

## **To: Quarantine and Biosecurity Review Panel**

**Please find below some feedback from the Research Branch, University of Adelaide**

### **AQIS and the University sector**

#### **1.Relevant knowledge for auditing University facilities**

It is pleasing to note that AQIS is attempting to align regulations with OGTR (eg PC2 and QC2) via employing the relevant Australian New Zealand Standards common to both.

Continuing in this direction, it would be worthwhile considering engaging with the University sector as it has different requirements to the corporate and indeed, public sector in many instances.

Whilst containment is an issue, the core functions of a University are research and education. Experiments utilising quarantine material generally represent a small percentage of the work undertaken at the University of Adelaide. Furthermore, material is often destroyed soon after receipt for the purposes of analysis.

AQIS may want to review the educational qualifications of auditors sent to laboratories engaged in research as this may have important consequences in terms of the efficient and effective inspection of University facilities. Whilst the guidelines for auditing would be governed by policy makers and the permit regulations, basic knowledge of the relevance of containment to some procedures will make decision-making in audits simpler. For instance, where biological material is imported but does not represent a quarantine issue as it cannot survive or reproduce unless in a host. Inspection officers with knowledge of recombinant DNA basics, for instance, could then make informed decisions about the relevant level, if any, of quarantine risk.

#### **2. Lack of accountability of AQIS to organisations**

By comparison to the OGTR - an entity with an almost overlapping authority and mandate - the responsibilities delegations, processes and guidelines for AQIS lack clarity.

Moreover, individuals can apply for an import permit and list a currently listed QAP without any checks or confirmations with the institution (QAP owner) in which the materials will be used.

#### **3. AQIS request for compilation of import permits.**

As the Review Issues Paper indicates (68), there is a shared responsibility in the Australian quarantine system. A prime example is represented by the request from AQIS for an inventory of what materials are held at the QAPs, and what permit number they were imported under.

As a pre-requisite to determination of quarantine containment levels under the new containment regime, this university, together with many other AQIS clients, has been asked to provide these records from information on import permits issued by AQIS. This is for the purpose of reassessment to align the imported material with containment risk.

AQIS charges a fee for issue of import permits and it would be logical to assume that records would be kept by them. The immediate question then arises as to why AQIS is requesting these records from clients?

This is not a simple process for large institutions such as universities and represents a considerable administrative imposition.

Greater clarity on clients vs. AQIS responsibility in terms of record keeping would be one aspect of operations that could be investigated.

#### **4. AQIS request for third party assessments**

Level 2 QAPs and above are required to be third party assessed. This is a prerequisite for registration with the new risk-based containment QC levels. This was first indicated in 2005 and since then the deadline has had to be extended three times.

There appear to be a number of reasons for this delay in implementation:

1. Absence of determination, by AQIS, of quarantine containment levels under the new containment regime.
2. Reluctance of organisations to spend on assessment of premises without knowledge of the QC status.
3. There were only three or four assessors available in 2005-7 for QAPs Australia-wide.
4. The lack of surety of the process in relation to the irresolute state of the guidelines.

Whilst AQIS has requested the list of import permits to assign QC status, as detailed above, the University of Adelaide is still awaiting feedback on the relevant QC levels. The required information was submitted some two years ago for advice on the QC status in relation to import permits. This was misplaced at AQIS and the information re-submitted recently. Until this feedback is received from AQIS, there is no foundation for assessment as there is no confirmation of materials that are QC2 level and above. Simultaneously, reminder letters have been sent that the latest deadline for third party assessments is June 30 2008. It could be assumed other organisations are also awaiting confirmation from AQIS on their QC status so are unwilling to have assessments done unnecessarily.

The above indicates that the planning and execution of this requirement has led to confusion, to be followed by a large cost in third party inspection fees and refurbishments to institutions such as universities whose infrastructure may pre-date

the third party assessor's criteria, which are based on AS/NZS 2982.1:1997 and 2243.3:2002.

The AQIS Customer Service Charter contains the statement:

“Being efficient, effective and consistent in administering our regulatory responsibilities.”

In light of the above, the implementation of the changes to containment risk assessment of QAPs and the new nomenclature appears inconsistent with this section of the Charter in terms of efficiency and effectiveness.

## **5. AQIS communications**

The University has, on several occasions, received information from AQIS Canberra of which the regional office was unaware. Copying in these communications to the states simultaneously would resolve the need for clients to relay information to them and make for more streamlined organisation. Similarly, individual permit holders may receive information that the University as QAP holder, may not receive.