under 15. Risk Management).

10.5 GMAC assessment: introduction of bees to sites when trial was being conducted

10.5.1 Monsanto introduced beehives to the trial sites, during the period when the canola plants were flowering, in order to facilitate pollination. Some concerns have been expressed about this practice by interested parties.

10.5.2 GMAC advises that the Committee was fully aware of the use of bees at trial sites. GMAC assessed the risks to be negligible. Bees occur

[2] Bing, DJ, Downey RK and Rakow GFW (1996) Hybridisation among *Brassica napus, B. rapa* and *B. juncea* and their two weedy relatives *B. nigra* and *Sinapis arvensis* under open pollination conditions in the field., *Plant Breeding* 115: 470 – 473.

naturally at sites and risk management measures were implemented to minimise flow of pollen off sites.

10.5.3 GMAC advised that due to the foraging pattern of bees within a flowering canola crop and the nature of pollen viability in crop varieties that produce pollen, there is a low chance of any bee pollinating plants beyond the trial site, and that the risk of this occurring is less than that for bees from hives outside the site. GMAC advised that placement of beehives on the site poses no additional risk than that posed by bees that would be occurring in trial sites naturally and that the risk of movement of pollen from GM canola from the trial sites was negligible. The public often hears that bees will carry pollen for several kilometres, and that this pollen can fertilise plants, but it is important to note that such experiments have used "male-sterile" canola varieties that do not produce their own pollen. With normal varieties of canola, as grown in Australia, the overwhelming proportion of pollination occurs within tens of meters of the crop.

10.6 Gene flow to other crop species (other than *Brassica* species)

10.6.1 A number of crops and pastures were planted on the canola trial sites. The post-trial crops planted and/or harvested in the 2000-2001 summer season included opium poppies, potatoes and pasture. Table 2 details the post-trial crops planted at sites where the IOGTR monitoring teams observed volunteer canola plants in flower or with seed pod formation.

10.6.2 GMAC advised that none of these post-trial crops are sexually compatible with canola and that there is no potential for gene flow to occur.

10.7 Gene flow to soil microorganisms

10.7.1 Transgenes from the GM canola to soil microorganisms has been raised as a potential risk.

10.7.2 GMAC considers the potential for transfer of the introduced genes from the GM canola to soil microorganisms as extremely unlikely, and that the risks are negligible.

10.7.3 Horizontal gene transfer from plants to bacteria has not been experimentally demonstrated under natural conditions[3][4] and deliberate

[3] Syvanen, M. 1999, "In search of horizontal gene transfer", *Nature*, vol. 17, pp. 833-834.
[4] Nielsen, K.M., Bones, A. M., Smalla, K. & van Elss, J. D. 1998, "Horizontal gene transfer from transgenic plants to terrestrial bacteria – a rare event?", *FEMS Microbiol. Rev*., vol. 22, pp. 79-103.

attempts to induce such transfers have so far failed.[5] Transfer of plant DNA to bacteria has been demonstrated under highly artificial laboratory conditions[46] but even then only at a very low frequency. Phylogenetic comparison of the sequences of plant and bacterial genes suggests that horizontal gene transfer from plants to bacteria during evolutionary history has been extremely rare, if occurring at all.[47]

10.7.4 It should be noted that the genes introduced to the GM canola plants trialed under PR-77X and PR-77X(2) were isolated from commonly occurring soil bacteria and these genes are therefore widespread in the environment. The *CP4 EPSPS* and *gox* genes conferring tolerance to glyphosate herbicide were derived from the bacteria *Agrobacterium* strain CP4 and *Ochromobactrum anthropii* strain LBAA (formerly *Achromobacter* sp.) respectively. The CP4 EPSPS enzyme is very similar to the EPSPS enzymes naturally expressed in plants. These proteins are found naturally in common soil microorganisms, and together they confer tolerance to glyphosate, the active ingredient of the herbicide Roundup®.

10.7.5 GMAC considers that the transfer of the genes from these naturally occurring bacteria, through well documented mechanisms for horizontal transfer between bacteria, is far more likely than transfer of the same genes from the GM canola.

11. GMAC risk assessment: transfer of antibiotic resistance genes to bacteria

11.1 The potential impact of the horizontal transfer of antibiotic resistance genes to bacteria has been postulated to represent a risk to public health. It is not, GMAC advises, a relevant risk in relation to the Monsanto breaches because the genetic manipulation involved no introduction of antibiotic resistance genes.

12. GMAC Risk Assessment: Movement of seed off-site

12.1 Dispersal of GM canola seed through harvesting of post-trial crops

12.1.1 A risk associated with the conduct of trials of GM canola is the movement of GM canola seed from the trial site. This increases the potential for the continued persistence of the GM canola in the

[5] Schlüter, K., Fütterer, J. & Potrykus, I. 1995, "Horizontal gene transfer from a transgenic potato line to a bacterial pathogen (*Erwinia chrysanthemi*) occurs- if at all- at an extremely low frequency", *Bio/Technology*, vol. 13, pp. 1094-1098.
[6] Gebhard, F. & Smalla, K. 1998, "Transformation of *Acinetobacter* sp. Strain BD413 by transgenic sugar beet DNA", *Appl. Env. Microbiol.*, vol. 64, pp. 1550-1554.
[7] Doolittle, W. F. 1999, "Lateral genomics", *Trends Cell Biol.*, vol. 9, M5-8.

environment beyond the period of the trial and dissemination of the GM canola beyond the trial site. GMAC therefore recommends that all GM plant material, including seed, be transported in a primary sealed container within a secondary unbreakable container. The container is to be clearly labelled to indicate that it contains transgenic material.

12.1.2 Post-trial crops had been harvested at some of the sites where the IOGTR monitoring team observed volunteer canola plants with flowers or seed pod formation. There is a potential risk that mature canola seed may have been harvested coincidentally with the post-trial crops and transported from the trial site. Table 2 details the post-trial crops at the sites where volunteer canola plants were observed, and whether the crop had been harvested at the time of the monitoring visit.

