National Response to Radcliffe Plant Biosecurity Review

The Context

Australia has a favourable plant health status from which we derive considerable benefits in economic, environmental and social terms. The purpose of quarantine is to protect this status while at the same time facilitating the reasonable movement of people and goods.

Constitutionally the Commonwealth is responsible for quarantine at the national level, while States and Territories are responsible for quarantine within their geographic boundaries. Previous reviews of the quarantine system (Lindsay 1988, Nairn 1996) have found that acting alone the Commonwealth, States and Territories cannot maintain the necessary level of protection because individually they do not have all the necessary resources, nor legislative power to control all points along the continuum of quarantine, or to deal with breaches when they occur. Thus protecting Australia's plant health status must be a responsibility shared between Commonwealth and State/Territory Governments, industry, the research community and the general public.

Previous reviews of Australia's quarantine system have also acknowledged that a "zero-risk" quarantine system cannot be achieved. A culture of awareness and shared ownership for biosecurity risk management must develop among all organisations and individuals involved.

Research and development activities aimed at improving agricultural production or protection often rely on the importation of exotic biological material. By definition, these activities may challenge the quarantine system. Under a model of shared responsibility, the Commonwealth and State/Territory governments are responsible for the framework and standards within which these activities occur. For their part, the research establishments (both government and private) must be responsible and must be accountable for the day-to-day activities. This accountability extends to the maintenance and security of approved quarantine laboratories and to the individual researchers who are holders of permits to import issued under the Quarantine Act 1908 (Commonwealth).

In the following sections a framework is described through which the biosecurity risks of research activities are managed via a partnership approach. Under this approach the Commonwealth, State/Territory governments and the research community (including individual establishments) agree to accept and manage biosecurity risks for the elements of the system under their control. Parts of this process already exist and are working well. Others exist but are inconsistently applied. Still others do not yet exist and must be created.

Pre-border

The chain of events, leading to the use of imported biological material in a research facility, begins with an application to import. In making that application, the research establishment should demonstrate that they (both researcher and institution) have considered the known and possible biosecurity risks. Wherever possible, risk management should commence in the source country through the development of bilateral arrangements between Governments and between research establishments. Possible pre-border measures include: collaborative research, facility audits, certification and treatment.

Australian Quarantine and Inspection Service (AQIS) assesses applications against a framework of established conditions and consults with Biosecurity Australia (BA) where import proposals fall outside this framework.

Border

In the context of the quarantine system, the border extends from the point of entry to all plant quarantine containment facilities.

AQIS is responsible for the regulatory framework which controls the importation of exotic biological material. This regulatory power is exercised primarily through the conditions specified on the import permit and quarantine approved premise systems.

The development and execution of an import permit is a critical step in the process. In order to issue an import permit AQIS considers: the nature of the import, the advice of BA, existing import conditions and whether the research establishment has the capacity to manage the biosecurity risk.

Operationally, AQIS inspectors have a direct role in the verification of imported materials as an initial screen and compliance with the import permit.

The second component in the management of biosecurity risks is the requirement that research establishments meet the necessary structural requirements to ensure that the risks can be contained. AQIS classifies such laboratories according to the National Standard on Physical Containment (PC) to specific classes of Quarantine Approved Premises. The class of the premise required is dependent on the nature of the risk being managed as reflected by the import permit.

An additional element for the management of the biosecurity risk (within certain defined circumstances) is the bilateral Compliance Agreement (CA) between AQIS and the research establishment. Through the CA, AQIS and the research establishment agree on the required standards, procedures, and controls for managing biosecurity risk in post-entry quarantine and beyond. The CA should clearly define the roles, responsibilities and accountabilities of all parties as well as the minimum acceptable level of competency required to manage the quarantine risk as set by AQIS.

In the research establishment a culture of responsible biosecurity risk management should prevail. An awareness of the critical need to discharge this responsibility should not only be reflected in accountabilities of line management, it must also pervade the workplace behaviour of all staff. Developing this culture in research establishments is a significant challenge for senior management of these establishments but its importance cannot be overstated.

