



Office of the Gene Technology Regulator

PROJECT PLAN FOR IMPLEMENTING RECOMMENDATIONS

**Audit of University of Western Australia:
Conduct of field trials in accordance with
GMAC recommendations.**



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Background

This document should be read in conjunction with “Report on Audit of University of Western Australia: Conduct of field trials in accordance with GMAC recommendations”.

The reason for the audit

On 28 September 2000, the University of Western Australia’s (UWA) Institutional Biosafety Committee (IBC) informed the Interim Office of the Gene Technology Regulator (IOGTR) that viable lupins which had reached or passed flowering stage had recently been discovered at past trial sites of genetically modified (GM) lupins. The potential breach involved two PR74 trials conducted in 1998, one at Mingenew and the other at Quairading (both in Western Australia).

UWA proposed a number of risk management actions that they would undertake at the two sites including hand weeding of the volunteer lupins on a continuous basis, destruction of the agronomy trial buffer and harvest of the agronomy trial and deep burial of the lupins. The sites would be inspected in August and October and would be monitored until two years clear of volunteer lupins.

An inspection of the Quairading site in November by the IOGTR discovered a number of volunteer lupins on the site that had passed flowering stage and had begun seed set. The Mingenew site was reported to have been cultivated to destroy all viable plants.

The investigation of the breaches at the Quairading and Minegew sites highlighted an apparent need to clarify the roles and responsibilities for ongoing management of the PR74 and PR75 trials since the discontinuation of CLIMA as a CRC. In addition, the investigation suggested a possible weakness in the operation of post-trial monitoring at all trial sites conducted under PR74 and PR75. The IOGTR therefore decided to conduct an audit to satisfy itself that the remaining trial sites were being appropriately managed.

Scope of the audit

The trials in question were conducted under the administrative system for the oversight of dealings with genetically modified organisms (GMOs) in Australia, and prior to the IOGTR implementing its compliance monitoring protocol in October 2000. The audit was therefore conducted in the absence of regulatory underpinning, and organisations dealing with GMOs under this system chose to voluntarily comply with GMAC recommendations.

As such, the IOGTR and GMAC did not have any legislative basis to access documents or information necessary for the conduct of this audit and relied on the cooperation of the UWA, and other parties involved in the management of the trials, to provide such information.

The information requested included:

- i) Any monitoring reports.
- ii) A description of the procedures that were in place for monitoring of field trials.
- iii) Minutes of any meetings that were relevant to the post trial monitoring and supervision of field trials.
- iv) Other documentation and correspondence that UWA believed to be relevant to the audit.
- v) Further information and clarification on the management of the field trials undertaken by UWA, and information concerning the management of particular trial sites.

Results

The Audit Committee has reported to the Gene Technology Regulator. The recommendations from the audit are designed to improve UWA's system of operations to ensure that management of GM trials is performed in an appropriate manner.

The committee found that management practices used in the GM trials under PR-74 and PR-75 were deficient in a number of areas. In particular poor communication between UWA and AGWEST and inadequate training and record keeping by UWA and AGWEST in relation to GM trials caused confusion over responsibilities for supervision of the trials and inadequate supervision of the trials.

As a result trial sites were not always accurately identified, some sites were not monitored appropriately and inappropriate crops were planted on trial sites during the monitoring period

However, the audit committee believes, based on GMAC advice that the original breaches presented negligible risk and as a result of the preventative steps implemented by UWA, that the risks to human health and to the environment resulting from these further concerns are negligible.

Recommendations:

Timing of implementation for each recommendation

UWA has agreed with the recommendations put forward by the Audit Committee in their entirety. The timing for the implementation of each recommendation is set out below (a summary can be found at Attachment 1).

1. Recommendations for Post Trial Monitoring

1.1 The continuation of the preventative post-trial monitoring actions that UWA have implemented at the trial site locations where potential management deficiencies were identified, and also at the Northam site (where potential volunteer problems post trial have been identified).

Ongoing Post trial monitoring to continue until the sites have been free from volunteer lupins for a period of two years.

2.2 The Office of the Gene Technology Regulator should investigate mechanisms to enforce these activities under the Gene Technology Act 2000.

Complete Additional monitoring requirements included in the advice to proceed issued with licences in June 2001.

2. Recommendations for Management of GM trial sites

In regards to improving the management of future GM trials and of post-trial monitoring the audit committee recommends that UWA;

2.1 develops a Quality Assurance system and/or Standard Operating Procedures for the management of GM crop trials

November 2001 UWA to provide OGTR with a draft copy of QA/SOP for management of GM crop trials.