Table 2
Monsanto GM canola sites of concern in Tasmania – post-trial broadleaf crops

Trial	Site ID	# of canola flowering and/or mature seed	Broadleaf crop	Cereal or pasture crop
PR-77X	Sites 16 &17**	2	No	ryegrass
PR-77X	Site 15	>1000	opium poppies	no
PR-77X(2)	Site 34	30	Potatoes* and opium poppies	no

* No volunteers were found within the potato crop and the potatoes had not been harvested.
** Trials sites were adjacent to one another.

12.2 GMAC assessment: harvested opium poppies

12.2.1 The whole seed capsule of the opium poppy is harvested and it is approximately 2-3 cm in diameter in comparison to about 2mm for individual canola seeds and approximately 3mm x 60mm for canola seed pods.

12.2.2 Poppy harvesting is conducted using a comb and cut harvesting method with a header that is quite different to those used for harvesting grains. The top 2.5 cm of the poppy plants (including the stem and capsule) are harvested. In contrast, the racemes (upper part of the canola plant that has the seed pods attached) of canola mature and set seed starting at the lower part of the plant and progressing towards the tip. Therefore any portions of the canola plants co-harvested with the poppy capsules are less likely to contain mature seed pods. Any canola seed co-harvested is likely to be immature and therefore unlikely to be viable.

12.2.3 The harvester captures the poppy heads while ejecting other material ('trash') out of the rear of the machine. It is more likely that only flowers and immature pods would be harvested. The action of the sieves, webbing and blowing mechanisms of the harvester are also likely to preclude capture of canola seed during poppy harvest.

12.2.4 Poppy capsules are processed and the seeds and latex are separated. Because of the sensitive nature of opium poppies the transport and processing of the capsules is strictly controlled. Also because opium poppies are considered a prohibited substance stringent guidelines and audits apply to the cleaning down of harvesters and other machinery used in harvest and transport of poppy seeds.

12.2.5 Poppy seed is cleaned and graded by size and density on a seed cleaner to separate the desired seed from other contaminants such as other plant material and weed seeds. The processing of poppy seeds involves steam and chemical treatments that would render seed, including canola seed if by remote chance some was present, unviable.

12.2.6 GMAC therefore considered that risk of removal and dissemination of GM canola seed from the trial sites through co-harvest with opium poppies was extremely low.

12.3 GMAC assessment: potatoes

12.3.1 The potato crops observed by the monitoring teams had not been harvested at the time of the visits. GMAC considered that the risk of any GM canola seed being co-harvested with potatoes is very remote because no volunteers were observed and in any event the physical process of harvesting and the difference in size between canola seeds and potatoes would reduce the potential for co-harvesting. Potatoes are sieved on site to remove soil contamination and the soil is returned to the harvest site. Any remedial action will be taken to remove volunteer canola plants by the company prior to harvest of the potatoes.

12.4 GMAC assessment: broadleaf crops as post trial crops

12.4.1 The highest incidences of volunteer canola plants with flowers and/or seed pods observed in post-trial crops by the IOGTR monitoring teams were in broadleaf crops, in particular opium poppies and potatoes. Crops to be grown on past canola sites has been an issue of concern for GMAC and a review of suitable crops was being undertaken. Whilst GMAC reviewed the types of crops to be used on past sites, normal farming practices were allowed to continue under the original advice, such as that for PR77X and PR77X(2), which did not explicitly preclude crops other than canola.

12.5 Risks associated with adventitious contamination of food

12.5.1 No volunteers were found in food crops sown at the Monsanto past canola sites by the IOGTR monitoring team, therefore, genetically modified crop products are unlikely to be in the food chain. GMAC have concluded, as detailed above, that the risk of any volunteer GM canola plants being co-harvested with post-trial crops and thereby entering the food chain is negligible. GMAC have also advised that, in the event that any contamination of food with material from the volunteer canola plants was co-harvested with post-trial crops the risks associated with any incorporation in food is negligible because of the very small amounts involved. The possible risks of any such contamination would be further ameliorated by the enormous dilution of any GM canola material by the actual crop.

12.5.2 The regulation of GM foods is the responsibility of the Australia New Zealand Food Authority (ANZFA) through Standard A18 - *Foods Produced using Gene Technology* of the *Food Standards Code*. Since 13 May 1999, all foods produced using gene technology have had to be scientifically assessed to confirm their safety for human consumption before being marketed. Those that are different from their conventional food equivalents require explicit labelling under Standard A18. However, the labelling requirement of Standard A18 does not apply where a GM food is unintentionally present at less than 1%.

12.5.3 Foods derived from glyphosate-tolerant canola approved for use in Australia by Australia New Zealand Food Standards Council (ANZFSC) in November 2000 and included in Standard A18 of the *Food Standards Code*. This approval was based on the risk analysis conducted by ANZFA. The published Draft Risk Analysis Report is provided at Attachment E. (The Final Risk Analysis Report is not publicly available, however the IOGTR has viewed this report). ANZFA's risk analysis addressed general safety issues, nutritional issues and toxicological issues, including the potential for the proteins produced as a result of the genetic modification to be toxic or allergenic. The report concluded that foods derived from glyphosate-tolerant canola did not pose any potential public health and safety concerns and that foods derived from the GM canola is equivalent to commercial non-GM canola in terms of its food safety and nutritional adequacy.

12.5.4 GMAC considers that, based on the risk analysis conducted by ANZFA, there is negligible risk associated with the adventitious contamination of food, should it indeed occur, with material from volunteer GM canola plants.

12.6 Dispersal by livestock (sheep)

12.6.1 The IOGTR monitoring teams observed grazing sheep at one trial site.

12.6.2 GMAC therefore considered the potential risk of dissemination of GM canola seed from the trial site via the action of grazing sheep. This might occur if sheep ingested viable GM canola seed and that seed passed through the digestive and was voided in droppings after the sheep were moved from the trial site.