The research establishment should be committed to maintaining the structures, operating procedures, control mechanisms, and staff to effectively manage biosecurity risk. One way this could be managed is through an internal quality assurance (QA) system. Such a QA system may be acknowledged in the Compliance Agreement. To the fullest extent possible the QA system should be self-regulating to ensure the impacts of any failures are minimised through early detection and rectification. The research establishment must allocate the staff resources, build and maintain their competencies to support this system.

The QA system should be independently certified and audited according to international best practice. Relevant national standards and accreditation schemes should be created where these do not already exist. The accredited auditors should undertake both compliance and performance audits on the system and make reports to both the research establishment and AQIS. Dependent on the inherent risk of the material being held and the previous performance of the facility, AQIS may also need to conduct its own audits of the QA system to verify the outcomes of the independent auditors and validate operational compliance.

Post-border

The responsibility of the research establishment does not end with the release of exotic material from post-entry quarantine. When the material is released the known quarantine risks have been ameliorated to an acceptable level, however due to an incomplete knowledge of plant pests and diseases, there is a possibility that the material could still pose a biosecurity risk, albeit much reduced. The research establishment (and agencies/individuals subsequently responsible) must maintain an appropriate level of monitoring and surveillance for pests to an agreed extent, an ability to perform initial diagnoses, and incident management procedures needed for early detection and response to exotic pest incursions. The ability to track all movements of biological material through traceback and traceforward is critical.

The States and Territories have primary legislative responsibility for the area immediately beyond the research establishments with post-entry quarantine facilities. Therefore there needs to be an awareness and acknowledgement by the State/Territory of the facility with its potential inherent biosecurity risks functioning in that jurisdiction. The research institution and researchers need to have good understanding of the legislative quarantine responsibilities of the State/Territory within which they function. In particular, they must be aware that the State/Territory is responsible for the management of any exotic incursion and must be informed of the nature of the biological material that they hold. The Review of Plant Biosecurity Protocols did not address the need for a robust relationship between the State/Territory plant quarantine authorities and research institutions (both private and government), however this is a potential gap in the existing system and is addressed in this response.

Communication

Strong linkages and communications are vital to the integrity of the quarantine system. No component operates in isolation. All groups involved need to have confidence and trust in the continuum of the quarantine system, including integrated and robust communication strategies. It is the responsibility of each individual involved in the importation process to ensure that all risks are appropriately managed.

People

Successful implementation of the model for managing plant biosecurity, described above, relies upon many individuals in a range of organisations understanding their roles and discharging their responsibilities. Staff at all levels in the system must maintain demonstrated competencies required for their role.

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The following is the national response to the review by Radcliffe *et al* "Review of Plant Research Biosecurity Protocols" made against the background of the model presented above. This was developed at a meeting of Primary Industries Health Committee (PIHC) representatives, CSIRO and Plant Health Australia (PHA) on 19 September 2003 and endorsed by the Primary Industries Standing Committee (by teleconference) on 25 September 2003.

An Action Plan (see Appendix A) has been prepared and PHC will ensure that this plan is implemented. For the recommendations that involve only actions within DAFF an internal implementation group (IIG) will be established and chaired by the Australian Chief Plant Protection

Officer. A list of the group/s responsible for the implementation/action of each recommendation is provided in Appendix B.

Several of the recommendations require the revision of existing standards and the development of new standards. Under the Action Plan a technical working group of PHC (Standards Working Group –SWG) will review/draft the standards for procedures, competencies and physical requirements for biosecurity of imported plant-related material. The SWG members will be selected to ensure a mix of scientific and regulatory expertise, and appropriate stakeholder representation. A communications package will also be developed.

In the time since the review report was made, action has been taken to implement a number of its recommendations. The proposed reviews of open quarantine and physical standards for post-entry quarantine facilities have commenced. Refinements have been made to the procedures for the management of plant emergencies, and the proposed spring survey for Wheat Streak Mosaic Virus has been revisited. Some research establishments have improved internal management procedures.

However, it will take some time to implement all recommendations. Accordingly, as an interim arrangement, the States/Territories will seek to raise awareness of plant biosecurity issues within the containment facilities that are operating in their respective jurisdictions. When new standards have been developed they will replace these interim arrangements.

Recommendation 1.

