

**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**

**AVENTIS CROPSCIENCE PTY LTD past canola trial sites in Tasmania**

**1. Overview**

- 1.1 This is the draft of a report to the Minister for Health and Aged Care concerning Aventis CropScience non-compliance with recommendations advised by the Genetic Manipulation Advisory Committee (GMAC) in respect of field trials involving genetically modified organisms (GMOs) in Tasmania. The draft report is being released to States and Territories (through the Commonwealth/State Consultative Group on Gene Technology) for comment and advice. At this point, the draft has been cleared by GMAC and the Australian Government Solicitor. Aventis CropScience has been given the opportunity to comment on matters of fact contained in the report.
- 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 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.
- 2.4 Each monitoring visit is tailored to the GMAC recommendations made in respect of a specific trial. A monitoring visit may involve, for example:
- 2.4.1 interviews with the company personnel, the owner of the property or other personnel involved in the trial or post trial monitoring;
  - 2.4.2 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

- 2.4.3 recording findings, either by photographing, video or audio recording, making sketches, making copies of relevant records, or taking samples for testing.
- 2.5 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 Follow-up visits were carried out on 15 February 2001 by an IOGTR monitoring officer.
- 3.5 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.
- 3.6 Monitoring of Aventis CropScience sites was conducted in 8 shires in Tasmania.
- 3.7 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 GM canola sites conducted by Aventis in Tasmania, the IOGTR found that 18 of the 49 sites visited did not comply with the GMAC advice in that Aventis CropScience had not complied 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 five sites used by Aventis CropScience for trialing of genetically modified (GM) canola (*Brassica napus*) in Tasmania. The monitoring took place on 13, 14 and 15 February 2001. One of the sites was for a current trial, four were past sites subject to post-trial monitoring. Aventis CropScience was notified of the pending IOGTR monitoring visit, including the specific sites to be visited. At the time of monitoring the Aventis sites, IOGTR also conducted monitoring of Monsanto and GlaxoSmithKline sites. A separate report, relating to non-compliance issues identified at certain Monsanto sites has been prepared.
- 4.3 The monitoring team (which comprised a representative of the IOGTR and an appropriate external expert) identified non-compliance issues at three of the five sites.
- 4.4 The three non-compliant sites were found with over 1000 canola volunteers on each site at various stages of growth including flowering and seed pod development. This is contrary to GMAC recommendations for the post-trial monitoring of the sites which require volunteers to be controlled before flowering to prevent the risk of pollen escape and gene flow. Volunteer canola should also be controlled before reaching the seed development stage to prevent the continued persistence of the genetically modified organism (GMO) in the environment.
- 4.5 The IOGTR monitoring officer returned to the IOGTR offices in the morning of 16 February 2001 and detailed the non-compliance issues. Immediate remedial action at the three sites was sought by the IOGTR in correspondence sent to Aventis CropScience on 16 February 2001 (refer Attachment A). Aventis CropScience responded to the correspondence indicating that some remedial action had commenced on 15 February 2001, commencing as soon as the monitoring visits revealed non-compliance problems (refer Attachment B). The remedial action was undertaken by Serve-Ag, the company contracted by Aventis CropScience to conduct trials and post-trial monitoring of past canola sites in Tasmania on behalf of Aventis CropScience.
- 4.6 The correspondence of 16 February 2001 from the IOGTR to Aventis CropScience also advised Aventis CropScience that the IOGTR intended to inspect all Tasmanian GM canola sites currently in post-trial monitoring periods to assess compliance with GMAC recommendations.

- 4.7 On 20 February 2001, the IOGTR sent two monitoring teams to Tasmania for a four day period during which 48 Aventis GM canola sites currently in post-trial monitoring periods were monitored. This included re-visiting the four past GM canola sites monitored between 13 and 15 February 2001.
- 4.8 Of the 44 additional Aventis CropScience sites visited, a further 14 sites were found to be non-compliant with GMAC recommendations. Of these sites:
- 4.8.1 10 sites had low numbers of flowering volunteer plants (between 1 and 30 flowering plants);
  - 4.8.2 1 site was found with over 1000 volunteers at various stages of growth up to seed pod development; and
  - 4.8.3 3 sites had obviously undergone some remedial work by Aventis CropScience or their agents, but residual material left at the sites indicated that the sites had contained canola volunteers at the flowering or seed pod stage.
- 4.9 In the morning of 21 February 2001, the Director of the Monitoring and Surveillance Unit, IOGTR, provided initial advice to the Head of the IOGTR that additional non-compliance issues (as set out above) were being identified. 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 subsequently briefed the General Manager, Food Agriculture and Fisheries, Tasmanian Department of Primary Industry and Environment (by telephone and in writing, refer Attachment C). On 22 February 2001, the IOGTR briefed relevant Commonwealth agencies, States and Territories (through the Commonwealth/State Consultative Group (CSCG) on Gene Technology) and sought advice from GMAC.
- 4.10 The IOGTR also convened an urgent meeting with the company, Aventis CropScience, on Friday 23 February 2001. The meeting was attended by IOGTR representatives, as well as a representative from the Office of the Minister for Health and Aged Care, the Australian Government Solicitor, 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 governments with the non-compliance, and to obtain information directly from Aventis CropScience.
- 4.11 Over the period 22 February to 16 March 2001, GMAC assessed the risks of flowering volunteers present at the 17 sites in Tasmania. 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 to place to mitigate

such dissemination. However, GMAC considered that the results of the monitoring visit clearly showed that Aventis CropScience had failed to maintain an appropriate level of control over the trial sites in question. GMAC further concluded that:

- 4.11.1 the remedial action identified by the IOGTR to Aventis CropScience (in correspondence of 16 February 2001) represented the most appropriate immediate response to the non-compliance;
  - 4.11.2 in the light of Aventis' subsequent advice (dated 20 February 2001) that herbicide 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; and
  - 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 of weedy relatives within 100m of non-compliant sites;
    - increased frequency of company monitoring of past sites – 1 monthly at periods of risk (eg. rain); and
    - increased independent monitoring of sites by the IOGTR. Further inspections of the trial sites were conducted on 13, 14 and 15 March 2001 (as set out below).
  - 4.11.14 In addition, the IOGTR will commission an independent study to verify whether any gene flow to related weeds from GM canola has occurred around the non-compliant sites.
- 4.12 On 13 March 2001, the IOGTR sent a monitoring team to Tasmania for a three day period during which the 17 Aventis CropScience GM canola sites previously identified as non-compliant on 13-14 February and 20-23 February 2001 were revisited to check the progress of remedial action. In addition the monitoring team visited two sites that were compliant with GMAC recommendations as observed during monitoring on 20-23 February 2001, but that had sufficient numbers of immature canola plants to warrant further attention. 1 of the 17 was found to be still non-compliant as one mature canola plant was found on the site. One of the 2 additional sites visited (which had previously been compliant) was found to have one flowering volunteer.
- 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 report, in earlier draft form, was provided to the Minister for Health and Aged Care, for information. This earlier draft of the report was, at the same time, provided to:
- 4.15.1 Aventis CropScience. On 22 March 2001 the company advised that they were comfortable with the general content of the draft report. Aventis CropScience will have a further period (until 5:00pm on 30 March 2001) to comment on this draft;
- 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 had provided comments on earlier drafts, which have been incorporated into this version. GMAC considered the earlier draft report at a meeting of the Committee on 22 March 2001; and
- 4.15.3 The Australian Government Solicitor for advice on the appropriate release of information contained in the report. The Australian Government Solicitor approved the report on 22 March 2001, with the confidentiality caveat at paragraph 1.2.
- 4.16 This draft report now be provided to the Minister for Health and Aged Care, as well as to CSCG on 23 March 2001. Comments from CSCG will be invited. These comments will inform the final report to the Minister for Health and Aged Care. CSCG will be asked to provide comments by 5:00pm on 30 March 2001.