12.6.3 No data are available specifically relating to the passage and viability of canola seed following ingestion by sheep. Reports indicate that for seeds of approximately 2mm in diameter (equivalent to the dimensions of canola seed) the vast majority of seed is expelled from sheep within 5 days.[8] However seeds of similar size to canola can be expelled in very small numbers for up to three weeks after grazing.[9] Reports also indicate that a proportion of seeds of a similar size to canola passed by sheep are viable and will germinate.[9] In addition, canola seed can show resistance to digestion[10] it must be presumed that, based on the data available for a range of other seeds, intact canola seed will be voided by the sheep and will in all probability be viable.

12.6.4 GMAC considered that the risk of dissemination of viable GM canola seed, as a result of ingestion by sheep and passage in droppings, was low. Specific management actions will be required to be undertaken by Monsanto to ensure that this small risk is not realised (as set out under 15. Risk Management)

12.6.5 Glyphosate canola is approved as stock feed in Canada, Japan and United States.

13. GMAC Risk Assessment: Continued persistence of viable canola seed in the environment

13.1 As mature plants may have been present with possible viable seed, there is a risk of continued persistence of the plants in the environment.

[8] Neto MS, Jones RM and Ratcliff D (1987) Recovery of pasture seed ingested by ruminants. Seed of six tropical pasture species fed to cattle, sheep and goats. *Australian Journal of Experimental Agriculture*. 27:239-246

[9] Heap JW and Honan I (1993) Weed seed excretion by sheep – temporal patterns and germinability. Pp431-4 in Vol 1 of the Proceeding of the 10th Australian Weeds Conference and 14th Asian pacific Weed Science Society Conference, Brisbane.

[10] Aldrich CG *et al*. (1997) The effect of chemical treatment of whole canola seed on lipid and protein digestion by steers. *Journal of Animal Science*. 77:502-511

13.2 A large number of seeds are dropped onto the soil following the harvest of a canola crop. In agricultural field conditions most of the seeds remain on the surface of the soil. Canola seed is generally acknowledged as having low dormancy and soil and seed moisture are critical for the early germination of canola seeds on the soil surface. GMAC therefore recommends the management practice of post-harvest cultivation of trial sites to encourage germination of canola seeds. GMAC also recommends that post-trial monitoring be undertaken for three years on the basis that all GM canola seed present on the site at the completion of the trial will have germinated and been destroyed over this time by control of volunteer canola plants.

13.3 GMAC considers that there is a significant risk of continuation of the GM canola plants in the environment because of production and shedding of potentially viable seed from volunteer GM canola plants. GMAC considers that because the seeds are confined to the trial sites the risk to the general environment can be reduced to negligible levels through management actions to be required of Monsanto (as set out under 15. Risk Management).

14. Tasmanian government issues relating to risk assessment

14.1 GMAC takes into account public and/or government submissions received on proposals to release GMOs into the environment through the public notification of proposals.

14.2 GMAC advises that the Tasmanian government had not previously provided advice or raised concerns with the Committee about risks associated with the release of the GM canola in that State as part of these trials under investigation.

14.3 A submission from the Tasmanian Department of Primary Industries, Water and Environment (DPIWE) dated 22 January 2001 after GMAC wrote to DPIWE seeking comments on the latest canola release proposal. The DPIWE submission raised concerns covering four areas:

- 14.3.1 The introgression of transgenes into *Brassica rapa* (wild turnip), a weedy relative of canola;
- 14.3.2 Concerns that isolation distances may not satisfactorily restrict transgene dispersal;
- 14.3.3 Concerns that canola seed dormacy may be longer than three years; and
- 14.3.4 The potential for genes to transfer to soil microorganisms.

14.4 GMAC advises that each of these have been considered by GMAC in the past and are clarified in the risk assessment parts of this report. In summary, GMAC has noted the following for each of the Tasmanian concerns.

14.4.1 In relation to *B. rapa*, GMAC considered the risks associated because crossing between canola and *B. rapa* is likely where both are present. The peer reviewed literature shows numerous examples of crossing between canola and *B. rapa* under controlled conditions such as hand pollination. In-field studies are limited but a peer reviewed paper by Bing *et.al* (1996) records fertile hybrids developing at a rate of 0.8% when the plants are co-cultivated[11]. GMAC employs isolation distances to minimise this risk further and currently a 50m exclusion zone from all weedy relatives applies to trial sites.

14.4.2 GMACs advice on isolation distances is based on the review of literature. GMAC's advice to proponents of GM canola field trials is that the crop site should be surrounded by a 15m buffer zone of non-modified canola plants and that the GM canola trial be isolated from commercial canola crops by at least 400m. The trial area and a 50m zone around the trial area should be free of flowering weeds that are sexually compatible with canola prior to, during flowering and until the GM crop stops flowering. The use of isolation distances is standard practice for field trials in Canada, USA and UK.

14.4.3 Canola seed is generally acknowledged as having low dormancy and soil and seed moisture are critical for the early germination of canola seeds on the soil surface. GMAC therefore recommends the management practice of post-harvest cultivation of trial sites to encourage germination of canola seeds. GMAC also recommends that post-trial monitoring be undertaken for three years on the basis that all GM canola seed present on the site at the completion of the trial will have germinated and been destroyed over this time by control of volunteer canola plants.

