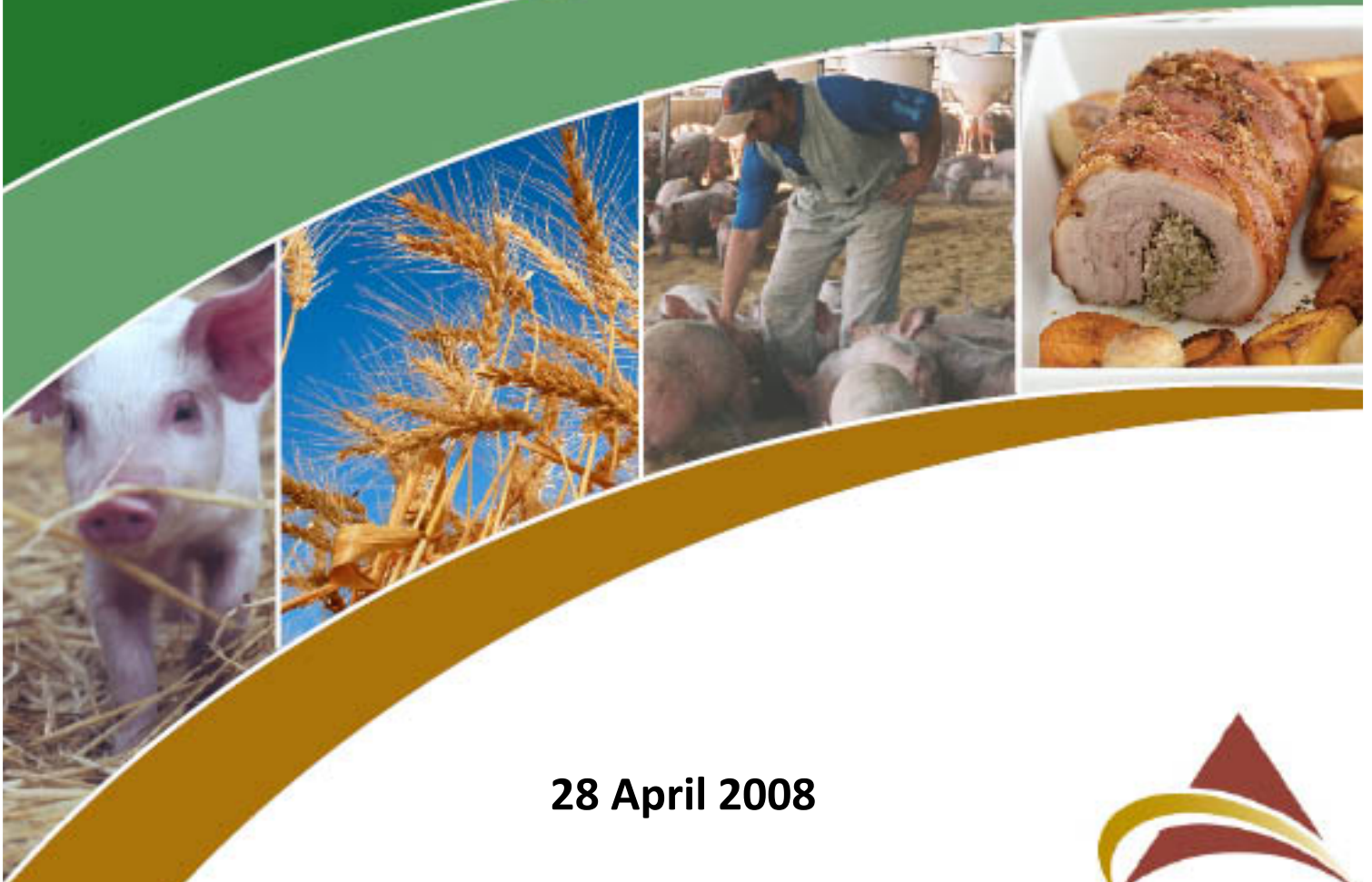


# AUSTRALIAN PORK LIMITED



28 April 2008



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## 1 Executive Summary

Australian Pork Limited (APL) welcomes the opportunity to contribute to the Department of Agriculture, Fisheries and Forestry: Quarantine Biosecurity Review. The Australian pork industry has the uncommon status in the Australian agricultural sector of being one of the few food producing industries to operate in a global market in the true sense. The industry competes in the export arena, with export markets in Asia, and imported product enters Australia from North America and Europe.

APL is well placed to contribute to the Quarantine Review having taken part in extensive Pigmear Import Risk Analysis (IRA), as well as related areas regarding quarantine. Our distinct standing comes from our first hand and comprehensive and extensive involvement with Australia's systems and processes which establish the framework and govern the operation of the import risk assessment process, quarantine, Biosecurity Australia (BA), the Australian Quarantine Inspection System (AQIS), market access and compliance and enforcement at the border, pre-border and post-border.