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

- |                 |   |
|-----------------|---|
| 1 February 2001 | Aventis CropScience notified of IOGTR inspections scheduled to begin on Wednesday, 7 February 2001.   |
| 5 February 2001 | The contracted external 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 services of an alternative expert, given the short notice, IOGTR staff members contacted Aventis CropScience to postpone inspections until the following week.
- 8 February 2001 Aventis CropScience 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 a brassicaceous weed expert) began inspections of Aventis CropScience sites. One site was inspected. This was a current trial conducted under tents in accordance with GMAC recommendations. The monitoring team did not identify any issues of non-compliance at this site at the time of the inspection.
- 14 February 2001 Four Aventis CropScience past canola sites (ie. sites where GM canola had been trialed in the past, and which are currently subject to post-trial monitoring requirements of GMAC) were visited by the IOGTR monitoring team. At three of the four sites inspected there was evidence of non-compliance with GMAC recommendations. Large numbers of flowering canola volunteers were present at three of the sites.
- 15 February 2001 The IOGTR official revisited the three non-complying sites to take photographs and make additional observations.
- A GMAC member with expertise in plant science was contacted about the non-compliance at the sites and the necessary remedial actions to be taken were outlined.
- The Office of the Minister for Health and Aged Care was notified of the non-compliance found at the three sites in Tasmania.
- 16 February 2001 The IOGTR official returned from the inspections in Tasmania and provided a detailed debrief to the Head, IOGTR and other staff.
- The Head, IOGTR, contacted the Chair of GMAC regarding the non-compliance, expressing strong concern about the non-compliance and advised that the IOGTR wished to write immediately to Aventis CropScience detailing immediate remedial action to be taken, pending further advice from GMAC. The Head, IOGTR, outlined the remedial action proposed. The Chair of GMAC agreed that this action was appropriate.

The IOGTR advised the Office of the Minister for Health and Aged Care of the non-compliance issue, and advised that written briefing would be developed.

The Head, IOGTR, wrote to Aventis CropScience seeking immediate remedial action at the three sites and seeking a response as to why the non-compliance had occurred (Attachment A refers). Aventis CropScience was also advised that follow-up monitoring of all past canola sites in Tasmania would be undertaken by the IOGTR in the week beginning 19 February 2001.

A copy of the letter to Aventis CropScience was forwarded to GMAC members.

19 February 2001      Aventis CropScience was advised of the details of the expanded IOGTR monitoring exercise, to commence on Tuesday, 20 February 2001. Aventis was advised that the 48 Aventis CropScience sites were to be visited by two IOGTR monitoring teams over four days until Friday, 23 February 2001. Each team would comprise an IOGTR staff member and an expert in canola/weed identification.

20 February 2001      Aventis CropScience responded to the letter from the Head, IOGTR, that requested immediate remedial action (refer Attachment B). Aventis CropScience advised of the remedial action that had been undertaken at the three sites where non-compliance had been identified by the IOGTR monitoring team on 14/15 February 2000.

Seven sites were visited by monitoring teams. The monitoring teams identified non-compliance problems at two of the seven sites: small numbers of flowering volunteers were present.

A Minute was sent to the Minister for Health and Aged Care outlining the issues of non-compliance identified to date.

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 further non-compliance problems had been identified 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.

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 C).

A further Minute was sent to the Minister for Health and Aged Care outlining the actions being taken by the IOGTR to investigate the non-compliance at sites in Tasmania.

The monitoring teams inspected a further 13 sites, and identified non-compliance issues at three of these.

Aventis CropScience were invited to attend a meeting with the IOGTR and the Tasmanian DPIWE, and others, on 23 February 2001 to discuss the non-compliance issues in Tasmania.

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 Aventis CropScience in the IOGTR's letter of 16 February 2001). GMAC members advised that they considered the risks to be negligible but advised that further action should also be taken to ensure that even the negligible risks were not realised.

The IOGTR held a meeting with key Commonwealth agencies (Prime Minister and Cabinet, Environment Australia, Industry Science and Resources and Agriculture Fisheries and Forestry 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 to-date by the IOGTR and GMAC was appropriate.

The IOGTR convened a teleconference with members of the Commonwealth-State Consultative Group (CSCG) 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.

The monitoring teams visited a further 16 sites, identifying non-compliance problems on 6 of these sites.

23 February 2001

The monitoring teams visited a further twelve sites, identifying non-compliance problems with three of these sites: small numbers of flowering volunteers were evident. The IOGTR monitoring teams returned to Canberra late in the evening of 23 February 2001.

A meeting was held with Aventis CropScience to discuss the non-compliance and GMAC's proposed further recommendations for minimising risks. IOGTR staff, a Tasmanian DPIWE representative, an Australian Government Solicitor representative and an adviser to the Minister for Health and Aged Care were in attendance. Aventis agreed with the IOGTR's approach and the proposed further 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 completed on 23 February.

The IOGTR officials involved in the monitoring visits began developing comprehensive site reports on observations at each of the 48 Aventis CropScience past sites visited over the period 20 to 23 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 IOGTR held discussions with a third expert used during IOGTR monitoring in Tasmania on observations made at various sites in Tasmania.
- A comprehensive list of non-compliant sites was provided to Aventis CropScience to confirm previous discussions between IOGTR monitoring teams and company field staff on sites at issue. The details of two sites that, while not in breach of GMAC recommendations, were identified as warranting further attention were also provided to Aventis CropScience
- Further information was requested of Aventis CropScience 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.
- The 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.
- Aventis CropScience 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 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 Aventis CropScience as a result of the deliberations of GMAC Release Sub-committee meeting of 2 March 2001.

6 March 2001

Further GMAC advice was 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 Aventis CropScience to inform the investigation report.

IOGTR discussions with the Australia New Zealand Food Authority to confirm that honey derived from genetically modified crops is not considered genetically modified food.

8 March 2001

Further confirmatory advice sought from GMAC on risks related to crops grown on past canola sites.

An early draft of the investigation report provided to GMAC for comments.

9 March 2001

Aventis CropScience was advised that the IOGTR would conduct follow-up monitoring of sites identified as non-compliant to commence on Tuesday, 13 March 2001. Aventis CropScience was advised that the 19 sites identified in correspondence by the IOGTR on 1 March 2001, comprised of 17 sites identified as non-compliant and 2 warranting further attention, were to be visited by an IOGTR monitoring team over three days until Thursday 15 March 2001. The team would comprise two IOGTR staff members.

A draft of the investigation report was provided to the Office of the Minister for Health and Aged Care for comment.

13 March 2001

An IOGTR monitoring team returned to Tasmania to view remedial action taken at all sites. One site was visited by the monitoring team. No issues of non-compliance were identified.

14 March 2001

Ten sites were visited by the monitoring team. The monitoring team identified a non-compliance issue at one site: a single flowering volunteer canola plant was present.

A teleconference with CSCG was held to keep CSCG informed of progress with the investigation. The IOGTR offered to involve a GMAC representative in further discussions on the breach, which

was included as an agenda item for the scheduled CSCG meeting of 20 March 2001.

- 15 March 2001 Eight sites were visited by the monitoring team. The monitoring team identified a non-compliance issue at one site: three flowering volunteer canola plant were present.
- 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 completed on 15 March 2001.
- The IOGTR officials involved in the monitoring visits began developing comprehensive site reports on observations at each of the 19 Aventis CropScience past sites visited over the period 13-15 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.
- 21 March 2001 A draft report was provided to the Minister for Health and Aged Care, the Genetic Manipulation Advisory Committee, the Australian Government Solicitor, and to Aventis CropScience.
- 22 March 2001 The Genetic Manipulation Advisory Committee met and endorsed the risk assessment component of the report.
- The Australian Government Solicitor cleared the report with the confidentiality caveat as at paragraph 1.2.
- Aventis CropScience provided comments on the draft report and advised that they were comfortable with the general content of the draft report.
- 26 March 2001 The report was prepared as a draft and forwarded to the Minister for Health and Aged Care.