14.4.4 Horizontal gene transfer from plants to bacteria has not been experimentally demonstrated under natural conditions[12][13] and deliberate attempts to induce such transfers have so far failed.[14] Transfer of plant DNA to bacteria has been demonstrated under highly artificial laboratory conditions[4][15] but even then only at a very low frequency. Phylogenetic comparison of the sequences of plant and bacterial genes suggests that

[11] Bing, DJ, Downey RK and Rakow GFW (1996) Hybridisation among *Brassica napus, B. rapa* and *B. juncea* and their two weedy relatives *B. nigra* and *Sinapis arvensis* under open pollination conditions in the field., *Plant Breeding* 115: 470 – 473.
[12] Syvanen, M. 1999, "In search of horizontal gene transfer", *Nature*, vol. 17, pp. 833-834.
[13] Nielsen, K.M., Bones, A. M., Smalla, K. & van Elss, J. D. 1998, "Horizontal gene transfer from transgenic plants to terrestrial bacteria – a rare event?", *FEMS Microbiol. Rev*., vol. 22, pp. 79-103.
[14] Schlüter, K., Fütterer, J. & Potrykus, I. 1995, "Horizontal gene transfer from a transgenic potato line to a bacterial pathogen (*Erwinia chrysanthemi*) occurs- if at all- at an extremely low frequency", *Bio/Technology*, vol. 13, pp. 1094-1098.
[15] Gebhard, F. & Smalla, K. 1998, "Transformation of *Acinetobacter* sp. Strain BD413 by transgenic sugar beet DNA", *Appl. Env. Microbiol.*, vol. 64, pp. 1550-1554.

horizontal gene transfer from plants to bacteria during evolutionary history has been extremely rare, if occurring at all.[416]

15. Risk Management: Immediate actions necessary to bring the sites back in compliance with GMAC recommendations

15.1 Within 24 hours of identifying non–compliance at three sites, IOGTR wrote to Monsanto on 21 February 2001 setting out immediate remedial action to be undertaken to minimise risks associated with the issues of non–compliance, pending further advice from GMAC. Actions specified were:

(a) the sites to be weeded immediately, by hand, to remove all flowering and mature volunteer canola. Hand-weeding was specified as:
- it is the most rapid form of remedial action available (ie. work can commence immediately); and
- if carried out carefully, it is an effective form of remedial action for removing volunteer canola plants.

(b) the three sites to be weeded immediately, by hand, to remove all flowering and mature weedy brassica plants on the sites and within 50m of the sites.

(c) all non-flowering volunteers to be destroyed either by hand weeding, chemical application or cultivation immediately.

(d) the weeding to commence immediately and with sufficient resources to be allocated to the task to allow the task to be completed expeditiously.

(e) all volunteer plant material removed from the sites be double-bagged and labelled, with the bags to be buried/destroyed in a manner consistent with GMAC advice on disposal of GM material.

16. Further risk management action to be implemented

16.1 Management of Risk: Gene Flow

16.1.1 Having assessed risks, as set out in Part 6 of this report, GMAC has recommended the following actions be implemented by Monsanto to manage the risk of gene flow:

(a) A 100 metre area around the site must be monitored for weedy relatives particularly *Brassica rapa*. Any weedy relatives of canola identified in the 100 mete zone must be removed and destroyed.

[16] Doolittle, W. F. 1999, "Lateral genomics", *Trends Cell Biol.,* vol. 9, M5-8.

(b) Monsanto must provide written confirmation to the IOGTR about the absence of commercial Brassica crops within 1 km of the non-compliant sites. Whilst the IOGTR monitoring team did not observe any commercial crops within 1 km of the sites of concern, this must be confirmed by the Company.

16.1.2 In addition, the IOGTR has decided that research should be conducted into whether any transfer of genes from the transgenic canola volunteers to related weeds (particularly *B. rapa*) has occurred around the non-compliant sites. The study should include weedy relatives within the 100m zone and *B. rapa* plants found within 1 km of the sites. This study will involve collection of *B.rapa* around non-compliant sites (if any can be found) and testing these plants for herbicide resistance. As herbicide resistance can occur naturally, PCR testing may also be required.

16.2 Management of Risk: Movement of seed off-site

16.2.1 GMAC have recommended that the following actions be implemented by Monsanto to manage the risk of movement of GM canola seed from the sites found to be non-compliant during this investigation:

(a) Monitor all sites where harvesters (and other machinery involved in the harvest of post-trial crops) for the presence of canola volunteers for three years and all canola volunteers must be destroyed prior to flowering.

(b) Where sheep that have grazed on trial sites where canola plants with green seed pods or mature canola seed were present, **either** contain all sheep off-site in one location for 3 weeks from the time of last grazing on the trial site, **or** if all volunteer canola plants have been removed from the trial site by remedial action, contain all sheep on the trial site for three weeks from the time the canola volunteers were removed. Monsanto has advised that all sheep that have grazed have remained on-farm.

(c) Monitor all sites where sheep (as described in (b)) have been moved to or held during the 3 weeks from the time of last grazing on the trial site, for three years and all canola volunteers must be destroyed prior to flowering.

(d) Ensure that no *Brassica* crops are grown on sites where sheep (as described in (b)) have been transported to or held during the 3 weeks since last grazing on the trial site with only the following crops to be grown on these sites:

i. grass pasture;

ii. cereal crops;
iii. crops agreed by GMAC/the GTR in writing with agreement obtained in advance.

16.3 Management of Risk: Continuation of viable seed in the environment

16.3.1 GMAC have recommended that the following actions be implemented by Monsanto to manage the risk of continuation of viable seed in the environment:

(a) The non-complaint trial sites and the 100 metre monitoring zone around the site must be monitored for volunteer plants for a further period of three years from 1 March 2001
- volunteer plants refers to progeny of the transgenic canola crop and if a buffer is used, progeny of the buffer plants.

(b) The company must monitor and report four–weekly to the IOGTR during periods of likely canola germination (such as after rain events and whilst irrigating sites) on post-trial canola sites.

(c) Subject to (b), during periods that canola germination is unlikely, monitoring must be conducted a minimum of once every two months.

(d) All monitoring must be undertaken by appropriately trained and qualified personnel.

(e) The results of the monitoring must be reported to GMAC within two weeks of the monitoring visit and must include details of:
(i) the number of volunteer plants observed;
(ii) the development stage reached by the volunteer plants;
(iii) whether the volunteers appeared on the trial site, in the 100 metre monitoring zone; and
(iv) the methods used for their control (as detailed (g)).