It is recommended that the extent of achievements of the government's response to Post-Entry Quarantine support and facilities suggested by the Nairn report be evaluated.

The review team acknowledged that the main recommendations of the Nairn review regarding plant quarantine containment have been implemented but they referred to inconsistency with the quality of the outcomes achieved. The performance of the plant quarantine containment systems will be evaluated. Identification and rectification of the suggested inconsistencies in the quality of the outcomes will be sought, with a view to report by the next standing committee meeting. [Responsibility: IIG]

Recommendation 2.

It is recommended that, as a matter of urgency, a uniform system be instituted for winter cereals to link records of lines of material, either held in quarantine, released or destroyed; to enable effective tracking of all lines of material which have entered Australia through quarantine, and that such a system subsequently be applied to all imported plant material used for research purposes.

It is acknowledged that there is a need for an improved tracking system that would enable the ultimate destination of all imported batches of material to be known. However, this would be a major undertaking if it was expected this information would be centrally managed under the Australian Quarantine and Inspection Service Import Management System (AIMS). A more efficient system would be for importers at Quarantine Approved Premises to maintain records that would enable rapid reconciliation with AIMS data when required, and the inclusion of appropriate conditions on import permits is under consideration. At the very least this would be an important first step if the full integration into AIMS were considered practicable. The records of the material should be qualitative (ie the types of germplasm) rather than quantitative (ie the number of seeds, plants etc). The current system and consideration of alterations required to improve the tracking of

material will be examined, with a view to reporting by the next standing committee meeting. [Responsibility: IIG, SWG]

Recommendation 3.

A re-evaluation be undertaken of risks inherent in current processing practices for examining mail and courier items at ports of entry. Consideration be given to issuing a standard, high visibility AQIS identification label with permits for use by consignors forwarding plant material to Australia.

A system of voluntary labeling may reduce the risk posed by material that is not initially detected by the Australian Quarantine and Inspection Service (AQIS) staff and subsequently being submitted by the importer, by improving the visibility of items in the mail system that carry an import permit. Such a system will be investigated in consultation with importers to address the issues raised by the review. A number of developments, either of procedures or infrastructure, have been made by AQIS to improve detection of germplasm entering Australia through the mail system. Improvements and further needs are under constant review and are documented to ensure consistent application. Further refinements will be made in consultation with importers. The IIG will examine this issue in conjunction with AQIS and importers and will aim to report on progress by the next Standing Committee meeting. [Responsibility: IIG]

Recommendation 4.

The current standards for all quarantine procedures and facilities should be appraised and then all facilities growing winter cereal seed in Post-Entry Quarantine should be examined to ensure that new standards are being met.

A stocktake of Post-Entry Quarantine (PEQ) facilities handling high-risk introductions is already underway. Current procedures for PEQ facilities growing cereals will be assessed following this stocktake to assess the appropriateness of the standards, to change these where necessary, and to ensure standards are being met consistently. Consideration will be given to the outcomes of this stocktake, as well as broadening its scope to include the standards and competencies required to function in or run containment facilities that handle imported plant and plant related material. A report on progress will be provided to the next Standing Committee meeting. [Responsibility: SWG]

Recommendation 5.

The Review Team recommends that institutions and AQIS urgently complete bilateral Compliance Agreements [particularly those in relation to the compliance agreements being established in relation to the Waite Campus (completion due July 2003) and the Australian Winter Cereal Collection (completion due December 2003)] as they will provide significant advantages in flexibility, easier access to specialised skills, the potential for cost savings to institutions and AQIS, and will serve to confirm the move towards a greater shared responsibility as recommended by the Nairn report.

Compliance agreements between the Australian Quarantine and Inspection Service (AQIS) and research establishments are an important initiative in ensuring agreed standards are maintained and form a pivotal link in the chain of shared responsibility. Agreements with the institutions identified in the review will be completed and AQIS will look to extend this approach to other institutions. It

should be noted that there is a compliance agreement already in place in SARDI with an update of this currently being incorporated.

Consideration needs to be given to the issue of breeders handling and testing their own imported material including the processing of quarantine material only by a third party. There will be a need for the institutions to demonstrate compliance with the revised physical, procedural and competency standards that come out of the Standards Working Group. [Responsibility: IIG, SWG]

Recommendation 6.