## **6. Background - GMAC recommendations for Aventis' canola sites**

- 6.1 The non-compliant sites which are the subject of this breach investigation relate to trials conducted under Planned Release (PR) 62X(4) and PR63X(4). In 1998, Aventis CropScience submitted a proposal to GMAC for risk assessment advice: PR-62X(4). Canola plants trialed in PR-62X(4) were genetically modified to confer tolerance to the herbicide glufosinate ammonium by the introduction of the

*pat* gene (which codes for the enzyme phosphinothricin acetyltransferase) from the soil bacterium *Streptomyces viridichromogenes*.

- 6.2 In 1999, Aventis CropScience submitted a proposal to GMAC for risk assessment advice: PR-63X(4). Canola plants trialed in PR-63X(4) were genetically modified to confer tolerance to the herbicide glufosinate ammonium by the introduction of the *bar* gene (which codes for the enzyme phosphinothricin acetyltransferase) from the soil bacterium *Streptomyces hygroscopicus*. These plants were also modified to contain a hybridisation system which comprises two genetically modified lines of canola – a male sterile line and a fertility restorer line. The male sterile line contains a gene (*barnase*) from the bacterium *Bacillus amyloliquefaciens* which prevents pollen production. The fertility restorer line contains a gene (*barstar*) from the bacterium *Bacillus amyloliquefaciens* which inhibits the action of the *barnase* gene in the male sterile line. Crosses between the male sterile line and the fertility restorer line therefore result in fertile hybrids. A marker gene derived from the bacterium *Escherichia coli* (*nptII* encoding neomycin phosphotransferase) that confers resistance to the antibiotics kanamycin and neomycin was also present in some of the lines trialed.
- 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 for the Aventis CropScience sites investigated by the IOGTR, are contained in advice issued to the company by GMAC in relation to:
  - 6.4.1 planned release proposal PR62X(4) - GMAC advice was issued on 2 September 1998; and
  - 6.4.2 planned release proposal PR63X(4) – 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:

‘GMAC has noted that the post-trial procedures, including monitoring of the trial sites, to be used for this extension to the proposal will be the same as for previous proposals. These conditions include monitoring the site for three years after the trial and eliminating any volunteer plants by cultivation or herbicide treatment. Harvested seed not required for future trials should be destroyed. Canola should not be grown on the sites for three years following the trial. The sites may be seeded to a grass pasture or cereal crops in which all *Brassica* and related species will be readily observed.’

- 6.6 The post-trial procedures for ‘previous proposals’ (as noted in the GMAC recommendation) were set out in the original applications for PR62 and PR63. In those applications Aventis CropScience included the following post-trial procedures:
- 6.6.1 For PR62: ‘The trial site will not grow canola for a further 3 years and the site will be inspected and sprayed or cultivated to control any subsequent canola.’
  - 6.6.2 For PR63: ‘Visual observations of emergence and crop vigour will be noted during the trial. In subsequent years, the trial site will be seeded to perennial ryegrass (*Lolium perenne*) in which all Brassica and related species will be readily observed and eliminated by herbicides as required.’
- 6.7 The purpose of GMAC recommendations is to:
- 6.7.1 minimise dissemination of the GMO and its genetic material;
  - 6.7.2 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
  - 6.7.3 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 AventisCropscience sites on 13 and 14 February 2001.**

- 7.1 Of the 5 sites monitored by the IOGTR on 13 and 14 February 2001, the monitoring team did not identify non-compliance problems at two trial sites. One trial site contained a current trial and the other trial site is subject to GMAC post-trial monitoring recommendations.
- 7.2 However, the monitoring team identified that 3 trial sites that are subject to GMAC post-trial monitoring recommendations did not comply with GMAC recommendations.
- 7.3 The monitoring team has prepared a detailed monitoring report on this monitoring exercise. Following is a summary of the results of monitoring at these three sites:

### **7.3.1 PR62X(4) – SW98/2 (site 1)**

The IOGTR monitoring team observed over 1000 volunteer canola plants at various stages of growth at the site. The monitoring team estimated that 20-30% of the canola volunteers were flowering. A small number of plants (approximately 6) had green seed pods.

### 7.3.2 *PR62X(4) – SW98/2 (site 2)*

The IOGTR monitoring team observed over 1000 volunteer canola plants at the site. The canola plants were at various stages of growth and the monitoring team estimated that 20-30% had mature seed pods, 60% had green seed pods and the remaining 10-20% were flowering.

### 7.3.3 *PR62X(4) – AG98/7*

The IOGTR monitoring team estimated that over 1000 volunteer plants were present at the site and that approximately 20-30% of the plants were flowering. The remainder of the volunteer canola plants were at pre-flowering stages of development. The volunteers were scattered throughout the site.

## **8. Details of non-compliant sites: Outcomes of the IOGTR monitoring visits of Aventis Cropscience sites from 20 February 2001 to 23 February 2001.**

- 8.1 From 20 February 2001 to 23 February 2001, the IOGTR monitoring team visited a total of 48 (four sites visited on 13 – 15 February were revisited). Non-compliance problems were identified at 14 of the 44 additional sites. The monitoring teams have prepared a detailed report on this monitoring exercise. Summaries of the outcomes of the monitoring visits are contained in this part of the report.
- 8.2 On 20 February 2001, the IOGTR monitoring team visited seven Aventis trial sites. The team identified that two of the seven Aventis sites visited were not compliant with GMAC recommendations:

### 8.2.1 *PR63X(4) DH99(10)*

The IOGTR monitoring team observed approximately 50 volunteer canola plants on the site: 15 of the volunteers were flowering; a further 20 were non-flowering volunteers; and 15 plants had mature seed pods. The canola plants with mature seed pods were hand pulled during the monitoring visit and contained for disposal in accordance with GMAC recommendations.

### 8.2.2 *PR63X(4) DH99 (14)*

The IOGTR monitoring team observed four flowering canola volunteers and three non-flowering smaller plants at the site.

- 8.3 On 21 February 2001, the IOGTR monitoring team visited 13 trial sites, identifying non-compliance problems at three of these sites due to the presence of flowering volunteers at the time of the visit or evidence that flowering plants had been present prior to the monitoring team visiting the site:

### **8.3.1 PR63X(4) AG99-9**

The IOGTR monitoring team observed one flowering volunteer canola plant and approximately 30 pre-flowering canola plants at the site. All plants observed were hand pulled and contained for disposal in accordance with GMAC recommendations.

### **8.3.2 PR62X(4) AG98/6**

The IOGTR monitoring team observed many shattered seed pods (estimated to be several hundred) of a *Brassica* species, most probably canola, across the site. The Serve-Ag representative accompanying the IOGTR monitoring team advised that the poppy crop sown on this site had been destroyed, at the direction of the Tasmanian Poppy Advisory and Control Board, by herbicide treatment because of the large number of canola volunteers in the crop. The Serve-Ag representative also advised that the canola volunteers were at the flowering and immature seed pod formation stages at the time of destruction. At the time of the monitoring visit, the site had been freshly cultivated.

### **8.3.3 PR63X(4) AG99-7**

The IOGTR monitoring team observed one flowering volunteer canola plant at the site. A further 20 (approximately) canola plants were observed and the upper parts of the plants had been removed in the harvesting of the post-trial crop. All canola plants observed were hand pulled during the course of the monitoring visit and contained for disposal in accordance with GMAC recommendations.

- 8.4 Two of the sites visited on 21 February 2001 had previously been identified as non-compliant by the IOGTR monitoring team on 13 and 14 February 2001 (PR62X(4) SW98/2 (1) and PR62X(4) SW98/2 (2)):

#### **8.4.1 PR62X(4) SW98/2 (1) and PR62X(4) SW98/2 (2)**

The IOGTR monitoring team observed that Serve-Ag on behalf of Aventis CropScience had taken remedial action at the two sites to destroy canola volunteers. The IOGTR monitoring team observed one mature plant with seed pods at site PR62X(4) SW98/2 (2). The plant was removed during the monitoring visit and contained for disposal in accordance with GMAC recommendations.

