Interim Office
of the
Gene Technology Regulator

AUDIT OF
AVENTIS CROPSCIENCE PTY LTD
Conduct of field trials
in accordance with
GMAC recommendations

INFORMATION BULLETIN No. 5
August 2000

INFORMATION BULLETIN No. 5:

AUDIT OF AVENTIS CROPSCIENCE PTY LTD
Conduct of field trials
in accordance with GMAC recommendations

Objectives

1. To identify whether there are any deficiencies in processes employed by Aventis CropScience Pty Ltd (Aventis) to control field trials in accordance with recommendations made by the Genetic Manipulation Advisory Committee (GMAC)

2. To identify and consider options for action in relation to any deficiencies identified in 1.

Context for the audit

In the absence of regulatory underpinning, the Interim Office of the Gene Technology Regulator (IOGTR) and GMAC operate within an administrative system. Companies dealing with genetically modified organisms (GMOs) choose to voluntarily comply with GMAC recommendations. The IOGTR and GMAC do not have any legislative basis to access documents or information necessary to the conduct of this audit and will rely on the cooperation of Aventis to provide such information.

Background

Herbicide tolerant canola has been trialed under GMAC Guidelines for approximately five years. Aventis (formerly AgrEvo) have conducted trials of herbicide tolerant hybrid canola to increase seed stocks and to continue breeding and evaluation trials.

Since 1996 Aventis has submitted proposals to conduct field trials of glufosinate-ammonium tolerant hybrid canola, including proposals PR-63 and PR-85 and their respective extensions. Aventis submitted PR-63X(4) in 1998 and PR-85X(2) in 1999. In concert these trials involved up to 83 sites in total, in South Australia, New South Wales, Victoria, Western Australia and Tasmania. The trials were conducted from Autumn 1999 to early 2000.

Following consideration of the proposals ((PR-63X(4) and PR-85X(2)) and on the basis of its risk assessment, GMAC advised Aventis that in conducting the trials, Aventis should ensure that:

- Each trial site was surrounded with a 15 metre buffer of non-transgenic canola to minimise the escape of pollen;
- The trial sites were separated from other Brassica crops by at least 400 metres;
- A 400 metre zone around each site was monitored for the presence of *B. napus*;
- A 50 metre zone around each site was monitored for species that were sexually compatible with the trial species;
- The person responsible for each site should also be responsible for monitoring and clean up of the site [PR-63X(4) only]
- All trial sites would be monitored for 3 years post trial to detect and remove volunteers;

- Harvested seed not required for other field trials was destroyed;
- There was compliance with GMAC Guidelines concerning seed transport;
- GMAC was notified of trial site locations prior to planting;
- GMAC was provided with a copy of a press release issued by the company;
- GMAC was notified of the procedure for appropriate disposal of field trial trash before these procedures were utilised.

GMAC provided advice to Aventis in relation to PR-63X(4) on 25 March 1999 and for PR-85X(2) on 17 June 1999.

The breach

In March 2000 alleged breaches by Aventis were identified as relating to PR-63X(4) and PR-85X(2) field trials that were being conducted in the Mt Gambier region of South Australia.

In response to these allegations, the IOGTR investigated Aventis' compliance with all GMAC recommendations for all trial sites under proposals PR-63X(4) and PR-85X(2), not only those in the Mt Gambier region. While recognising that such an investigation would take additional time and resources, the IOGTR considered it important to establish whether any breach was a 'one-off' problem or the result of a systemic fault in the company's processes.

On the basis of expert advice, the IOGTR investigation found:

1. That the company did not fully comply with GMAC recommendations in respect of:

- always establishing a 15m buffer zone of non-transgenic canola around plantings at summer trial sites to minimise pollen escape;
- monitoring of a 50m zone for all sexually compatible species;
- monitoring for, and removal of, volunteer plants after the trials; and
- compliance with procedures for the transport and disposal of field trash.

2. There were no increased risks to human health as a result of these breaches.

3. The risks to the environment were low. Primarily the risks involved the possibility of transfer of the herbicide-tolerance gene to related weeds or other canola plants. This is unlikely because no commercial canola crops are grown in the area during the summer trial season and there is evidence indicating that hybridisation between canola and brassicaceous weeds is of low frequency and progeny is of low reproductive fitness.

4. Any environmental risk can be further minimised through the risk management plan.

The IOGTR has developed a risk management plan which will address the small increased risks resulting from the breaches. The plan includes:

- the implementation of a program for monitoring the potential out-crossing of GM canola in relevant areas.;

- expansion of the current monitoring plan to include *Raphanus raphanistrum, Hirschfeldia incana* and *Sinapis arvensis*; and
- inspection for volunteers on a monthly basis for three years after the trial.