It is recommended that research should be initiated to identify alternative technologies capable of meeting reasonable quarantine requirements for the disposal of material of quarantine concern (eg potting mix and plant residue) from Post-Entry Plant Quarantine facilities.

While this recommendation is accepted, it is not clear how the research should best be approached. Consideration will be given as to how this would be most effectively done and by whom. Current technologies are capable of dealing with the quarantine risks associated with the waste material produced from plant quarantine containment facilities. However due to environmental requirements, it is difficult to carry out treatment on site or have access to facilities close by to do the treatment. The concerns arise from the significant distances that the material is sent for treatment. Hence this recommendation needs to be considered from the point of view of development of novel treatments as well as the security of transportation to have treatment done using current technology. [Responsibility: IIG]

Recommendation 7.

It is recommended that a comprehensive review of Open Post-Entry Quarantine in relation to the importation of winter cereal genetic material be completed as a matter of urgency.

Plant Biosecurity has commenced a review of open post-entry quarantine of cereal seed from New Zealand. The IIG will work with Plant Biosecurity to monitor progress of this review and to examine the quarantine implications for imports of cereal seed from other sources. The Plant Biosecurity Review of open post-entry quarantine will need to take account of the outcomes of the Standards Working Group to ensure harmonisation of standards and competencies. [Responsibility: IIG]

Recommendation 8.

It is recommended that appropriate, comprehensive, skills based, in-service training for the AQIS inspectorate be developed and maintained to ensure high standards of scientific competency, particularly in the biological science areas affecting quarantine.

Consideration will be given to the knowledge and skills set required by all staff directly involved in the management of biosecurity risks posed by the importation of exotic plant material to ensure sound underlying biological knowledge. The scope of this review will extend beyond AQIS, as initially recommended, to other encompass Government officers and staff in research establishments. The competencies of existing staff will then be assessed to identify any systematic gaps and training programs modified or developed to address these needs. The broader aspect to be encompassed is capacity building through the whole chain of personnel who deal with containment facilities associated with plant and plant related material. [Responsibility: IIG, SWG]

Recommendation 9.

It is recommended that the effectiveness and adequacy of the lines of communications between the various sectors of AFFA concerned with plant biosecurity be reviewed.

The IIG will examine the robustness of the current communication arrangements including the need for and the means to improve communication within the Department on plant biosecurity matters. The operational and policy areas of the Department concerned with plant biosecurity were segregated in 2000 to promote clear lines of responsibility. It is considered that currently there are relatively good lines of communication, however this will be examined to consider ways of enhancing the current methods. [Responsibility: IIG]

Recommendation 10.

It is recommended that linkages between winter cereal breeders and AQIS be developed and fostered to further enhance the biosecurity system.

This recommendation goes hand in glove with Recommendations 4 and 5 to identify the critical steps in the partnerships that need to form between the Australian Quarantine and Inspection Service and the research establishments to ensure the integrity of the quarantine system. Consideration will be given as to how these linkages would best be developed. However the scope of this recommendation needs be broadened to encompass the development of linkages between the breeders and the State/Territory authorities that are responsible for plant quarantine. It also needs to include issues such as mandatory screening in certain circumstances. [Responsibility: SWG]

Recommendation 11.

It is recommended that breeders make provision with any contracted service providers to ensure that their research material is maintained in a biologically isolated location, independent of that from other breeding programs.

The risk posed by third party contractors is not readily controlled by government but can be addressed in Compliance Agreements. The IIG will consider the way in which the Australian Quarantine and Inspection Service Compliance Agreements interface with research facility Quality Assurance (QA) schemes to manage the risk. Consideration needs to be given to the incorporation of contractual obligations that require alert provisions, hygiene provisions and appropriate management of recently imported material (and recent descendants of this material). Institutions need to have in place appropriate reporting mechanisms for suspicious material and a risk mitigation response plan in the case of a suspected or confirmed incident.

The IIG will examine how the Government can facilitate the development of QA arrangements in all post-entry plant quarantine facilities and the incorporation of plant biosecurity into QA programs. [Responsibility: IIG, SWG]

Recommendation 12.