The Australian pork industry is technically proficient and has advantages over its international competitors largely in terms of health and disease. Current quarantine protocols for pork imports allow extensive use of imported meat for processing, including hams and bacons. APL is concerned with the gradual relaxation of quarantine requirements over time, despite the assessment by the Government that a "shrinking globe" increases the risk of the proliferation of diseases that would damage agricultural industries. Put simply, with the increasing volume of imports the commensurate risk of disease incursion also rises but without a corresponding strengthening of our quarantine system and/or protocols.

There are some serious weaknesses and flaws in our quarantine system and the industry has experienced this first hand. Some of the key issues raised and recommendations made by APL in this submission include:

- **The setting of the Australia's appropriate level of protection (ALOP):** Under the current approach adopted by BA, Australia's ALOP is defined as very low risk and is set by a reference to a semi-qualitative, and in some respects arbitrary, risk analysis – rather than by an identifiable objective standard. However, a qualitative risk assessment cannot effectively take account of variation or uncertainty in the probability it assigns to an event and therefore does not provide for a conservative approach to be adopted in the management of risk. This is especially so in a situation of scientific uncertainty as to aetiology and epidemiology of diseases where the science is relatively unknown. APL does not

believe that the risk management measures proposed by BA in the Pigmeat IRA Report were adequate and thereby failed to reduce the risk to meet an ALOP.

- **The import risk assessment framework, methodology and process:** Application of the ALOP begins with the IRA process – it affects the risk ranges and limitations in the methodology where the science is unknown. APL contends that the Pigmeat IRA did not competently and comprehensively assess risk and risk management issues. The methodology applied in assessing risk management procedures and unavailability of necessary scientific knowledge underpin APL’s ongoing concerns with the Pigmeat IRA, including the preference for quantitative risk assessment over a qualitative risk assessment. Despite the review and strengthening of the IRA process post 2004, these issues remain and the principles raised in relation to ALOP, methodology and transparency are relevant to the IRA process in general. In particular, APL advocates that the precautionary approach should always be applied to managing risk in relation to any disease about which there is a great deal of unknown science. Risk estimates, based on a qualitative assessment, should err on the side of caution.
- **Strengthening the independence and resourcing of BA:** Quarantine processes should operate within a regulatory framework and within a structure where there is effective governance processes in place to ensure quarantine and IRA activities and outcomes are managed independently and with minimal political interference. To enable greater procedural fairness for IRA stakeholders, it is essential that, amongst other things; a truly independent IRA Appeals Panel (IRAAP) is established, where required, and legitimate channels of appeal be available relating to the science.

This issue is of critical importance to all Australian stakeholders following the ruling of the Full Court of the Federal Court in 2005 when APL mounted a legal challenge to have the IRA for Pigmeat set aside. An industry’s right to appeal, or at the very least to have some recourse to ensure that its claims are effectively answered, is now severely reduced and for all intent purposes non-existent when compared to the rights of our trading partners. Australia’s trading partners have recourse to challenge the import protocols through the IRA process and also through the WTO. The effect of the Federal Court’s decision is that it would be extraordinary for any domestic producer to be able to challenge an IRA outcome because of the content of quarantine measures (as opposed to the process for making it). On the other hand, each of the successful WTO challenges under the SPS agreement has been on the basis of some aspect of the content of quarantine measures – so trading partners can challenge on content, but domestic industries cannot.

APL sees merit in the idea of establishing BA as an independent authority as an effective means for addressing the major problems that have occurred with IRAs. This will help ensure that the resulting IRA quarantine proposals relating to imports are science based and are developed in a manner clearly distinct from any broader policy considerations such as trade, the socio-economic impacts and political influences. While it can be argued that BA as an agency has been formally separated from DAFF, this has still not addressed the fundamental problems.

- **The jurisdictional authority of AQIS and its ability to enforce and provide confidence in compliance with import protocols:** It is equally important that the execution of risk management measures pre-border and at the border, are adequate in practice. There is a natural tendency to focus on the principles of risk management and then to assume that the finalised principles will be competently observed. Appraisal of risk management measures in practice is as important as the design and should be addressed in the IRA so that sufficient resources are made available by AQIS to ensure that the proposed protocols are effective in minimising the identified risk.

APL is seriously concerned with the weaknesses and flaws in the current audit and compliance system undertaken by AQIS. It seems to be an outdated system which has not kept pace or reflects changes in technology, product development and market changes, despite AQIS's best of intentions and the restrictions it faces under the authority invested in it under the Quarantine Act. We believe that it is open to misuse and deception, either intentionally or indirectly which puts the industry at risk of an exotic disease incursion. APL shows that in the absence of mass balance reconciliation of imports and their intended use, as well as a robust audit process, there is the potential for substitution of imported pork with domestic post border within the manufacturing process. The generality of the Tariff Statistical Codes is an issue to the pork industry and is potentially contributing to misuse of product in the processing of pigmeat products. Treatment of waste products, specifically liquid from the thawing process and 'trim' from imported meat, is an area that requires closer scrutiny. The treatment and disposal of waste products is potentially vulnerable to short cuts to reduce the costs of disposal.

In addition to this, APL remains concerned that it is still not notified in a timely manner when AQIS has identified potential and actual *major* breaches in compliance to the quarantine protocols. Based on past experience, APL is not been not alerted to these incidents until long after the fact and not until they have been almost resolved. This raises serious questions about the timeliness of advice

provided by AQIS to industry. APL recommends that AQIS notification processes to industry are improved.