- 8.5 On 22 February 2001, the IOGTR monitoring team identified that 6 of 16 Aventis CropScience sites visited were not compliant with GMAC recommendations due to the presence of flowering volunteers at the time of the visit or evidence that flowering plants had been present prior to the monitoring team visiting the site:

#### **8.5.1 PR63X(4) – AG99-15**

The IOGTR monitoring team estimated that there were over 1000 flowering volunteer canola plants at the site, in cultivated areas between rows of slashed and raked poppy stubble. The IOGTR monitoring team also observed desiccated mature canola plants (estimated to be over 1000) within the raked poppy stubble. These plants had shattered seed pods and fully developed seed pods containing mature seed. The Serve-Ag representative accompanying the IOGTR monitoring team advised that the flowering canola volunteers had been sprayed with herbicide on 20 February 2001, and evidence of herbicide effects on these plants was observed by the monitoring team.

#### **8.5.2 PR63X(4) – AG99-2**

The IOGTR monitoring team observed one flowering volunteer canola plant at the site. This plant had a small number of green seed pods. The monitoring team also observed over 100 immature volunteer canola plants (ie had not flowered or set seed) at the site. Some of these volunteer canola plants exhibited immature flower bud formation. The one flowering canola plant and those with immature buds were hand pulled during the visit and contained for disposal in accordance with GMAC recommendations.

#### **8.5.3 PR63X(4) – AG99-16**

The IOGTR monitoring team observed one flowering volunteer canola plant and three mature canola plants with shattered seed pods at the site. The monitoring team also observed approximately 200 immature canola plants with evidence of early flower bud formation. The flowering canola plant was hand pulled during the visit and contained for disposal in accordance with GMAC recommendations.

#### **8.5.4 PR63X(4) – AG99/1**

The IOGTR monitoring team observed six flowering volunteer canola plants and one canola plant with mature seed pods at the site. The monitoring team also observed over 1000 volunteer canola plants at the site, comprised of two distinct populations: immature canola plants (4-6 leaf stage); and mature plants damaged by recent cultivation and also exhibiting signs of herbicide damage.

#### **8.5.5 PR63X(4) – AG99/4**

The IOGTR monitoring team observed one small flowering volunteer canola plant and two immature volunteer canola plants at the site. The flowering plant was hand pulled during the monitoring visit and contained for disposal in accordance with GMAC recommendations.

#### **8.5.6 PR62X(4) AG98/2**

The IOGTR monitoring team observed over 1000 volunteer canola plants at all growth stages at the site. The monitoring team estimated that approximately 20% of the volunteers were flowering and approximately 10% had mature seed pods.

- 8.6 One of the sites visited on 13 and 14 February 2001 and found to be non-compliant was re-visited on 22 February 2001:

#### **8.6.1 PR62X(4) – AG98/7**

The IOGTR monitoring team observed that remedial action had been undertaken at the site to destroy canola volunteers.

- 8.7 On 23 February 2001, the IOGTR monitoring teams identified that 3 of 12 Aventis sites visited were not compliant with GMAC recommendations due to the presence of flowering volunteers at the time of the visit:

#### **8.7.1 PR63X(4) DH99-13**

The IOGTR monitoring team observed one flowering volunteer canola plant and two smaller volunteers (4 leaf stage) at the site. The flowering plant was hand pulled during the monitoring visit and contained for disposal in accordance with GMAC recommendations.

#### **8.7.2 PR-63X(4) DH99(8)**

The monitoring team observed approximately 20 flowering volunteer canola plants with green seed pods at the site.

#### **8.7.3 PR-62X(4) SW98/7**

The monitoring team observed approximately 10 flowering volunteer canola plants with green seed pods at the site. The plants were hand pulled during the monitoring visit and contained for disposal in accordance with GMAC recommendations.

## **9. Risk Assessment – contextual overview**

- 9.1 As set out in section 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 section 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 Aventis CropScience for the trial of GM canola under trials PR-62X(4) and PR-63X(4).
- 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 teams observed flowering plants of *Raphanus raphanistrum* (commonly referred to as wild radish), a weedy relative of canola, at six of the non-compliant sites where the monitoring team also detected flowering canola volunteers:
- at one site, where over 1000 volunteer canola plants were observed, the monitoring teams also identified 3 flowering *R. raphanistrum* plants; and
  - at a further six sites, the monitoring teams also observed flowering weedy relatives (including *Sinapsis* sp.) in the presence of very low numbers (ie between 1 and 30) of flowering volunteer canola plants.
- 10.1.3 A summary of the incidence of weedy relatives (considered by GMAC to be capable of crossing with canola) observed at the sites of concern is provided in Table 1 below.

**Table 1: Aventis GM canola sites of concern in Tasmania – incidence of weedy relatives\***

<b>Trial</b>	<b>Site ID</b>	<b>Number of canola with flowers and/or mature seed pods observed</b>	<b>Number of flowering <i>R. raphanistrum</i> observed</b>	<b>Number of <i>Brassica rapa</i> observed</b>	<b>Other weedy relatives* Observed</b>
PR-63X(4)	DH99(14)	4	0	0	20 <sup>a</sup>
PR-63X(4)	DH99(10)	30	>100	0	0
PR-63X(4)	AG99-7	1	<20	0	0
PR-62X(4)	AG98/6	>1000 (seed pods)	0	0	0
PR-62X(4)	SW98/2 (1)	>300 (>1000 pre-flowering)	0	0	0

<b>Trial</b>	<b>Site ID</b>	<b>Number of canola with flowers and/or mature seed pods observed</b>	<b>Number of flowering <i>R. raphanistrum</i> observed</b>	<b>Number of <i>Brassica rapa</i> observed</b>	<b>Other weedy relatives* Observed</b>
PR-62X(4)	SW98/2 (2)	>1000	0	0	0
PR-63X(4)	AG99-9	1	0	0	0
PR-63X(4)	AG99-15	>1000 (seed pods/flowering <sup>b</sup> )	0	0	0
PR-63X(4)	AG99-2	1	0	0	0
PR-63X(4)	AG99-16	4	0	0	0
PR-62X(4)	AG98/7	>300 (>700 pre-flowering)	3	0	0
PR-63X(4)	AG99/1	6 (>1000 pre-flowering)	0	0	0
PR-63X(4)	AG99/4	1	0	0	0
PR-62X(4)	AG98/2	>300 (>1000 green)	0	0	0
PR-63X(4)	DH99-13	1	<20	0	0
PR-63X(4)	DH99(8)	<20	>200	0	0
PR-62X(4)	SW98/7	10	50-100	0	0
PR63X(4)	AG99-5	1	0	0	0

\*: sexually compatible weedy relatives as detailed in columns I, II and III of the table provided at Attachment D.

a: *Sinapsis arvensis*

b: green plants showed signs of herbicide damage, flowers probably infertile

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)<sup>1</sup> 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 section 16).

## 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<sup>2</sup>. 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 section 16).

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<sup>1</sup>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).

<sup>2</sup> 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.

## 10.4 Gene flow: other weedy relatives

- 10.4.1 Other weedy relatives that have the potential to cross pollinate with canola are 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. *Sinapis* species are listed in column II of the table and can be considered to have similar hybridisation development as wild radish. Reports have, however, suggested that the hybridisation development in *Sinapis* is much less than wild radish<sup>3,2</sup>.
- 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 section 16).

## 10.5 Gene flow assisted by the introduction of bees to sites when trial was being conducted

- 10.5.1 Aventis CropScience 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 naturally at sites and risk management measures were implemented to minimise flow of pollen off sites. GMAC advice included the following conditions:
- PR62-X(4), a 15 m buffer of non-transgenic canola plants around the transgenic plants, isolation of the transgenic canola from other *Brassica* crops by at least 400 m, and monitoring of a 100 m zone around the crop for the presence of sexually compatible species before the trial and during flowering of the crop, with removal of any such plants using appropriate herbicides; and
  - PR63-X(4), a 15 m buffer of non-transgenic canola or a non-*Brassica* crop surrounding the trial site; separation of the transgenic canola from other *Brassica* crops by at least 400 m; monitoring of a 50 m zone around the site for sexually compatible species before and during the trial, and removal of any such plants; and monitoring of the 400 m zone around the site during the same period for the presence of *B. napus*.