The IOGTR has underpinned these, and other measures needed, with a system of 'spot checks' that will be in addition to the periodic monitoring and surveillance to be undertaken by the IOGTR from July 2000.

A 'spot check' conducted by IOGTR staff on 27 July 2000 raised some issues which might give rise to a concern with Aventis' post trial monitoring. These are:

- stock grazing on stubble which may lead to seed being transported off the site; and
- broadleaf crops being grown as follow up crops on canola trial sites which may make it difficult to control volunteers.

The cumulative effect of the breaches, and the issues raised as a result of the spot check, indicates a possible weakness in Aventis' processes may have arisen. The IOGTR needs to satisfy itself that Aventis has the ability to maintain full control of field trials of genetically modified canola. An audit of Aventis' processes would ascertain if improvements can be made to their system of operation to give greater certainty in the control of field trials.

Audit Committee

The audit will be conducted for, and on behalf of, the Interim Office of the Gene Technology Regulator.

To ensure that the IOGTR has access to the best advice possible, the IOGTR will convene a committee to conduct the audit consisting of:

1. a person with expertise in agricultural farming systems;
2. a person with expertise in canola/weed identification;
3. an officer of the Australian Government Solicitor; and
4. an IOGTR staff member.

An auditor from the Therapeutic Goods Administration will assist the committee with the audit.

Terms of Reference

In accordance with the processes and detail contained in this document, the Audit Committee will investigate the internal processes of Aventis for ensuring compliance with GMAC recommendations. This will include a review of Aventis' Standard Operating Procedures and site visits to all current field trial locations. Attachment 1 provides a plan for on-site inspections of Aventis' field trials.

Scope

The scope of the paper audit will be current and previous field trial proposals conducted by Aventis. There are three current proposals for winter trials and approximately 20 proposals that have completed field activities (but have ongoing monitoring).

Reporting

The Audit Committee will be responsible to the Head of the IOGTR for the conduct of this audit. The Audit Committee will provide a written report to the Head of the IOGTR no later than 5 October 2000.

Audit process and timeframes

Step 1: The Head, IOGTR to seek additional information from Aventis regarding the possible breach of GMAC recommendations in respect of PR-63X(4) and PR-85X(2) to inform the audit process and request information relating to compliance with all conditions at all sites for all proposals. By end August 2000.

Step 2: The Audit Committee to be briefed on the scope and conduct of the audit. By 5 September 2000.

Step 3: Site inspections of all current field trials to commence. By 7 September 2000.

Step 4: Aventis to provide the additional information requested by the IOGTR. By 15 September 2000.

Step 5: The Audit Committee to meet and review documents submitted by Aventis. By 22 September 2000.

Step 6: Draft report on findings from site visits to be provided to the Audit Committee. By 26 September 2000.

Step 7: The Audit Committee to meet with Aventis to review findings of site visits, documents and processes. By 28 September 2000.

Step 8: A report is to be prepared by the Audit Committee. This will also identify any further work to be undertaken. A copy is to be provided to the Head, IOGTR and to Aventis. By 5 October 2000.

Step 9: The Head, IOGTR to review the report, provide a copy to Aventis and advise the Minister for Health and Aged Care of the outcome of the audit process, with advice on any recommendations made by the Audit Committee. By 6 October 2000.

Step 10: A project plan for implementing any recommendations accepted from the audit report is to be prepared in conjunction with Aventis. By 20 October 2000.

Step 11: A report on the process, the conduct of the audit, the findings and the project plan for giving effect to the audit to be made available on the IOGTR website. By 25 October 2000.

Conduct of the audit

It is the IOGTR's intention that a full report be made available to any interested member of the Australian community on the results of this audit.

The Audit Committee will be required to review a range of material, including material relating to private individuals or third parties, and material that is commercial-in-confidence. Members of the Audit Committee will, therefore, be required to sign a Deed of Confidentiality that will apply throughout the audit process and subsequently.

All decisions about the release of information will be made by the Head of the IOGTR. The IOGTR will, however, protect commercial-in-confidence information and information relating to third parties.

All questions on the conduct of the audit and the results of the audit should be directed to the Head of the IOGTR.

The IOGTR is also conscious that the Audit Committee will need to disclose any interests or conflicts that may impact on the conduct of the audit. This is an important step to not only provide the Australian community with confidence in the process, but also to facilitate the provision of information by the company involved.

Attachment 1

On-site audit of Aventis' compliance with GMAC recommendations for field trials

Site Visit Plan

1. Aim

To identify whether there are any deficiencies in Aventis' compliance with GMAC recommendations at all current field trial sites.