(g) Any volunteer plants identified during monitoring must be destroyed before flowering of the volunteer plants by:
(i) cultivation;
(ii) herbicide treatment;
(iii) slashing/mowing;
(iv) burning;
(v) grazing;
(vi) hand weeding; or
(vii) a combination of the techniques detailed at (i) to (vi)

(f) No canola crops are to be grown on the non-compliant trial sites, or the 100 metre monitoring zone around the sites, for at least three years from 1

March 2001. If the trial sites and/or the 100 metre monitoring zone around the trial site are to be planted, only the following may be grown:

- grass pastures;
- cereal crops; or
- crops agreed in writing by GMAC before planting. If Monsanto wishes to plant other crops, they must demonstrate to the satisfaction of GMAC that despite the planting of an alternative crop, management actions can, and will, be implemented to enable ready identification and removal of volunteers from the site before flowering.

16.4 Other General Risk Management actions:

16.4.1 The IOGTR requires that the Company must report to the IOGTR on the implementation of the risk management actions recommended above. The IOGTR will provide reports to the Minister for Health and Aged Care on the implementation of risk management actions undertaken by Monsanto.

16.4.2 GMAC has also indicated that its most recent advice for post-trial monitoring of canola sites (as described under 'Management of Risk 3: Continuation of viable seed in the environment'), must apply to all future activities on past canola sites still under active monitoring by the company across Australia (the exemption being that all compliant sites require only a 50m isolation distance rather than 100m ie. substitute 100m for 50m).

16.4.3 The IOGTR has already commenced further independent monitoring of the breach trial sites. This monitoring was undertaken on 13 March 2001 and involved a further visit by IOGTR officials to each of the three sites that were identified as non-compliant sites on 20 February 2001.

16.4.4 The monitoring team found one mature canola plant on site PR77X/15, and two flowering canola plants on site PR77X(2)/34.

16.4.5 The information relating to the results of the further monitoring visits have been conveyed to GMAC and advice sought about risks and further actions. GMAC advised that the presence of the three plants detected represented negligible increased risk.

16.4.6 The IOGTR is, however, concerned at the apparent problems encountered by the company in the management of trials and has sought advice from GMAC about the implications of the results of this investigation on current and future applications to conduct GM canola trials under the interim arrangements.

17. Agreement of relevant parties to the risk assessment and risk management plan

17.1 Tasmanian Government

17.1.1 On 21 February 2001, the General Manager, Food Agriculture and Fisheries, Tasmanian Department of Primary Industries, Water and Environment (DPIWE), was notified by the Head, IOGTR, of the issues of non–compliance found at various sites in Tasmania. The Head, IOGTR, explained that, on advice from the Australian Government Solicitor, the IOGTR was (under the voluntary system) required to act with due diligence and according to the principles of natural justice and therefore the standard operating procedure was that the investigation be completed prior to public announcement. The Head, IOGTR, reiterated this advice to the Commonwealth-State Consultative Group on Gene Technology in the telephone conference, making it clear there would be full public disclosure as soon as possible and that all possible resources within the office would be allocated to finalising the investigation as soon as possible.

17.1.2 The General Manager, Food Agriculture and Fisheries, Tasmanian DPIWE advised the Head, IOGTR, that the Minister for Primary Industries, Water and Environment (Tasmania) had been informed of the non-compliance and had agreed to keep the information provided by the IOGTR confidential, understanding that, as GMAC operates under a voluntary system, the company involved must be assured of procedural fairness and an opportunity to respond to the IOGTR findings.

17.1.3 On 21 February 2001, the General Manager, Food Agriculture and Fisheries, Tasmanian DPIWE was invited to attend a meeting on 23 February 2001 with Monsanto representatives to explore the non-compliance found at various sites in Tasmania and to seek any information necessary to Tasmania directly from the company.

17.1.4 On 23 February 2001, the meeting was held with Monsanto representatives In attendance for Monsanto were the Technical Director and the Regulatory Affairs and Product Development officer. Representatives of the IOGTR were present along with the General Manager, Food Agriculture and Fisheries, Tasmanian DPIWE; the Chair of GMAC; a representative from the Office of the Minister for Health and Aged Care; and a representative from the Australian Government Solicitor.

17.1.5 The General Manager, Food Agriculture and Fisheries, Tasmanian DPIWE, indicated his Department's preparedness to leave the issue in the hands of the IOGTR to investigate and expressed satisfaction with the process put in place by the IOGTR. However, on 28 February 2001, Minister Llewellyn made an

announcement in the public forum about issues of non–compliance and the handling of the investigation by the IOGTR.

17.2 Relevant Commonwealth Departments

17.2.1 On 22 February 2001, the IOGTR briefed relevant Commonwealth Departments on the non-compliance in Tasmania. Relevant agencies were the Department of Agriculture, Fisheries and Forestry; the Department of Environment and Heritage; the Department of Industry, Science and Resources; and the Department of Prime Minister and Cabinet. The key agencies at this meeting agreed with the action taken to-date by the IOGTR, the process for the investigation and the proposed remedial action.

17.3 Monsanto

17.3.1 On 23 February 2001, a meeting was held with Monsanto representatives to discuss the non-compliance found at various sites in Tasmania. In attendance for Monsanto were Monsanto's Technical Director and Regulatory Affairs and Product Development officer. Representatives of the IOGTR were present along with the General Manager, Food Agriculture and Fisheries, Tasmanian DPIWE; the Chair of GMAC; a representative from the Office of the Minister for Health and Aged Care; and a representative from the Australian Government Solicitor.

17.3.2 At the meeting the Monsanto representatives expressed sincere regret that the issues of non–compliance with GMAC recommendations had occurred.

18. Further Action

18.1 A copy of the report will be provided to Monsanto in confidence, with the covering letter indicating that the report is provided for information only and that it should not be copied or quoted, verbally or in writing, in part or in full, without the prior agreement of the IOGTR.

18.2 A letter indicating our findings will be sent as cover to the report.

18.3 A summary of the alleged breach and investigation outcome will be provided to Commonwealth agencies, relevant State government representatives and reported in the GMAC Annual Report and IOGTR Quarterly Report. The summary will also be sent to Monsanto.