- **The Food Import Inspection process:** APL believes that food imports do not undergo the same treatment as domestic food in that certain chemicals used in overseas production, which are not allowed to be used in Australia, are not necessarily tested at the border. There is a cross-over between AQIS' Food Inspection Program, the National Residue Survey and the Food Standards Code in setting three different standards for imports, exports and food for human consumption. APL recommends a review of the AQIS' Imported Food Inspection Program, and AQIS' Export Meat Program, to ascertain whether Australian exporters are unduly disadvantaged in any way and to advance an agenda for regulation harmonisation across these two programs.
- **Australian Stockfeed Standard:** APL recommends that work on development and implementation of an Australian Stockfeed Standard, incorporated in Commonwealth and State legislation, be accelerated to urgently address the current food safety and trade risks associated with imported stockfeed and feed ingredients.
- **Fast-tracking of Vaccination Imports and Emergency Import Permits:** The process for importation of vaccines for use in prevention of exotic and endemic animal diseases is complicated and stifled by the fact that the APVMA will not accept vaccine efficacy data that has not been generated in Australia. APL recommends that the acceptance of overseas generated efficacy data for vaccines be considered for importation of vaccine for use in animal health. APL also recommends that Emergency Permits for vaccines be developed prior to any disease outbreak as a significant step in an emergency disease response plan.

APL contends that it is essential that these matters be satisfactorily addressed in order for the pork industry to retain confidence in the ability of Australia's quarantine system to deliver protection for Australia's animal, plant, human health and the environment.

## 2 Introduction

The Australian pork industry has the uncommon status in the Australian agricultural sector of being one of the few food producing industries to operate in a global market in the true sense. The industry competes in the export arena, with export markets in Asia, and imported product enters Australia from North America and Europe. Our distinct standing comes from our first hand and comprehensive and extensive involvement and knowledge of Australia's systems and processes which establish the framework and govern the operation of the import risk assessment process, quarantine, Biosecurity Australia, the Australian Quarantine Inspection System (AQIS), market access and compliance and enforcement at the border, pre-border and post-border.

The issue of food safety and animal health is equally as important as competitive access to export markets in influencing the growth prospects of the industry over the next decade. Australia's unique animal health status, including freedom from some of the world's major pig diseases (such as Post Weaning Multi-systemic Wasting Syndrome (PMWS) and Porcine Reproductive and Respiratory Syndrome (PRRS)) makes Australian pigs and pig products desirable. Our strong quarantine systems are key strategic international marketing advantages and are vital to the competitiveness and growth of the industry.

Consequently, whilst the North American and European experiences highlight the devastating effect on productivity, competitiveness (and thereby market share) that diseases such as PMWS and PRRS can have, it is also the potential damage to favourable international perceptions about Australia's disease status - its clean, green image - that are of extreme concern. These perceptions represent a key competitive advantage to market Australian pork internationally as a premium product with a clean health status, which is the envy of many other countries. It has even been rumoured that other countries have sought access into the Australian market in order to use their access as an example of their high health status, a "marketing advantage" to other trading partners.

As a global player that operates in both an import and export market, the Australian pig industry, through its representative body Australian Pork Limited (APL), clearly does not support zero level risk management. Zero risk would be detrimental to the pork industry, far more than is currently appreciated by some commentators. This is because any loss of export markets would result in oversupply of pigmeat in the domestic market causing further havoc with producer prices - something the

industry can ill afford. Any export market that provides the industry with the opportunity to diversify its demand base is welcomed.

Nor does APL support an open door policy: it is not reasonable that Australia should maintain an open border to all trade products and assess the risks as they arise. This is akin to closing the gate after the horse has bolted. For example, once an exotic disease like PMWS becomes endemic, the impact on production is significant and ongoing. Risk management measures therefore would be inadequate, as the damage to the industry would have already been done. It would be near impossible to recover from since costs of production would increase, (which would not be recoverable in the market place), resulting in declining competitiveness and in turn lead to a loss of market share.

Border, pre-border and post-border activities are a critical part of our quarantine processes. An appropriate balance between these activities is required. This must be based on an assessment of risk. In order to undertake an assessment of risk, adequate resources and skills must be available. The Australian pork industry requires assurance and confidence regarding compliance and effective implementation of quarantine measures both at the border, pre-border and post-border.

### 3 Industry Background

#### 3.1 Australian Pig Industry

APL is the peak national body representing the interests of Australia's pork producers. It is a unique agricultural organisation underpinned by legislation that enables the organisation to combine the functions of marketing, research and strategic policy direction and implementation, supported by industry funds. APL's members represent approximately 92 percent of the Australian pig production.

Australia's pigmeat production is built around an estimated 1,500 pork producers and approximately 2.6 million pigs according to ABS data as of 30 June 2007; the largest state herds are located in New South Wales (741,000 pigs) and Queensland (669,000 pigs)<sup>1</sup>. ABS data indicates that the national breeding herd in 2005-06 consisted of 302,000 sows (excluding gilts), declining by 8.6 percent to 278,000 sows in 2006-07; the average herd size was 159 sows<sup>2</sup>. It is estimated that the Top 50 producers in Australia account for some 54 percent of production.