It is recommended that* PlantPlan *and the projects relating to the databases of potential plant threats from significant pests not yet recorded in Australia and existing pests and diseases within Australia, be expedited and completed within the current financial year.

Effective management of future exotic incursions will rely upon successful implementation of PlantPlan, plant industry biosecurity plans, and the associated plant industry cost-sharing agreement. Plant Health Australia's annual operational plan for 2003-04 reflects the urgent need to complete projects and Plant Health Committee is working closely with Plant Health Australia to achieve these shared goals. Development of databases on potential and existing pests is an on-going activity and will not be completed in the current financial year. [Responsibility: PHA, OCPPO]

Recommendation 13.

It is recommended that a comprehensive strategy be developed to ensure that an effective diagnostic capacity for the identification of plant pests and diseases is available to Australia.

Effective management of biosecurity risk relies upon building and maintaining a strong and responsive diagnostic capability. Plant Health Australia and Plant Health Committee are addressing Australia's diagnostic capacity in the context of a national plant health system. There is a need to consider resources available to put into capacity building and define more clearly what are the goals that need to be achieved to build an acceptable level of protection for plant health. This review has highlighted the need for the research community to be aware of potential pest problems, to be able to detect unusual symptoms, and to have immediate access to appropriate diagnostic services. [Responsibility: PHC, PHA]

Recommendation 14.

It is recommended that to maintain an effective and efficient management and decision-making process, participation on management and decision-making committees be restricted to nominated members and technical experts required for the specific incursion.

There is a well-structured animal health emergency response plan that is formalised by agreement. There is a defined list of 64 animal diseases with clearly defined testing methodologies with an associated plan for response. The plant emergency response system is not as formalised and there is no equivalent listing for the handling and detecting diseases of plants. Currently, the formalised plant emergency health framework is in its infancy, but work is underway to develop this to encompass similar standards to those required for animals.

During the Wheat Streak Mosaic Virus incident the Consultative Committee on Exotic Plant Pests and Diseases (CCEPPD) teleconferences were effective but were inefficient. Deliberations of the CCEPPD would benefit from a greater understanding by the participants of their responsibilities. This is likely to be an even more important issue when, in future, industry representatives participate under the cost-sharing agreement. The Office of the Chief Plant Protection Officer and Plant Health Australia will collaborate to develop a more clearly articulated process for CCEPPD and in the provision of training for participants. [Responsibility: OCPPO, PHA]

Recommendation 15.

It is recommended that wherever possible, after initial responses for containment of an incursion, rapid delimiting surveys should be conducted to determine the costs and benefits of eradication or any alternative action prior to final decision-making.

It is generally accepted by the Consultative Committee on Exotic Plant Pests and Diseases (CCEPPD) members that a rapid delimiting survey will be requested if eradication in the front-line State is being contemplated. In the case of Wheat Streak Mosaic Virus the delimiting surveys quickly found the virus to be present in four States and after a short delay found it to be widespread in those States. As a result, the CCEPPD was able to recommend to the National Management Group that eradication was not technically feasible.

In anticipation of the plant industry cost-sharing agreement Plant Health Committee will review, and where necessary revise, activities and related procedures followed in the management of plant emergencies. This will include procedures to be followed by the combat State/Territory, other States and Territories, and industry, as well as for CCEPPD and NMG committees. [Responsibility: PHC]

Recommendation 16.

It is recommended that all emergency response plans contain an effective information/media communication strategy.

This recommendation is accepted, however, the reasons for any misinformation during the Wheat Streak Mosaic Virus (WSMV) incident lay largely outside the control of the Consultative Committee on Exotic Plant Pests and Diseases (CCEPPD). In the WSMV incident a strategic approach was taken to communicating the unfolding events including: requiring confidentiality of CCEPPD proceedings, limiting media contact to designated spokesmen, regular briefings of Senior Executives and Ministers, and circulating agreed talking points. In the future a greater effort will be made to ensure that all stakeholders understand their roles, responsibilities and the process being followed to remove any confusion. [Responsibility: OCPPO]

Recommendation 17.

It is recommended that the need for, and dimension of, the Spring 2003 targeted survey for wheat streak mosaic virus, should be revisited.