18.4 The investigation report will be provided to the Australian Government Solicitor in draft form for advice on any issues of confidentiality.

18.5 The investigation report will be provided to the Commonwealth-State Consultative Group on Gene Technology in draft form to seek comments on the report, including the risk assessment.

19. Attachments to this report

Attachment A

IOGTR letter to DPIWE

Attachment B

IOGTR letter to Monsanto of 21 February

Attachment C

Monsanto response of 22 February

Attachment D

Table of sexually compatible weeds

Attachment E

Draft Risk Analysis Report, Application A363. Food produced from glyphosate-tolerant canola line GT73. Australia New Zealand Food Authority, 19 June 2000.

TGA THERAPEUTIC GOODS ADMINISTRATION
PO Box 100 Woden ACT 2606 Australia
Telephone: (02) 6271 4222 Facsimile: (02) 6271 4202
ABN 40 939 406 804

Commonwealth Department of Health and Aged Care

Mr Glenn Appleyard
General Manager
Food Agriculture and Fisheries
Department of Primary Industries, Water and Environment
GPO Box 44A
HOBART TAS 7001

Dear Mr Appleyard

Further to our phone discussion, I am writing regarding outcomes of monitoring visits to trial sites of genetically modified canola in Tasmania.

Last week an IOGTR staff member and an expert in canola/weed identification, who is contracted to my Office, conducted monitoring visits of certain GM canola sites in Tasmania. The monitoring visits were conducted in accordance with the monitoring procedures established in consultation with States and Territories through the Commonwealth State Consultative Group (CSCG) on Gene Technology.

Visits were conducted in respect of the following sites, in order to monitor compliance with GMAC recommendations:

(a) GlaxoSmithKline's trial of poppies [redacted] (PR129)
(b) GlaxoSmithKline's trial of poppies [redacted] (PR129X)
(c) Monsanto's current canola trial [redacted] (PR77X(3)/40)
(d) Aventis CropScience's current canola trial [redacted] (PR63X(5) – DH001)
(e) Monsanto's past site sown to canola in 1999 [redacted] (PR77X(2)/35)
(f) Aventis CropScience's past site sown to canola in 1998 [redacted] (PR62X(4) – SW98/4)
(g) Aventis CropScience's past site sown to canola in 1998 [redacted] (PR62X(4) – SW98/2(1))
(h) Aventis CropScience's past site sown to canola in 1998 [redacted] (PR62X(4) – SW98/2(2))
(i) Aventis CropScience's past site sown to canola in 1998 [redacted] (PR62X(4) – SW98/7).

I received a preliminary report on the monitoring exercise and on that basis, I am advised that of the sites visited, the IOGTR monitoring team found appropriate compliance with GMAC recommendations at sites (a) - (f).

However, I am advised that, at sites (g) and (h) and (i) above, there was evidence of non-compliance with GMAC's recommendations regarding post-trial monitoring for canola volunteers. In summary, volunteer canola was identified on all three sites, with a number of plants having achieved flowering and/or seeding stages. GMAC requires that volunteer plants, during the post-trial monitoring period, be eliminated before flowering occurs to ensure that there is not continued dissemination of the GMO past the post-trial monitoring period.

As an immediate priority, I wrote to Aventis seeking their assurance that:

(a) the three sites will be weeded immediately, by hand, to remove all flowering and mature volunteer canola. I am seeking hand-weeding of the sites because:
- it is the most rapid form of remedial action available (ie. work can commence immediately); and
- if carried out carefully, it is an effective form of remedial action for removing volunteer canola plants.

(b) the three sites will be weeded immediately, by hand, to remove all flowering and mature weedy brassica plants on the sites and within 50m of the sites.

(c) all non-flowering volunteers will be destroyed either by hand weeding, chemical application or cultivation immediately.

(d) the weeding commence immediately and that sufficient resources be allocated to the task to allow the task to be completed expeditiously. I understand that some remedial action may have already commenced following discussions between the IOGTR monitoring team and representatives from Aventis and Serve-Ag who were present during the inspections.

(e) all volunteer plant material removed from the sites be double-bagged and labelled and that the bags are buried in a manner consistent with GMAC advice on disposal of GM material.

To ensure that appropriate remedial action was taken by the company, IOGTR staff commenced follow-up monitoring yesterday and also commenced monitoring of all other GM canola sites in Tasmania.

I understand that this will include a number of sites managed by the Department of Primary Industries, Water and Environment. I understand that relevant personnel within your Department have been contacted to organise such visits.

While the monitoring visit will not be complete until Friday, 23 February 2001, preliminary reports from the first day of follow-up monitoring have indicated that further sites appear to be not meeting GMAC's recommendations for post-trial monitoring.

Given these further incidents, and in an effort to fully brief State and Territory agencies on the issue, I am organising a teleconference with CSCG, tomorrow, Thursday, 22 February for 3:00pm to discuss necessary actions in relation to the apparent non-compliance and any further necessary actions. Non-compliances appear to be evident not only on Aventis sites by also Monsanto sites.

I am also seeking to meet with the companies conducting trials in Tasmania, namely Aventis and Monsanto, on Friday, 23 February 2001. The times for these meetings are yet to be confirmed but I would like to invite you to attend. The purpose of the meetings is to discuss with the companies, face to face, the problems in Tasmania and any necessary follow-up action. Mr Neil Ellis of my Office will call to confirm the timings for these meetings.

As you will appreciate, it is important that under the current administrative arrangements, companies are assured procedural fairness and an opportunity to respond to the IOGTR's findings. It is equally important that the investigation be thorough and that GMACs advice on the issue be sought. Until such time as the investigation is complete, and the companies have had the opportunity to respond to IOGTR's findings, I would appreciate your assurance that the matters dealt with in this letter remain confidential to the internal workings of government. Once the investigation is complete, the IOGTR will consider the most appropriate form of public notification and will, of course, consult your office on the issue.

In the meantime, if you have any queries, or require further information, please contact me on 02 6271 4222.