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<sup>3</sup> Rieger MA, Preston C and Powles B (1999) Risks of gene flow from transgenic herbicide-resistant canola (*Brassica napus*) to weedy relatives in southern Australian cropping systems. *Australian Journal of Agriculture Research* 50:115-128

- 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, onions, beans, peas, lupine beans, wheat, triticale 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 The transfer of 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<sup>45</sup> and deliberate

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<sup>4</sup> Syvanen, M. 1999, "In search of horizontal gene transfer", *Nature*, vol. 17, pp. 833-834.

<sup>5</sup> 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.<sup>6</sup> Transfer of plant DNA to bacteria has been demonstrated under highly artificial laboratory conditions<sup>57</sup> 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.<sup>58</sup>

- 10.7.4 It should be noted that the genes introduced to the GM canola plants trialed under PR-62X(4) and PR-63X(4) were isolated from commonly occurring soil bacteria and these genes are therefore widespread in the environment. The *pat* and *bar* genes conferring tolerance to glufosinate ammonium herbicide were derived from the bacteria *Streptomyces viridichromogenes* and *S. hygroscopicus* respectively. The *nptII* gene, that confers resistance to the antibiotics kanamycin and neomycin, is prevalent in naturally occurring bacteria found in soil and in animal and human digestive systems. The *nptII* gene occurs naturally on transmissible genetic elements (transposons and plasmids) that are readily transferable between bacterial species.<sup>9</sup> It should also be noted that the *nptIII* gene introduced to the GM canola is not present on a transmissible genetic element, but has been integrated into the plant genome. The *barnase* and *barstar* genes are derived from the bacterium *Bacillus amyloliquefaciens*.
- 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. GMAC considered the potential impact on clinical medicine of the transfer of the *nptII* gene from the GM canola to other bacteria, although the risk of such a transfer was concluded to be extremely unlikely.
- 11.2 As noted above, horizontal transfer to bacteria is extremely unlikely. Kanamycin and neomycin are not administered orally nor are they extensively used in human clinical medicine.

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<sup>6</sup> 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.

<sup>7</sup> Gebhard, F. & Smalla, K. 1998, "Transformation of *Acinetobacter* sp. Strain BD413 by transgenic sugar beet DNA", *Appl. Env. Microbiol.*, vol. 64, pp. 1550-1554.

<sup>8</sup> Doolittle, W. F. 1999, "Lateral genomics", *Trends Cell Biol.*, vol. 9, M5-8.

<sup>9</sup> US FDA Draft Guidance Document on Use of Antibiotic Resistance Marker Genes in Transgenic Plants, 1998

11.3 The incidence of naturally occurring bacterial strains resistant to the antibiotics in question is already very high, and the antibiotic-resistance genes in these bacteria are often located on transmissible genetic elements that are readily transferable between bacterial species.

11.4 GMAC concluded that in the unlikely event that the *nptII* gene was transferred from the GM canola to a bacterium, this would be unlikely to have any detectable impact on the level of resistance in microbial populations and the risks to human health or the environment are negligible.

## **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 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: Aventis GM canola sites of concern in Tasmania – post-trial crops**

<b>Trial</b>	<b>Site ID</b>	<b>Number of canola Flowering and/or mature seed observed</b>	<b>Post-trial crops</b>	<b>Harvested yes/no</b>
PR-63X(4)	DH99(14)	4 flowering	beans	no
PR-63X(4)	DH99(10)	30	potatoes	no
PR-63X(4)	AG99-7	1	peas & wheat	<b>yes yes</b>
PR-62X(4)	AG98/6	>1000 seed pods	opium poppies	<i>destroyed prior to harvest</i>

<b>Trial</b>	<b>Site ID</b>	<b>Number of canola Flowering and/or mature seed observed</b>	<b>Post-trial crops</b>	<b>Harvested yes/no</b>
PR-62X(4)	SW98/2, site 1	>300 flowering (>1000 pre-flowering)	opium poppies	yes
PR-62X(4)	SW98/2, site 2	>1000	peas & wheat	yes <sup>a</sup> yes <sup>b</sup>
PR-63X(4)	AG99-9	1	peas & lupine bean	yes yes
PR-63X(4)	AG99-15	>1000 (seed pods/flowering) <sup>c</sup>	opium poppies	yes
PR-63X(4)	AG99-2	1 flowering	pasture	no
PR-63X(4)	AG99-16	4	triticale	yes <sup>d</sup>
PR-62X(4)	AG98/7	>300 (>700 pre-flowering)	opium poppies	yes
PR-63X(4)	AG99/1	6 (>1000 pre-flowering)	opium poppies	yes
PR-63X(4)	AG99-4	1 flowering	pasture	No
PR-62X(4)	AG98/2	>300 (>1000 green)	potatoes	No
PR-63X(4)	DH99-13	1	beans	no <sup>e</sup>
PR-63X(4)	DH99(8)	<20	potatoes	No
PR-62X(4)	SW98/7	10	onions	no <sup>f</sup>
PR-63X(4)	AG99-5	1	pasture	No

a,b: no canola volunteers were observed within the area sown to wheat, only two volunteers were observed in the area sown to peas

c: green plants showed signs of herbicide damage, flowers probably infertile

d: volunteers were not observed within the area sown to triticale

e: beans were scheduled for harvest on the day of the monitoring visit, the one flowering canola volunteer was removed during the monitoring visit

f: onions had been dug/lifted in preparation for harvest

## 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 back onto the site. 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 remote because of the physical process of harvesting and the difference in size between canola seeds and potatoes. Potatoes are sieved on site to remove soil contamination and the soil is returned to the harvest site. Remedial action to remove volunteer canola plants will be undertaken by the company prior to harvest of the potatoes.

### **12.4 GMAC assessment: peas**

- 12.4.1 GMAC considered that the risk of co-harvest of GM canola seeds with post-trial peas is negligible because of the physical process of harvesting and the difference in size between canola seeds and pea seeds. The action of sieves, webbing and blowing mechanisms on the

harvesting equipment ensures that a minimum of material other than pea seeds is removed from the site. Very few canola volunteers were observed in areas actually sown to peas. At trial site SW98/2 site 2 (see Table 2) some of the site was sown to peas. This site had significant numbers of canola volunteers but only two canola plants were observed within the pea crop.

## **12.5 GMAC assessment: wheat and triticale**

- 12.5.1 GMAC considered the risk of co-harvest of GM canola seeds with post-trial wheat. Very few canola volunteers were observed in areas actually sown to wheat. At trial site SW98/2 site 2 (see Table 2) some of the site was sown to wheat. This site had significant numbers of canola volunteers but no canola plants were observed within the wheat crop.

## **12.6 GMAC assessment: onions**

- 12.6.1 The onion crop observed by the monitoring team had been dug and lifted, but not been harvested at the time of the visit. GMAC considered that the risk of any GM canola seed being co-harvested with onions is remote because of the physical process of harvesting and the difference in size between canola seeds and onions. Remedial action to remove volunteer canola plants was undertaken by the company prior to harvest of the onions.

## **12.7 GMAC assessment: beans**

- 12.7.1 The bean crops observed by the monitoring teams had not been harvested at the time of the visit. GMAC considered that the risk of any GM canola seed being co-harvested with beans is remote because of the physical process of harvesting and the difference in size between canola seeds and beans. Very few canola volunteers with flowers were observed at the sites sown to beans. No volunteers with seed pods were observed. Remedial action to remove volunteer canola plants was taken at both sites during the monitoring visit.

## **12.8 GMAC assessment: lupine beans**

- 12.8.1 GMAC considered that the risk of any GM canola seed being co-harvested with lupine beans is remote because of the physical process of harvesting and the difference in size between canola seeds and lupine beans. The action of sieves, webbing and blowing mechanisms on the harvesting equipment ensures that a minimum of material other than

bean seeds is removed from the site. Very few canola volunteers with flowers or seed set were observed at the site sown to lupine beans.

## **12.9 GMAC assessment: broadleaf crops as post trial crops**

12.9.1 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. GMAC provided advice regarding post-trial crops for PR-62X(4) and PR-63X(4) (as set out in 4. Background - GMAC recommendations for Aventis' canola sites):

‘The sites may be seeded to a grass pasture or cereal crops in which all *Brassica* and related species will be readily observed.’