**Table 1 Total Pig Numbers in Australia per State 2003-04 to 2006-07 (in '000)<sup>3</sup>**

State	2003-04	2004-05	2005-06	2006-07
NSW	683	653	660	741
Vic	541	545	605	536
Qld	667	696	715	669
SA	357	358	427	347
WA	270	274	277	304
Tas	14	14	16	20
NT	3	3	2	na
ACT	na	na	na	na
Australia total	2533	2543	2702	2617

The estimated Gross Value of Production (GVP) for Australian pig production was \$889 million for the period 2005-06 increasing to \$944 million for the period 2006-07<sup>4</sup>. Pork currently represents approximately 2.38 percent of total Australian farm production<sup>5</sup>. This figure has remained relatively constant since 2005.

The Australian pork industry provides a significant positive impact to local, regional, state and national economies through substantial income generation and employment. In 2004, the pig production sector generated \$3.2 billion in output and

<sup>1</sup> Australian Bureau of Statistics (ABS): *Principal Agricultural Commodities 7111.0*

<sup>2</sup> Australian Bureau of Statistics (ABS): *Principal Agricultural Commodities 711.0*

<sup>3</sup> *ABS Principal Agricultural Commodities 7111.0*

<sup>4</sup> Australian Bureau of Statistics (ABS): *Value of Principal Agricultural Commodities Produced 7501.0 2004-05*

<sup>5</sup> ABRE: *Email conversation*. Figures based on 2005-06 data

\$967 million in value added product<sup>6</sup>, compared to an estimated \$2.9 billion in generated output, \$840 million in value added product and 7,928 full time jobs when flow on effects are taken into account in 2006-07.<sup>7</sup>

Around 56 percent of the 5 million pigs slaughtered in the Australian industry today are part of an integrated supply chain which includes primary processing and production. The remaining pigs sold for slaughter are sourced either through saleyards (5 percent), spot market or through forward and general contracts.

## **3.2 Imports and Exports**

### **3.2.1 Liberalisation of the Australian market for pork**

The Australian market for pork has been liberalised in two ways since the mid 1990s: through the removal of tariff protection in the WTO, and through progressive relaxation of quarantine controls.

The Australian market for pork was first liberalised through commitments made by Australia during the Uruguay Round of trade negotiations, which established the WTO, in 1994. Australia accepted a bound tariff rate of zero on imports of pigmeat under the WTO Agreement on Agriculture, effective from 1 January 1995. Liberalisation was undertaken without adjustment assistance or any form of compensation.

Between May 1990 and May 2004, quarantine restrictions against imports have been progressively reduced. Before 1990, only imports of canned hams were allowed entry into Australia. These measures reflect decisions by the Australian Government to relax quarantine controls to allow the import of frozen, uncooked pigmeat from Canada. In 1992 these restrictions were strengthened requiring imported frozen pigmeat to be boned prior to export and to be used for processing in Australia. Most recently, following quarantine changes in 2004, imports of pork from the United States (U.S.) have augmented those from major pork exporting countries like Canada and Denmark (refer to Table 2 below).

Before the change of import policies to the current quarantine requirements on 10 May 2004, import of uncanned, uncooked pigmeat was restricted to Canada, Denmark and the south island of New Zealand. The current import policy is based on an Import Risk Analysis (IRA) conducted by BA, which recommended that imports of pigmeat be permitted subject to conditions depending on the health status of the export country.

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<sup>6</sup> Western Research Institute 2005, *Socio-Economic Impacts of the Australian Pork Industry*

<sup>7</sup> Western Research Institute 2008, *Socio-Economic Impacts of the Australian Pork Industry - preliminary report*

The following countries currently have permission to export deboned pigmeat to Australia:

- Canada (Cooked and uncooked for further processing)
- Denmark (Cooked and uncooked for further processing)
- United States of America (Cooked and uncooked for further processing)
- Finland (Uncooked for further processing)
- Sweden (Uncooked for further processing);
- Spain (Dry cured Serrano type ham)
- Italy (Dry cured Parma type ham)

Brazil, Chile, the Republic of Korea, South Africa, Taiwan, Mexico, New Zealand, and Hungary have also requested market access since the establishment of the new import policy, but due to disease risks have been refused.