2. Background

Aventis' current field trials are conducted under a number of proposals submitted to GMAC for advice. Thirteen proposals representing approximately 111 separate field trial sites occurring in NSW, Victoria, Tasmania, Western Australia, Queensland and South Australia, were recently assessed by GMAC. GMAC has advised that these trials may proceed, subject to certain conditions. However, Aventis has recently advised GMAC that it will only be proceeding with three of these trial proposals, representing 24 sites, during the winter 2000 season. The remaining trials are expected to commence in October 2000. The winter trials are of hybrid canola.

In March 2000, the IOGTR received reports of non-compliance by Aventis with GMAC recommendations. An IOGTR investigation resulted in breaches of GMAC recommendations being identified. A follow up inspection found potential issues with Aventis' post trial monitoring of sites.

Background on the monitoring processes by the IOGTR is set out in *Information Bulletin No2: Monitoring compliance with GMAC recommendations for the conduct of field trials.*

3. Overview of the on-site audit of field trials

In summary, the on-site audit of field trials involves:

- Identification of the crucial periods for monitoring to occur in respect of each field trial considered by GMAC. Part 4 of this paper refers;
- Identifying which trials will be monitored for compliance. Part 5 refers;
- Identifying appropriately qualified people to undertake the monitoring visits. Part 6 refers;
- Conducting the monitoring visits. Part 7 refers;
- Other methods for investigating compliance. Part 8 refers;
- Reporting on the audit. Part 9 refers; and
- Appeal of process. Part 10 refers.

It should be noted that the IOGTR has no legislative underpinning for the conduct of investigations into an entity's voluntary compliance with recommendations made by the GMAC to manage risks associated with GMOs.

Pending the establishment of the new regulatory system, the IOGTR has 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. The IOGTR will, therefore, need to work cooperatively with Aventis to secure appropriate outcomes.

4. Identifying when monitoring will occur

Crucial monitoring points common to trials of many crops are planting, flowering and harvest periods as well as post trial periods.

4.1 Current field trials

Aventis' winter planting of canola will be approaching or beginning their flowering period during September. Conducting the on-site audit at this time provides an ideal opportunity to verify compliance with GMAC's recommendations.

5. Identifying which trials will be monitored for compliance

5.1 Number of trials to be monitored

All current trial sites are to be monitored. The number of trial sites to be inspected will be approximately 24.

5.2 Current trials

The current winter trials of canola represent 3 proposals, PR63X(5), PR85X(3) and PR90X(2), which totals approximately 24 separate field trial sites. In total, these sites are on less than 80 hectares and occur in four states: New South Wales, Victoria, South Australia and Western Australia.

6. Identifying appropriately qualified people to undertake monitoring visits

Each monitoring visit will be undertaken by a minimum of two persons with an independent expert relevant to the particular monitoring activity. In this case, a canola/weed expert is required. An IOGTR staff member may accompany the expert.

7. Conducting the monitoring visits

The purpose of monitoring visits is to assess compliance against GMAC recommendations for conduct of field trials.

7.1 Informed prior consent of the landowner

Under the interim system, the IOGTR will, as a minimum, contact the landowner of the trial site prior to the conduct of a monitoring visit. This contact with the landowner will usually be by telephone, but may be in writing.

The Australian Government Solicitor has advised that, in the absence of any legislative underpinning for this monitoring system, agreement from the landowner for the conduct of a monitoring visit is absolutely necessary.

If consent of the property owner is not obtained, monitoring cannot occur.

Aventis will be advised that trial sites are to be audited. The audit committee may choose a random selection of sites to visit at any stage during the audit process.

7.2 The monitoring visit

A monitoring visit would be tailored to the GMAC recommendations made in respect of a specific trial.

A monitoring visit may involve:

- interviews with the owner of the property or other personnel on the property;
- observation of activities, and the property, for objective evidence of compliance. 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
- recording findings, either by photographing, video or audio recording, making sketches, making copies of relevant records, or taking samples for testing. Prior approval for recording findings must be obtained from the owner of the property and the company notified if samples of GM plant material are taken.

8. Other methods of investigating compliance

The paper audit conducted by the audit committee may be used to inform the on-site inspection team.

9. Reporting on the monitoring visits and implementing follow-up action

The on-site inspection team will provide a draft report on the on-site visits to the audit committee by 26 September 2000.

10. Appealing a decision

In the absence of a legislative base for approval of GMOs, administrative review processes have been established as set out in *Information Bulletin No2: Monitoring compliance with GMAC recommendations for the conduct of field trials*.