Yours sincerely

for Elizabeth Cain
Head
IOGTR
21 February 2001

TGA THERAPEUTIC GOODS ADMINISTRATION
PO Box 100 Woden ACT 2606 Australia
Telephone: (02) 6271 4222 Facsimile: (02) 6271 4202
ABN 40 939 406 804

Commonwealth Department of Health and Aged Care

Dr Bill Blowes
Technical Director
Monsanto Australia Ltd
PO Box 2145
KAMBAH ACT 2902

FAXED 21/2/01

Dear Dr Blowes

On 19 February 2001, Neil Ellis, A/g Director of the Monitoring and Surveillance Section of the Interim Office of the Gene Technology Regulator contacted Helen Arthur to advise that the IOGTR proposed to conduct monitoring visits of the following trial sites (used in respect of genetically modified canola) in Tasmania:

1. PR77X(2)/33
2. PR77X(2)/16
3. PR77X(2)/17
4. PR77X/15
5. PR77X(2)/34
6. PR77X/14

The site visits to sites 1 to 5 above were conducted by Dr Peter Thygesen of this Office and Dr John Virtue, our contracted expert in brassica weeds, on 20 February 2001. Site 6 above was visited today, 21 February 2001, by the same team.

I have received a preliminary report on the findings of the site visits.

I am writing to you to advise some serious concerns regarding compliance with recommendations set by the Genetic Manipulation Advisory Committee (GMAC) for the conduct of the trials, in relation to post-trial monitoring of sites which were identified through the site visits.

In relation to post trial monitoring of these sites, GMAC made the following recommendation:

> "GMAC has noted that the post-trial procedures to be used for this extension to the proposal will be the same as for the previous proposal. The area will be cultivated and/or treated with a herbicide other than glyphosate. The field will be planted in the following year to a cereal crop and in the year after that to a crop other than canola. Over the three years following the trial the sites will be monitored for the emergence of volunteer canola plants, which will be destroyed by cultivation or appropriate herbicide treatment."

My concerns regarding compliance with this recommendation are set out below.

PR77X/15 [redacted]

This site had been sown to poppies which are now harvested. The monitoring team reported finding large numbers of canola volunteers on the site and estimated the number to be over 1000 which were flowering or had developing seed pods.

PR77X(2)/34 [redacted]

This site was sown to potatoes and to poppies (which had been harvested). Immediately adjacent to the site a number of canola volunteers were found. The Serve-Ag representative at the site believed that the canola was more then likely dragged off the trial site during cultivation. Approximately 30 volunteers were estimated to be flowering adjacent to the site.

PR77X(2)/16 and PR77X(2)/17 [redacted]

This site had a number of volunteers at the pre-flowering stage. One volunteer was found to be flowering.

On the basis of the preliminary information I have received from the monitoring team, it would appear that there are clear cases of non-compliance with GMAC recommendations regarding post-trial monitoring of trial sites.

I seek your urgent advice on two matters:

(1) the circumstances which allowed these situations to occur. I am concerned at the apparent non-compliance with GMAC recommendations.

(2) The actions to be taken by Monsanto to address the non-compliance with GMAC recommendations. As an immediate priority, I seek your assurance that:

(a) the three sites will be weeded immediately, by hand, to remove all flowering and mature volunteer canola. I am seeking hand-weeding of the sites because:
- it is the most rapid form of remedial action available (ie. work can commence immediately); and
- if carried out carefully, it is an effective form of remedial action for removing volunteer canola plants.

(b) the three sites will be weeded immediately, by hand, to remove all flowering and mature weedy brassica plants on the sites and within 50m of the sites.

(c) all non-flowering volunteers will be destroyed either by hand weeding, chemical application or cultivation immediately.

(d) the weeding commence immediately and that sufficient resources be allocated to the task to allow the task to be completed expeditiously. I understand that some remedial action may have already commenced following discussions between the IOGTR monitoring team and representatives from Serve-Ag who were present during the inspections.

(e) all volunteer plant material removed from the sites be double-bagged and labelled and that the bags are buried/destroyed in a manner consistent with GMAC advice on disposal of GM material.

I have confirmed the need for the above action to be taken with relevant GMAC members. Should you have any queries about these requirements, you should contact my Office immediately. Otherwise, I would appreciate your written advice confirming that arrangements are in place in respect of the above matters by 5 pm on Friday 23 February 2001.

In addition to the consultation I have already undertaken with GMAC members, I have also sought the further advice of GMAC on additional action that is necessary as a result of the apparent non-compliance with GMAC recommendations. I will convey GMAC advice to you on this shortly.

Given the additional controls of GMOs in Tasmania through state legislation, I will also be advising the Department of Primary Industry, Water and Environment of the aforementioned monitoring results, and the remedial action requested of Monsanto.

Yours sincerely

for Elizabeth Cain
Head
IOGTR
21 February 2001

cc Kevin Eke, Monsanto Australia Ltd

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MONSANTO AUSTRALIA LIMITED
A.C.N. 006 725 560
12TH FLOOR, 600 ST KILDA ROAD
MELBOURNE VIC 3004
POSTAL ADDRESS: PO BOX 6051
ST KILDA ROAD CENTRAL
VICTORIA 8008, AUSTRALIA
PHONE 61 3 9522 7122
GENERAL FAX 61 3 9525 2253
ORDERS FAX 1800 249 888
www.monsanto.com.au

22 February 2001

Neil Ellis
Monitoring and Surveillance Unit
IOGTR
PO Box 100
WODEN ACT 2606

Dear Mr Ellis,

Re: Inspections in Tasmania

Further to the monitoring your office conducted this week in Tasmania, and your letter of 21 February, expressing concerns about compliance with GMAC recommendations in relation to post trial monitoring of sites, we have completed a preliminary investigation into the situation.

As a result of this investigation, we have formulated an action plan to address the issues, on a site specific basis and will also look at opportunities for improving the systems we have in place for managing post trial monitoring. These actions are detailed below.