12.9.2 The *Brassica* and related species referred to are listed in columns I, II and III of the table provided at Attachment D. It should be noted that this advice did not explicitly preclude the sowing of post-trial crops other than recommending grass pasture or cereal crops be grown.

12.9.3 The IOGTR conducted an audit of Aventis CropScience compliance with GMAC recommendations in the conduct of GM field trials. The audit report was published in November 2000. The Audit Committee found that broadleaf crops that had been grown on past trial sites may make it difficult to control volunteer canola. The Audit Committee recommended that GMAC consider the risks associated with the sowing of broadleaf crops on past trial sites.

12.9.4 Aventis CropScience has submitted a list of crops, other than crop pastures or cereal crops, to GMAC for review as suitable for sowing during the post-trial monitoring period. Aventis CropScience have supported an approach that only other *Brassica* crops should be precluded from being grown on past GM canola sites because they contend that effective control measures could be implemented to control volunteer canola plants in other types of crops.

12.9.5 GMAC had been reviewing the issue of what post-trial crops may be grown on sites used for trials of GM canola. Given the non-compliance in Tasmania, GMAC has recommended that pasture and cereal crops be grown and that all other crops require specific agreement from GMAC before being sown on a site (see section 16).

## **12.10 Risks associated with adventitious contamination of food**

12.10.1 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.

- 12.10.2 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%.
- 12.10.3 Aventis CropScience has submitted an application to the ANZFA for approval of foods derived from glufosinate ammonium tolerant and pollination controlled canola (ie with the same genetic modifications as the plants trialed under PR-62X(4) and PR-63X(4)). Foods derived from glufosinate ammonium tolerant canola are currently permitted for use in human foods in Australia under interim arrangements instituted by ANZFA to allow GM foods currently in the market place to remain there while they are being assessed for safety. These arrangements only apply if: ANZFA had received an application for approval of the GM food by 30 April 1999; the GM food was on the market lawfully overseas and considered safe by a respected overseas regulatory agency; and the Australia New Zealand Food Standards Council must have no evidence to indicate that the food is unsafe.
- 12.10.4 ANZFA has recently published its Draft Risk Analysis Report on oil derived from glufosinate ammonium tolerant and pollination controlled canola. The report is provided at Attachment E. 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 the introduced genes in the GM canola do not produce any additional risk to public health and safety and that oil derived from the GM canola is equivalent to commercial non-GM canola in terms of its food safety and nutritional adequacy.
- 12.10.5 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.

## **12.11 Dispersal by livestock (sheep)**

- 12.11.1 The IOGTR monitoring teams observed grazing sheep at two trial sites (PR-63X(4) AG99-2 and PR62X(4) SW98/2 (1)). The first site had a single volunteer canola plant with flowers and immature seed pods. The second site had a small number of plants with green seed pods.
- 12.11.2 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 system and was voided in droppings after the sheep were moved from the trial site.
- 12.11.3 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.<sup>10</sup> However seeds of similar size to canola can be expelled in very small numbers for up to three weeks after grazing.<sup>11</sup> Reports also indicate that a proportion of seeds of a similar size to canola passed by sheep are viable and will germinate.<sup>11</sup> In addition, canola seed can show resistance to digestion<sup>12</sup>
- 12.11.4 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.
- 12.11.5 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 Aventis CropScience to ensure that this small risk is not realised (as set out under section 16)
- 12.11.6 Glufosinate ammonium tolerant canola has been approved as stock feed in Canada, Japan and the USA.

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<sup>10</sup> 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

<sup>11</sup> 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 10<sup>th</sup> Australian Weeds Conference and 14<sup>th</sup> Asian pacific Weed Science Society Conference, Brisbane.

<sup>12</sup> 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. GMAC Risk Assessment: Continued persistence of viable canola seed in the environment**

- 13.1 The IOGTR monitoring teams observed volunteer canola plants with seed pods at a number of sites. The monitoring teams also observed desiccated canola seed pods containing mature seeds and desiccated canola seed pods that had shattered and therefore dispersed seed at some of the sites visited. There is a risk of continuation of the GM canola plants in the environment from these mature plants shedding potentially viable canola seed onto the trial sites.
- 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 risk of continuation of the GM canola plants at the trial site because of production and shedding of potentially viable seed from volunteer GM canola plants. GMAC considers that because the seeds are essentially confined to the trial sites the risk to the general environment can be reduced to negligible levels through management actions to be required of Aventis CropScience (as set out under section 16).

### **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. Whilst the Tasmanian government has not previously provided or raised concerns with GMAC about risks of releasing GM canola as trials in that State, a submission was recently received, on 22 January 2001, from the Tasmanian Department of Primary Industries, Water and Environment (DPIWE) after GMAC wrote to DPIWE seeking comments on the latest canola release proposal. The DPIWE submission raised concerns covering four areas:
- The introgression of transgenes into *Brassica rapa* (wild turnip), a weedy relative of canola;
  - Concerns that isolation distances may not satisfactorily restrict transgene dispersal;
  - Concerns that canola seed dormancy may be longer than three years; and
  - The potential for genes to transfer to soil microorganisms.

14.2 Each of these have been considered by GMAC in the past and are clarified in this report. In summary, GMAC has noted the following for each of the Tasmanian concerns.

14.2.1 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<sup>13</sup>. GMAC employs isolation distances to minimise this risk further and currently a 50m exclusion zone from all weedy relatives applies to trial sites.

14.2.2 GMAC's 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.

14.2.3 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.

14.2.4 Horizontal gene transfer from plants to bacteria has not been experimentally demonstrated under natural conditions<sup>14,15</sup> and deliberate attempts to induce such transfers have so far failed.<sup>16</sup> Transfer of plant DNA to bacteria has

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<sup>13</sup> 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.

<sup>14</sup> Syvanen, M. 1999, "In search of horizontal gene transfer", *Nature*, vol. 17, pp. 833-834.

<sup>15</sup> 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.

<sup>16</sup> 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.

been demonstrated under highly artificial laboratory conditions<sup>517</sup> 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.<sup>518</sup>

### **15. Risk Management: Immediate actions necessary to bring the sites into compliance with GMAC recommendations**

- 15.1 To promptly address potential risks associated with sites found to be non-compliant during monitoring on 13-15 February 2001, the Head, IOGTR, wrote to Aventis on 16 February 2001 seeking assurance from the company that the following remedial action be taken immediately:
- (a) the sites will be weeded immediately, by hand, to remove all flowering and mature volunteer canola. Hand-weeding was chosen 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 sites to be weeded immediately, by hand, to remove all flowering and mature weedy brassicaceous 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, with sufficient resources allocated to the task to allow the task to be completed expeditiously.
  - (e) all volunteer plant material removed from the sites to be double-bagged and labelled with bags to be buried in a manner consistent with GMAC advice on disposal of GM material.

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<sup>17</sup> Gebhard, F. & Smalla, K. 1998, "Transformation of *Acinetobacter* sp. Strain BD413 by transgenic sugar beet DNA", *Appl. Env. Microbiol.*, vol. 64, pp. 1550-1554.

<sup>18</sup> Doolittle, W. F. 1999, "Lateral genomics", *Trends Cell Biol.*, vol. 9, M5-8.