**Table 2 Import Revision Timeline for the Pork Industry**

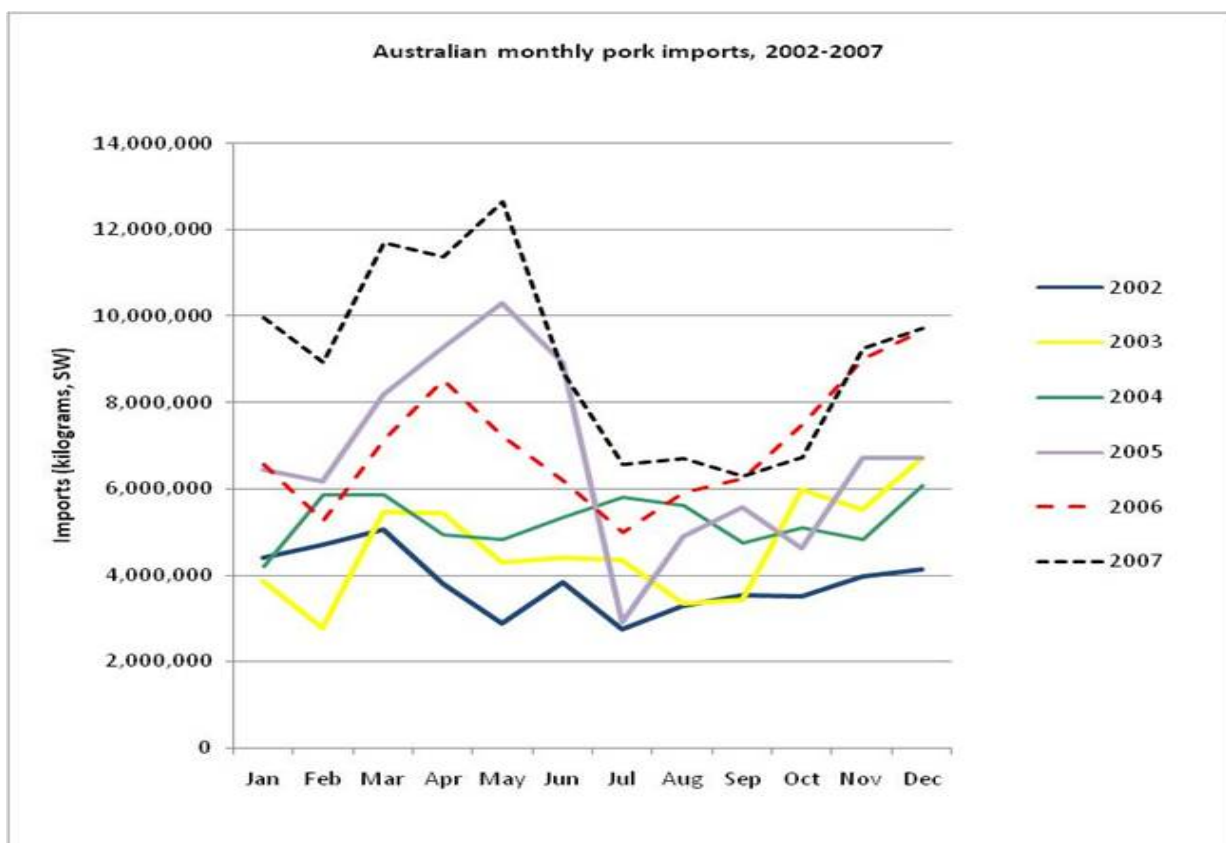
Year/Period	Event
1990	<p><b>May 1990:</b> Imports of uncooked, unfrozen pigmeat are permitted from the South Island of New Zealand.</p> <p><b>July 1990:</b> Revision of import regulations allowing frozen and uncooked Canadian pig meat imports into Australia. Prior to 1990, only canned hams were permitted as imports.</p>
1992	<p><b>Late 1992: Import regulations strengthened</b> requiring all imported frozen pig meat to be de-boned prior to shipment and processed (cooked) on arrival under quarantine control. The imported meat is used for further processing in Australia.</p>
1996	<p><b>May 1996: Canada</b> permitted to export chilled, de-boned pork cuts for further processing (cooking) in Australia.</p>
1997	<p><b>November 1997: Canada</b> permitted to export cooked, de-boned pigmeat; <b>Denmark</b> permitted to export uncooked, de-boned pigmeat to be processed (cooked) on arrival under quarantine control.</p>
1998	<p>Work on the Import Risk Analysis commences on 26 May 1998. Panel established to conduct a risk analysis, following requests from: Brazil, Canada, Chile, EU member states, Hungary, Republic of Korea, Mexico, New Zealand, South Africa, Taiwan; and the United States.</p> <p>Productivity Commission Inquiry into Pigmeat Safeguards is announced by the Federal Government.</p>
2001	<p>Reduced pork supply due to FMD impact ex Europe;</p> <p>Issues Paper released for the Import Risk Analysis on January 8, 2001</p>
2004	<p>Revision of import regulations:</p> <p><b>February 19, 2004:</b> Biosecurity Australia releases the IRA for pigmeat.</p> <p><b>May 10, 2004:</b> Director of Animal and Plant Quarantine made a determination setting out new quarantine requirements for the importation of pig meat, <b>allowing imports from the U.S.</b></p> <p><b>9 July 2004:</b> Australian Pork Limited files legal action in the Federal Court Registry, aimed at preventing any reduction in quarantine regulations which could allow the entry of the disease, Post Weaning Multi-Systemic Wasting Syndrome (PMWS). A Directions Hearing of the application had been set down for <b>10 August, 2004.</b></p>