Wheat Streak Mosaic Virus (WSMV) is now considered to be well established and widespread in four States. The National Management Group meeting of 30 May 2003 agreed that eradication was not feasible. A spring survey will not now be required in all States. The WSMV Technical Working Group circulated guidelines for spring surveys and several States have commenced targeted surveys. [Completed]

Recommendation 18.

It is recommended that biosecurity protocols for all facilities working with biological control agents address all possible risks and that the quarantine protocols be well documented, widely understood and fully implemented.

The SWG will address the need for new and improved standards for facilities importing biological control agents. As a start AQIS is reviewing current physical standards for containment facilities commensurate with the risk posed by biological control agents. It is planned that the appropriate Australian/New Zealand Physical Containment standard will be adopted and implemented at these facilities. New Class 5 Quarantine Approved Premises criteria include adoption of relevant Australian/New Zealand physical containment standards. Final implementation of new Class 5 criteria is due June 2004. [Responsibility: PHC, SWG, AQIS].

Acronym List

AIMS	AQIS Import Management System
AQIS	Australian Quarantine and Inspection Service [an operating group within DAFF]
CCEPPD	Consultative Committee on Exotic Plant Pests and Diseases
DAFF	Department of Agriculture, Fisheries and Forestry
IIG	Internal Implementation Group
MAB	Market Access and Biosecurity [an operating group within DAFF]
OCPPO	Office of the Chief Plant Protection Officer [a functional unit within PIAPH]
PEQ	Post Entry Quarantine
PHA	Plant Health Australia [a company jointly established by the Commonwealth and State/Territory Governments and Industry to facilitate an Industry/Government partnership approach to the development and implementation of plant health policies and programs.]
PHC	Plant Health Committee
PIAPH	Product Integrity, Animal and Plant Health [an operating group within DAFF]
Plant Biosecurity	[a functional unit in Market Access and Biosecurity]
QA	Quality Assurance
QAP	Quarantine Approved Premise
SWG	Standards Working Group
WSMV	Wheat Streak Mosaic Virus

Appendix A

ACTION PLAN

1. All States and Territories should take immediate steps to assess the biosecurity risks within their jurisdictions through research and breeding activities involving imported plant and plant-related material, and take appropriate action.

    - Australian Chief Plant Protection Officer will write to all State/Territory Chief Plant Quarantine Officers,

    - AQIS will, where possible, provide lists of registered containment facilities.

2. There is an urgent need to develop national standards for the procedures and competencies for management of biosecurity risks in plant research/breeding containment facilities to complement existing standards for physical structures. DAFF-OCPPO will coordinate development of the standards while PHC will be responsible for maintaining them. The following steps will be taken:

    - A national workshop on the management of biosecurity risks will be held including representation from: Commonwealth, States/Territories, CSIRO, private sector research, and Universities,

    - A technical working group will be established to draft new procedural and competency standards, revise structural standards, and consult broadly with those stakeholder groups identified above on draft standards (Standards Working Group – SWG),

    - The Plant Health Committee will refine these standards, agree on implementation and communication processes and recommend to PISC for endorsement,

    - The agreed new standards will be launched and promoted,

    - PHC will ensure these standards are maintained.

3. For all recommendations where DAFF is mostly or entirely responsible, implementation will be done by an internal group, led by the Chief Plant Protection Officer, reporting on progress to PHC.

4. Progress reports on implementation will be provided to Primary Industries Standing Committee by PHC.

Appendix B

Table of Responsibilities for Implementation/Action of Recommendations

Recommendation	**Responsible Group/s**
Recommendation 1	IIG
Recommendation 2	SWG, IIG
Recommendation 3	IIG
Recommendation 4	SWG
Recommendation 5	SWG, IIG
Recommendation 6	IIG
Recommendation 7	IIG
Recommendation 8	IIG, SWG
Recommendation 9	IIG
Recommendation 10	SWG
Recommendation 11	SWG, IIG
Recommendation 12	PHA, OCPPO
Recommendation 13	PHC, PHA
Recommendation 14	OCPPO, PHA
Recommendation 15	PHC
Recommendation 16	OCPPO
Recommendation 17	Completed
Recommendation 18	PHC, SWG, AQIS