## **16. Further risk management action to be implemented**

### **16.1 Management of Risk: Gene Flow**

- 16.1.1 GMAC have recommended that the following actions be implemented by Aventis CropScience to manage the risk of gene flow from volunteer GM canola plants at the sites found to be non-compliant during monitoring on 13-15 February, 20-23 February and 13-15 March 2001:
- (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 metre zone must be removed and destroyed.
  - (b) Aventis CropScience 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 to commission an independent research study to verify 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 involves collection of *B.rapa* around non-compliant sites and testing 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 Aventis CropScience to manage the risk of movement of GM canola seed from the sites found to be non-compliant during monitoring on 13-15 February, 20-23 February and 13-15 March 2001:
- (a) Monitor all sites where harvesters (and other machinery) involved in the harvest of post-trial crops were cleaned 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. Aventis CropScience have advised that all sheep that have grazed sites 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 Aventis CropScience to manage the risk of continuation of viable GM canola seed in the environment:

- (a) The non-compliant 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 when 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 shall include details of:
  - (i) the number of volunteer plants observed;

- (ii) the development stage reached by the volunteer plants;
  - (iii) whether the volunteer plants appeared on the trial site or in the 100 metre monitoring zone; and
  - (iv) the methods used for their control (as detailed (g)).
- (f) 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)
- (g) No canola crops are to be grown on the non-compliant trial site, or the 100 metre monitoring zone around the site, for at least three years from 1 March 2001. If the trial site 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 Aventis CropScience wishes to plant other crops, they must demonstrate to the satisfaction of GMAC/the GTR 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.

#### 16.4 Other General Risk Management actions:

- 16.4.1 The IOGTR require 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 Aventis CropScience
- 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 further monitoring was undertaken in the period 13 –

15 March 2001, and involved a further visit by IOGTR officials to each of the trial sites identified in this report as having breached GMAC recommendations.

- 16.4.4 No sites visited by the monitoring team on 13 March were identified to have any on-going non-compliance problems. Remedial actions had been taken by the company. There was no evidence of flowering canola volunteers.
- 16.4.5 On 14 March 2001, the IOGTR monitoring team visited 10 Aventis CropScience past trial sites. Eight of these sites were previously identified as non-compliant and two were compliant but identified as sites that required further action to remain compliant. The IOGTR monitoring team identified a single flowering volunteer on one of the two Aventis CropScience sites that were previously compliant. The site was in relation to PR-63X(4) AG99-5. The flowering plant was hand pulled during the monitoring visit and contained for disposal in accordance with GMAC recommendations. Nine of the ten sites visited were compliant at the time of the monitoring visit, including the eight previously non-compliant sites.
- 16.4.6 On 15 March 2001, the IOGTR monitoring team visited 8 Aventis CropScience past trial site previously identified as non-compliant during the monitoring visits of 13-14 February 2001 and 20-23 February 2001. One of the eight sites was still non-compliant in that the IOGTR monitoring team identified three flowering volunteer plants at the site of PR-63X(4) AG99-4. The flowering plants were hand pulled during the monitoring visit and contained for disposal in accordance with GMAC recommendations. Seven of the eight sites visited were compliant at the time of the monitoring visit as remedial action had taken place.
- 16.4.7 The information relating to the results of the further monitoring visits has been conveyed to GMAC and advice sought about risks and further actions. The risks that apply to the original breaches apply to the non-compliant sites found during follow-up monitoring. With the low numbers of flowering volunteers and the immediate remedial action taken, GMAC considers the risks are negligible.
- 16.4.8 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.
- 16.4.9 GMAC considered this issue at a meeting on 22 March 2001. GMAC has postponed its consideration of a current application pending the provision of further advice from the company.

## **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 accord the companies procedural fairness and therefore the standard operating procedure was that the investigation be completed prior to public announcement. The Head, IOGTR, reiterated this advice to CSCG 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 been advised that the information provided by the IOGTR is 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 Aventis CropScience 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 Aventis representatives. In attendance from Aventis CropScience were: the CEO of the Seeds, Biotechnology and Crop Improvement Division; the Public and Government Affairs Manager; and the Technical Manager, Breeding and Product Development. Representatives of the IOGTR were present along with the General Manager, Food Agriculture and Fisheries, Tasmanian DPIWE, 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 Aventis CropScience

- 17.3.1 On 23 February 2001, a meeting was held with Aventis representatives to discuss the non-compliance found at various sites in Tasmania. In attendance from Aventis CropScience were: the CEO of the Seeds, Biotechnology and Crop Improvement Division; the Public and Government Affairs Manager; and the Technical Manager, Breeding and Product Development. Representatives of the IOGTR were present along with the General Manager, Food Agriculture and Fisheries, Tasmanian DPIWE, 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 Aventis CropScience representatives expressed sincere regret that the issues of non-compliance with GMAC recommendations had occurred and indicated that they would be implementing a number of management actions to ensure circumstances such as this do not occur in the future. Aventis CropScience representatives agreed with the basis of the risk management actions developed by GMAC (as set out under section 16).

## **18. Further Action**

- 18.1 A copy of the investigation report will be provided, in confidence, to Aventis CropScience, with a 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.
- 18.4 A copy of the investigation report, in draft form, will be provided to the Australian Government Solicitor for advice on any issues of confidentiality.
- 18.5 A copy of the investigation report, in draft form, will be provided to the Commonwealth-State Consultative Group on Gene Technology to seek comments on the report, including the risk assessment.

## **19. Attachments to this report**

### **Attachment A**

IOGTR letter to Aventis CropScience of 16 February

### **Attachment B**

Response from Aventis CropScience of 20 February to IOGTR letter of 16 February

### **Attachment C**

IOGTR Letter to General Manager, Food Agriculture and Fisheries, Tasmanian Department of Primary Industries, Water and Environment of 21 February

### **Attachment D**

Potential gene flow between canola (*B. napus*) and *Brassicacae* species

### **[Attachment E](#)**

[Draft Risk Analysis Report, Application A372. Oil derived from glufosinate-ammonium tolerant canola lines Topas 19/2 and T45 and Oil derived from glufosinate-ammonium tolerant and pollination controlled lines Ms1, Ms8, Rf1 and Rf3. Australia New Zealand Food Authority, 7 March 2001.](#)

Ms Naomi Stevens  
Public and Government Affairs Manager  
Aventis CropScience Pty Ltd  
391 – 393 Toorong Road  
EAST HAWTHORN VIC 3123

Dear Ms Stevens

On 1 February 2001, Neil Ellis, Ag Director of the Monitoring and Surveillance Section of the Interim Office of the Gene Technology Regulator contacted you 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. PR62X(4) – SW98/4
2. PR62X(4) – SW98/2 (site 1)
3. PR62X(4) – SW98/2 (site 2)
4. PR62X(4) – AG98/7

The site visits were conducted by Mr Michael Koppman of this Office and Dr Mary Rieger, our contracted expert in brassica weeds, on 14 February 2001. I am advised that Mr Koppman and Dr Rieger were accompanied by Mr Bill Balch, from Aventis and Serve-Ag staff, Mr Darren Wilson and Mr Lee Peterson (site 4 only). On 15 February 2001, Mr Koppman conducted follow-up visits to these same sites for reasons discussed below.

Late yesterday afternoon, I received a preliminary report of the findings of the monitoring visit.

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, including monitoring of the trial sites, to be used for this extension to the proposal will be the same as for previous proposals. These conditions include monitoring the site for three years after the trial and eliminating any volunteer plants by cultivation or herbicide treatment. Harvested seed not required for future trials should be destroyed. Canola should not be grown on the sites for three years following

the trial. The sites may be seeded to a grass pasture or cereal crops in which all *Brassica* and related species will be readily observed."

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

#### **PR62X(4) – SW98/2 (site 1)**

This site was sown to poppies this season. The 14 hectare site was observed to have scattered growth of canola volunteers across the entire site, with higher concentrations of volunteer growth in some areas. Over 1000 plants were estimated by the monitoring team to be present on the site. The stages of volunteer growth varied. Approximately 20-30% of the volunteers were flowering and the remainder were at pre-flowering stage.

The Serve-Ag representative accompanying the IOGTR team to the site reportedly knew of the volunteers but was reluctant to exercise physical or chemical control as this would disrupt the poppy growth and subsequently decrease poppy yield.

#### **PR62X(4) – SW98/2 (site 2)**

The north east border of this past trial site was observed to contain several areas of localised canola volunteer growth in a particular section of the trial site. Several areas of growth were observed within an area approximately 100 metres by 300-350 metres. Over 1000 plants were estimated by the IOGTR monitoring team to be present on the site. The proportions were estimated to be as follows:

- Flowering canola 10-20%;
- Post-flowering plants with pod and seed development 60%; and
- Physiologically mature plants (with seed pods containing mature seed) 20-30%.