Year/Period	Event
2005	<p><b>27 May 2005:</b> Litigation in the Federal Court successful in the first instance before Mr. Justice Wilcox, handing down judgement.</p> <p><b>20 June 2005:</b> the Commonwealth lodged an Appeal with the Federal Court against the original decision of the Court.</p> <p><b>16 September 2005:</b> the Full Bench of the <b>Federal Court overturns Justice Wilcox' determination.</b></p> <p><b>26 October 2005:</b> APL denied Special Leave to take its case to the High Court of Australia; Pigmeat IRA remains legal.</p>
2007 - current	<p>Countries that now have permission to export pigmeat de-boned for further processing into Australia:</p> <ul style="list-style-type: none"> <li>• Canada (Cooked and uncooked for further processing);</li> <li>• Denmark (Cooked and uncooked for further processing);</li> <li>• United States of America (Cooked and uncooked for further processing);</li> <li>• Finland (Uncooked for further processing);</li> <li>• Sweden (Uncooked for further processing);</li> <li>• Spain (Dry cured Serrano type ham); and</li> <li>• Italy (Dry cured Parma type ham).</li> </ul>

### 3.2.2 Imports

Current quarantine protocols for pork imports allow extensive use of imported meat for processing, including hams and bacons. In 2004-05 imports from Canada, Denmark and the U.S. amounted to approximately 128,000 tonnes CWE. Pork imports in 2006-07 moving annual total (MAT) volume has increased by 48 percent from 2005-06 and the value of these imports increased by 61 percent during the last financial year. ABS data<sup>8</sup> shows that for the first eight months of financial year 2007-08 imports amounted to 62,441 tonnes shipped weight (SW) with a maximum of 8,211 tonnes SW in February 2008 . Chart 1 and 2 below outline the development of average monthly import volumes from 2002 to 2007.

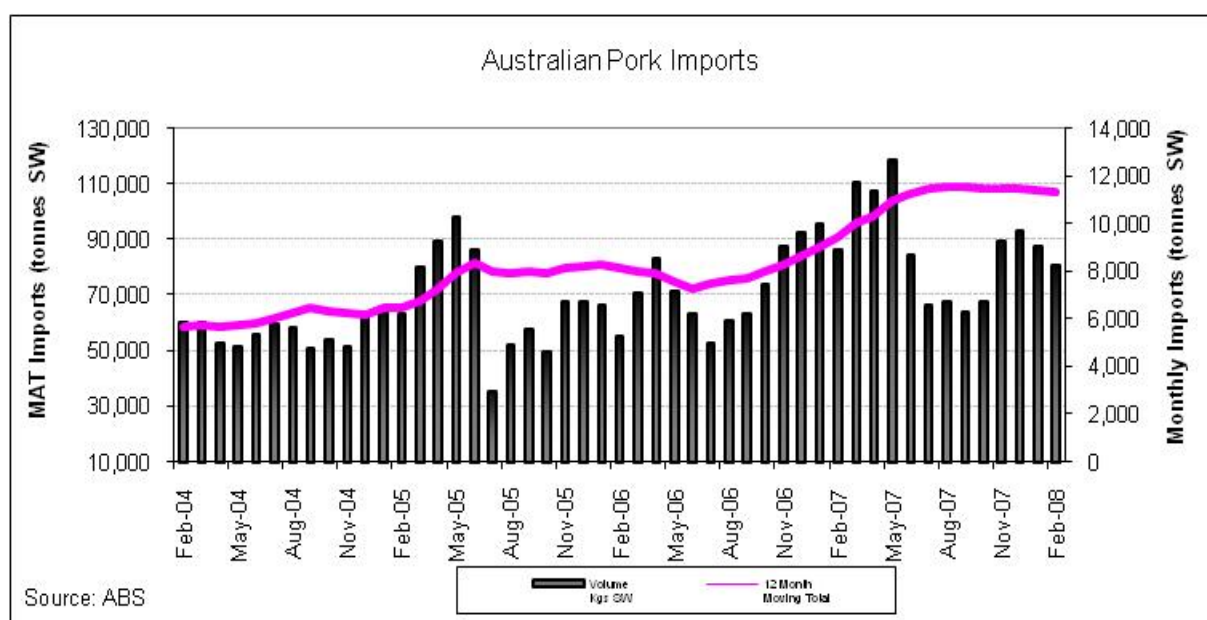
Chart 1 Australian Monthly Pork Imports, 2002-2007



Source: APL from ABS data

<sup>8</sup> ABS data (February 2007)

**Chart 2 Australian Monthly Pork Imports and MAT, Nov 03 to Feb 2008**



The share of imports of the processed pork sector has steadily increased since 2002-03 accounting to around 67 percent (January MAT 2008) of the processed pork market. Imports share of the Australian market for pigmeat has increased by approximately 10 percentage points, a further increase to an existing high base of 58 percent when compared to January MAT 2007, effectively threatening to capture the total market (short of a small volume restricted by quarantine restrictions on bone-in products).

Over the last five years the pork industry has aggressively marketed Australian pork, achieving consistent rapid growth in fresh pork consumption and resulting in a 35 percent increase in fresh pork consumption. However, as shown above it has been imports that have taken an increasing share in the growth of the Australian pork market relative to production and consumption. Import penetration measured through the share of imports of total apparent consumption (i.e. imports' share of domestic production plus imports minus exports) has also markedly increased, rising from around 20 percent in 2002-03 to 34 percent in 2006-07.