December 2001 Final QA/SOP for management of GM crop trials forwarded to OGTR.

Ongoing Updates of QA/SOP forwarded to OGTR as they occur.

2.2 provides appropriate training for all staff involved in GM crop trials.

November 2001 UWA to provide information to the OGTR on the number of staff that require training and details on what training will be provided.

January 2001 Training to be completed.

Copies of training manuals to be provided to OGTR.

Details of staff who undertook training and type of training to be forwarded to OGTR.

Ongoing Training to be updated as QA/SOP updated or as new staff commence work in GM trial crop monitoring.

2.3 appropriately documents the location of all trial sites using GPS coordinates.

November 2001 GPS coordinates for all site locations to be recorded and/or confirmed by UWA and forwarded to OGTR.

2.4 *record details of all monitoring activities, including the personnel undertaking these activities and any changes in personnel.*

November 2001 UWA to record all the details of monitoring activities and forward the information to the OGTR

Ongoing Details of monitoring activities to be forwarded to OGTR

Details of all changes in personnel undertaking GM monitoring activities to be maintained in a central recording system at UWA.

2.5 *reports any identified breaches of field trial conditions as soon as possible to the OGTR.*

Ongoing UWA to report any identified breaches to the OGTR as soon as possible.

2.6 *develops a central recording system to ensure information relating to the GM crop trials is easily accessible by appropriate people, including the OGTR.*

December 2001 UWA to provide details on the finalised central recording system and its method of operation to the OGTR.

2.7 *ensures that UWA IBC does not approve any future GM research proposals unless the above recommendations are incorporated into the research proposal.*

November 2001 UWA to notify the UWA IBC of this requirement.

December 2001 Any changes to IBC SOP in relation to approval of GM research proposals are to be completed and details forwarded to the OGTR

3. OGTR Auditing

3.1 *That OGTR monitoring staff undertake an inspection of trial sites, and of UWA's record-keeping procedures, by the end of 2001 to ensure that the recommended management practices have been implemented and are being maintained.*

November 2001 OGTR to conduct site inspections and audit implementation of other recommendations as appropriate.

Attachment 1: Summary of Project Plan for Implementation of Audit Committee Recommendations

Timing	Recommendation	Action	Responsibility	Progress to date
Complete	1.2 – Post Trial Monitoring	Additional monitoring requirements included in the advice to proceed.	OGTR	Complete. Information included in licences issued in June 2001.
November 2001	2.1 – Management	UWA to provide OGTR with a draft copy of QA/SOP for management of GM crop trials.	UWA	
	2.2 – Management	UWA to provide information to the OGTR on the number of staff that require training and details on what training will be provided.	UWA	
	2.4 – Management	UWA to record details of all monitoring activities including the personnel undertaking these activities and any changes to these personnel. The information is then to be forwarded to OGTR.	UWA	
	2.7 – Management	UWA to notify UWA IBC that all future GM research proposals incorporate audit committee recommendations.	UWA	
November 2001	2.3 – Management	GPS coordinates for all site locations to be recorded and/or confirmed by UWA.	UWA	
	2.6 – Management	UWA to provide OGTR with details on	UWA	

		the finalised central recording system and its method of operation.		
	2.7 – Management	Changes to UWA IBC SOP's in relation to approval of GM trials to be completed and forwarded to OGTR.	UWA IBC	
December 2001	2.1 - Management	Final QA/SOP for management of GM crop trials forwarded to OGTR.	UWA	
	2.3 – Management	GPS coordinates for all site locations to be forwarded to OGTR.	UWA	
	3.1 – OGTR Auditing	OGTR to conduct site inspections and audit of other recommendations as appropriate.	OGTR	
January 2001	2.2 – Management	Training of staff to be completed and copies of manual and staff who undertook training forwarded to OGTR.	UWA	
Ongoing	1.1 – Post Trial Monitoring	Post trial monitoring to continue until the sites have been free from volunteer lupins for a period of two years.	UWA	
	2.1 - Management	Updates of QA/SOP for management of GM crop trials forwarded to OGTR as they occur.	UWA	
	2.2 – Management	Training to be updated as QA/SOP updated or as new staff commence work on GM crop trial monitoring.	UWA	

	2.4 – Management	Details of GM monitoring activities and changes to personnel undertaking such activities to be forwarded to OGTR.	UWA	
	2.5 – Management	UWA to report any breaches to OGTR as soon as possible.	UWA	