#### **PR62X(4) – AG98/7**

This site was sown to poppies this season. Over 1000 volunteer plants were observed by the IOGTR monitoring team at this site. Approximately 20-30% of the plants were flowering. These were smaller plants not affected by the recent poppy harvesting. The remainder of the volunteers were small, at the leaf production stages prior to flowering. Volunteers were scattered throughout the site. One weedy relative, believed to be wild radish (*Raphanus raphanistrum*) but yet to be confirmed, was also observed on the site.

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. Since the completion of the Mount Gambier investigation report at the end of June 2000, this Office has stressed to Aventis the need for compliance with GMAC recommendations. I am concerned at the apparent further non-compliance with GMAC recommendations.

- (2) The actions to be taken by Aventis 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 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.


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 Tuesday 20 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.

In addition, I have asked Mr Ellis to arrange for follow-up monitoring to occur next week in respect of the sites referenced above and for monitoring to occur of all other Tasmanian sites, which are currently subject to GMAC recommendations in respect of post-trial monitoring. Mr Ellis will contact you shortly regarding these monitoring visits.

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 Aventis.

Yours sincerely



Elizabeth Cain  
Head  
IOGTR

16 February 2001

**Aventis CropScience**

**Fax**

**To:**  
**Elizabeth Cain**  
**IOGTR**  
**Fax: + 02 6271 4202**  
**Number of pages: 2**

**From:**  
**Naomi Stevens**  
**Seeds/Crop Improvement**

**Date** 20/02/01  
**Subject:** Confirmation of Site Cleanup - Tasmania

Dear Liz,

We refer to your facsimile dated 16<sup>th</sup> February 2001, under cover of which you requested written advice confirming the arrangements for immediate and effective clean-up of the three sites identified in a recent GMAC visit to Tasmania.

We can confirm that all volunteer canola from the three sites indicated have been removed or treated as required. Actions taken at each of the sites are summarised as follows;

Site Identification	Action/Date	Comments
PR62X(4) – SW98/2 (site 1)	Site sprayed out on 15/2 Disced on 18/2 Hand rogued on sandy banks on 19/2(not able to be discd) Pulled plants contained & ready for transport to disposal site (incineration or burial) – to be advised.	No Brassicaceous species present in surrounding 50 metres Spraying and discing occurred at site prior to advice dated 16/2 being conveyed
PR62X(4) – SW98/2 (site 2)	Hand rogued entire site on 15/2 under supervision from M. Koppman (IOGTR). Pulled plants double contained and labelled. Transported to ServeAg premises in Bellfield for incineration or burial (to be advised).	No Brassicaceous species present in surrounding 50 metres
PR62X(4) – AG98/7	Entire site sprayed with MCPA and Roundup on 15/2. All plants noticeably dying. Site to be hand weeded & cultivated during this week.	Spraying occurred prior to advice dated 16/2 being conveyed

Page: 2

Non-compliance reports are currently being completed as per our Standard Operating Procedures. These will be forwarded to IOGTR in due course in addition to a full account of the issues raised.

Please note that some of the sites have not been hand weeded as requested as it was agreed at the time of the GMAC inspection at each site that the most effective means of volunteer canola clean-up was to spray and follow-up with cultivation. Where required, hand weeding has been undertaken and the pulled plants will be disposed of by incineration or burial at an approved site. We will forward the stock movement and final disposal details in due course.

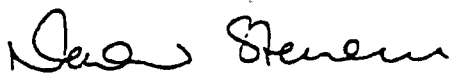
We are currently working through the corrective actions necessary to ensure no further breaches of this nature arise in future. This includes a full review of contractual arrangements with all external consultants, an update for all field agronomists (especially third parties) of the GMAC conditions post trial and a review of quality measures and Aventis resources required to ensure compliance. We will be happy to provide a full account of these actions for your records as soon as possible.

In the meantime, we are working with your field team to complete the comprehensive site visits of previous trial sites in Tasmania. We trust you will keep us informed as to your intentions and timing for making public any of the current matters under investigation.

Aventis was deeply disappointed with the breaches identified last week. We are well aware of the importance of a clean compliance record as a result of our activities last year and understood that our processes and paper trails were working well – clearly this incident indicates something went wrong. Aventis will undertake regular and closer supervision of all contractor activities in relation to GM field trials in future. We are committed to ensuring responsible field practices in relation to our GM canola trials regardless of who is contracted to complete the work and will keep you informed of our progress in this regard.

We trust this information satisfies your initial requirements in relation to this matter. We will keep you informed.

Kind regards,



Naomi Stevens  
Public & Government Affairs Manager



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]  
[REDACTED] (PR77X(2)/35)
- (f) Aventis CropScience's past site sown to canola in 1998 [REDACTED]  
[REDACTED] (PR62X(4) - SW98/4)
- (g) Aventis CropScience's past site sown to canola in 1998 [REDACTED]  
[REDACTED] (PR62X(4) - SW98/2(1))
- (h) Aventis CropScience's past site sown to canola in 1998 [REDACTED]  
[REDACTED] (PR62X(4) - SW98/2(2))
- (i) Aventis CropScience's past site sown to canola in 1998 [REDACTED]  
[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

## Attachment D

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

Category	I	II	III	IV	V	VI
Tribe	<i>Brassicaceae</i>	<i>Brassicaceae</i>	<i>Brassicaceae</i>	<i>Brassicaceae</i>	<i>Brassicaceae</i>	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*				
<i>Weeds</i>	<i>Brassica rapa</i> <i>Brassica juncea</i> #	<i>Raphanus raphanistrum</i> <i>Hirschfeldia incana</i> <i>Sinapis arvensis</i>	<i>Brassica fruticulosa</i> <i>Brassica nigra</i> <i>Brassica tournefortii</i> <i>Diplotaxis muralis</i> <i>Diplotaxis tenuifolia</i> <i>Rapistrum rugosum</i>	<i>Brassica oxyrrhina</i> <i>Diplotaxis tenuisiliqua</i>	<i>Conringia orientalis</i> <i>Carrichtera annua</i> <i>Cakile maritima</i>	<i>Capsella bursapastoris</i> <i>Cardaria draba</i> <i>Lepidium sp.</i> <i>Myagrum perfoliatum</i> <i>Sisymbrium orientale</i> <i>Sisymbrium irio</i> <i>Sisymbrium erysimoides</i> <i>Sisymbrium officinale</i>
<b>Condiment, fodder &amp; vegetable species</b>	Forage <i>B. napus</i> # <i>B. napus</i> vegetables# <i>B. rapa</i> vegetables# Condiment <i>B. juncea</i> #		<i>Brassica alboglabra</i> <i>Brassica chinensis</i> <i>Brassica nigra</i> <i>Brassica oleracea</i> <i>Brassica pekinensis</i> <i>Raphanus sativus</i> <i>Sinapis alba</i>			

→ 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	<i>Brassicaceae</i>	<i>Brassicaceae</i>	<i>Brassicaceae</i>	<i>Brassicaceae</i>	<i>Brassicaceae</i>	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*				
<i>Native species</i>						<i>Arabidella</i> (6 sp.) <i>Balbaretinia</i> (1 sp.) <i>Barbarea</i> (2 sp.) <i>Blennodia</i> (25 sp.) <i>Cardamine</i> (5 sp.) <i>Carinavalva</i> (1 sp.) <i>Cheesemania</i> (1 sp.) <i>Cuphonotus</i> (2 sp.) <i>Geococcus</i> (1 sp.) <i>Harmsiodoxa</i> (3 sp.) <i>Irenepharsus</i> (3sp.) <i>Lepidium</i> (35 sp.) <i>Menkea</i> (6 sp.) <i>Microlepidium</i> (2 sp.) <i>Pachymitus</i> (1 sp.) <i>Phlegmatospermum</i> (4 sp.) <i>Rorippa</i> (4 sp.) <i>Scambopus</i> (1 sp.) <i>Stenopetalum</i> (9sp.)

→ DECREASING SEXUAL COMPATIBILITY →