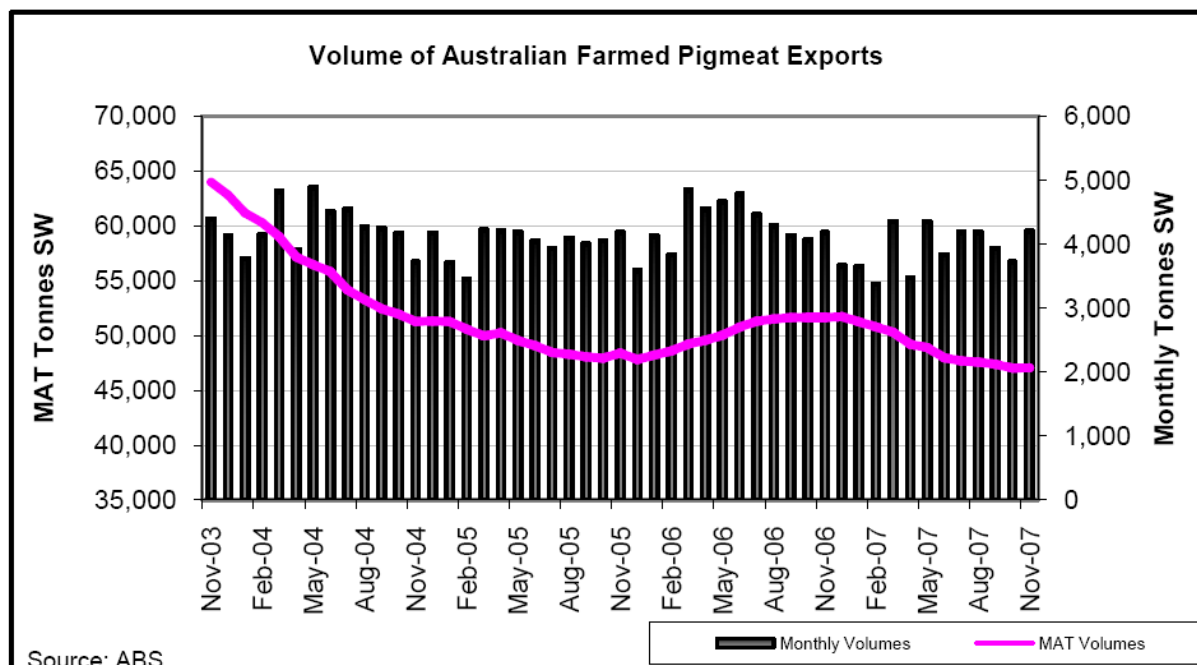
### 3.2.3 Exports

Australia's pork exports are primarily built around the market of Singapore, New Zealand and Japan representing 49 percent, 20 percent and 4 percent of Australia's total pork exports for 2006-07 respectively<sup>9</sup>. These key markets cover 73 percent of Australia's pork exports with an additional 11 percent going to Hong Kong, the Philippines and South Korea. In total, these countries constitute 84 percent of

<sup>9</sup> APL from ABS Statistics (2007)

Australia's total pigmeat export volumes, 2006-07. APL's focus is on access to Asian markets. Chart 3 below outlines the development of Australian pork export volumes since November 2003.

**Chart 3 Volume of Australian Farmed Pigmeat Exports, Nov 03 to Nov 07**



Pigmeat export volumes were 48,017 tonnes for 2006-07, a decrease by 6 percent on 2005-06, due to a significant decrease in export volumes to Japan and South Korea. Total farmed pigmeat exports for 2006-07 were valued at \$156.5 million, which is equivalent to \$3.26 per kilogram. Exports to Singapore and Japan provide income of \$77 million and \$54 million per year respectively (2006-07). Of major significance is the fact that both of these markets place a particularly high level of importance on food safety and animal health issues. An appreciating dollar has significantly undermined exports.

### 3.2.4 Industry Competitiveness: animal health and exotic diseases

The Australian pork industry is technically proficient and has advantages over its international competitors largely in terms of animal health and disease. For example, whilst Australia has the more common pig diseases such as Mycoplasma pneumonia, swine dysentery, pleuro pneumonia and ileitis, it is free of the more devastating diseases such as Post-weaning Multi-systemic Wasting Syndrome (PMWS), Porcine Reproductive and Respiratory Syndrome (PRRS), Swine Influenza Virus and Circo Virus Related Diseases. All these diseases have had marked adverse effects on animal mortality and the efficiency and costs of production in virtually all other countries over the last 5-10 years. Australia is also free of exotic diseases such

as Foot and Mouth and Classical Swine Fever, both of which affect global export opportunities.<sup>10</sup>

While the North American and European experiences highlight the devastating effect diseases such as PMWS and PRRS can have on productivity, consideration must also be given to the adverse impact that this can have on our markets both real and perceived. These perceptions are what enable us to market Australian pork internationally as a premium product.