A. Trial Site PR77X/15[redacted]

"This site had been sown to poppies which are now harvested. The monitoring team reported finding large number of canola volunteers on the site and estimated the number to be over 1000 which were flowering or had developing seed pods."

At this site, the poppy crop sown this summer was harvested on Friday 16 February. Following harvesting, the site was assessed by the monitoring contractor, Serve-Ag, and this monitoring revealed a number of patches containing flowering canola volunteers across the site. It appeared that canola was restricted to a number of small patches across the site, where it is believed that herbicide spraying may not have been as effective as elsewhere on the site, or competition from the poppy plantation was poor. No volunteers were observed beyond the site boundaries.

Consequently the monitors recommended that the cultivation of the site proceed immediately, and this had already begun when IOGTR inspectors visited the site on Tuesday.

In discussions with IOGTR inspectors, and liaison with your office, we agreed to continue cultivation with the following course of action:

- Continue ploughing of the field to destroy existing Canola plants.
- Sow oats on the field and irrigate.

- Monitoring contractor shall monitor the field at regular intervals following cultivation, for signs of emergence of volunteer canola.
- Remove any volunteers by hand, should they be evident.
- Follow up inspection by Monsanto to assure effectiveness of monitoring.

B. Trial Site PR77X(2)/34 [redacted]

"This site was sown to potatoes and to poppies (which had been harvested). Immediately adjacent to the site a number of canola volunteers were found. The Serve-Ag representative at the site believed that the canola was more than likely dragged off the trial site during cultivation. Approximately 30 volunteers were estimated to be flowering adjacent to the site."

To manage this problem we intend to immediately weed this site by hand to remove all flowering and mature volunteer canola and brassica plants, including the 50m immediately surrounding the site.

Follow up action will include inspection of the site by Monsanto staff to ensure that monitoring and hand weeding has been effective.

C. Trial Site PR77X(2)/16 and PR77X(2)/17

"The site had a small number of volunteers at the pre-flowering stage. One volunteer was found to be flowering."

During the inspection the volunteers were removed by hand. We will arrange for the monitoring contractor to re-inspect the site, and ensure that all volunteers have been removed.

In addition to these specific actions, and as an organisation committed to the continual improvement of our management system and procedures, we look forward to identifying any opportunities we may have to improve our post trial monitoring, and we will discuss this with you in the meeting scheduled for tomorrow between your office and our representatives.

We trust this action plan meets your requirements, however if you have any questions or concerns please do not hesitate to contact me directly via phone (03 9522 7121) or fax (03 9525 2253).

Yours sincerely

David Penna
Biotechnology Compliance Manager
Monsanto Australia Limited

Attachment D

POTENTIAL GENE FLOW BETWEEN CANOLA (*B. NAPUS*) & *BRASSICACEAE* SPECIES

Category	I	II	III	IV	V	VI
Tribe	*Brassiceae*	*Brassiceae*	*Brassiceae*	*Brassiceae*	*Brassiceae*	Other
Glasshouse 'rescued' hybrids	Yes	Yes	Yes	Yes	No	No
Glasshouse hand hybrids	Yes	Yes	Yes	No	No	No
Field hybrids	Yes	Yes	Not reported	Not reported		
Gene introgression	Yes/Likely#	Not reported*				
Weeds	*Brassica rapa* *Brassica juncea#*	*Raphanus raphanistrum* *Hirschfeldia incana* *Sinapis arvensis*	*Brassica fruticulosa* *Brassica nigra* *Brassica tournefortii* *Diplotaxis muralis* *Diplotaxis tenuifolia* *Rapistrum rugosum*	*Brassica oxyrrhina* *Diplotaxis tenuisiliqua*	*Conringia orientalis* *Carrichtera annua* *Cakile maritima*	*Capsella bursapastoris* *Cardaria draba* *Lepidium sp.* *Myagrum perfoliatum* *Sisymbrium orientale* *Sisymbrium irio* *Sisymbrium erysimoides* *Sisymbrium officinale*
Condiment, fodder & vegetable species	Forage *B. napus#* *B. napus* vegetables# *B. rapa* vegetables# Condiment *B. juncea#*		*Brassica alboglabra* *Brassica chinensis* *Brassica nigra* *Brassica oleracea* *Brassica pekinensis* *Raphanus sativus* *Sinapis alba*			

→ DECREASING SEXUAL COMPATIBILITY →

Considered likely to happen over a period of time **if** the species are in physical proximity and have flowering synchrony.
* Frequency of interspecific hybrids approx. 10^{-6}. Likelihood of subsequent introgression or formation of fertile amphidiploids significantly less again.

POTENTIAL GENE FLOW BETWEEN CANOLA (*B. NAPUS*) & *BRASSICACEAE* SPECIES cont.

Category	I	II	III	IV	V	VI
Tribe	*Brassiceae*	*Brassiceae*	*Brassiceae*	*Brassiceae*	*Brassiceae*	Other
Glasshouse 'rescued' hybrids	Yes	Yes	Yes	Yes	No	No
Glasshouse hand hybrids	Yes	Yes	Yes	No	No	No
Field hybrids	Yes	Yes	Not reported	Not reported		
Gene introgression	Yes/Likely#	Not reported*				
Native species						*Arabidella* (6 sp.) *Balbaretinia* (1 sp.) *Barbarea* (2 sp.) *Blennodia* (25 sp.) *Cardomine* (5 sp.) *Carinavalva* (1 sp.) *Cheesemania* (1 sp.) *Cuphonotus* (2 sp.) *Geococcus* (1 sp.) *Harmsiodoxa* (3 sp.) *Irenepharsus* (3sp.) *Lepidium* (35 sp.) *Menkea* (6 sp.) *Microlepidium* (2 sp.) *Pachymitus* (1 sp.) *Phlegmatospermum* (4 sp.) *Rorippa* (4 sp.) *Scambopus* (1 sp.) *Stenopetalum* (9sp.)

→ DECREASING SEXUAL COMPATIBILITY →