As a global player that both exports and imports, APL does not support zero level risk management. Zero risk would be detrimental to the pork industry, far more than is currently appreciated by some commentators: because of the dominance of imports in our domestic market any loss of export markets would result in oversupply of pigmeat in the domestic market causing further havoc with producer prices - something the industry can ill afford. Any export market, which provides the industry with the opportunity to diversify its supply base, is welcomed.

Nor does APL support an open door policy: it is not reasonable that Australia should maintain an open border to all trade products and assess the risks as they arise. This is akin to closing the gate after the horse has bolted. For example, once an exotic disease like PMWS becomes endemic, the impact on production is significant and ongoing. Risk management measures therefore would be inadequate, as the damage to the industry would have already been done. It would be near impossible to recover from since costs of production would increase, (which would not be recoverable in the market place), resulting in declining competitiveness and in turn lead to a loss of market share.

There are, however, some serious weaknesses and flaws in our quarantine system. The industry has experienced this first hand and has specific and continuing concerns in relation to:

- The setting of the Australia's appropriate level of protection
- The import risk assessment framework, methodology and process
- Strengthening the independence and resourcing of Biosecurity Australia
- The jurisdictional authority of AQIS and its ability to enforce and provide confidence in compliance with import protocols

These concerns are explored in detail in the following sections.

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<sup>10</sup> APL Submission #3, Safeguards Inquiry into the Import of Pigmeat, p.74

## 4 Setting Australia's Appropriate Level of Protection

The Senate Rural and Regional Affairs and Transport Legislation Committee (2000) in its report on the Appropriate Level of Protection (ALOP) and importation of salmon<sup>11</sup> acknowledged that *“no single method of import risk assessment is applicable in all situations – that different methods will be appropriate for different circumstances.”*<sup>12</sup> The Senate Report claimed that both AQIS and DFAT were unable to articulate clearly what the ALOP was and by whom it was determined.<sup>13</sup> (AQIS, in evidence before Committee, defended the generality of the ALOP, describing it as a qualitative matter rather than a quantitative matter.<sup>14</sup>) It acknowledged the failure of AQIS to undertake a substantial quantitative analysis in the initial Salmon IRA (1999). Although the 1999 IRA was endorsed by the WTO, the Committee recommended that a quantitative risk analysis methodology be used whenever possible and as appropriate to avoid challenges in the WTO.

The Committee also recommended that if AQIS used a qualitative risk analysis methodology that it ensure there is no ambiguity in the terminology used to describe risk factors. This was a critical problem in the salmon IRA with the lack of distinction between some of the terminology and the language of the conclusions, leading to subjectivity. APL believes this recommendation remains relevant today.

Australia has assigned a ‘very low risk’ conservative categorisation as fulfilling our ALOP. Under the current approach adopted by BA, Australia’s ALOP is defined as very low risk and is set by a reference to a semi-qualitative, and in some respects arbitrary, risk analysis – rather than by an identifiable objective standard. However, a qualitative risk assessment cannot effectively take account of variation or uncertainty in the probability it assigns to an event and therefore does not provide for a conservative approach to be adopted in the management of risk.<sup>15</sup> This is especially so in a situation of scientific uncertainty as to aetiology and epidemiology of diseases where the science is relatively unknown.

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<sup>11</sup> Senate Rural and Regional Affairs and Transport Legislation Committee (2000), “An Appropriate Level of Protection? The Importation of Salmon Products: A case study of the Administration of Australian Quarantine and the Impact of International Trade Arrangements, Commonwealth of Australia, p. 187.

<sup>12</sup> Senate Rural and Regional Affairs and Transport Legislation Committee (2000), “An Appropriate Level of Protection? The Importation of Salmon Products: A case study of the Administration of Australian Quarantine and the Impact of International Trade Arrangements, Commonwealth of Australia, p. 187.

<sup>13</sup> Senate Rural and Regional Affairs and Transport Legislation Committee. (2000). An Appropriate Level of Protection? The Importation of Salmon Products: A case study of the Administration of Australian Quarantine and the Impact of international Trade Arrangements (2000). Commonwealth of Australia. P. 89: 4.26

<sup>14</sup> AQIS, Evidence, RRAR, 24 September 1999, p. 35 from Senate Rural and Regional Affairs and Transport Legislation Committee. (2000). An Appropriate Level of Protection? The Importation of Salmon Products: A case study of the Administration of Australian Quarantine and the Impact of international Trade Arrangements (2000). Commonwealth of Australia, p. 83.

<sup>15</sup> Senate Rural and Regional Affairs and Transport Committee Interim Report on the Proposed Importation of Fresh Apple Fruit from New Zealand at 8.9

Another effect of this approach is that it is almost impossible for stakeholders to determine what the ALOP actually is or means in concrete terms in terms of potential consequences for them. It also creates difficulty for stakeholders to respond effectively in the Import Risk Assessment process. It is impossible to calculate whether any of the proposed risk management measures will in fact reduce the risks to meet any objective or defined or clearly described risk level, since no risk level has been defined (objectively or otherwise) or clearly described.

It has been APL's contention that the approach used in the Pigmeat IRA (2004) to setting the ALOP was problematic for the very reasons outlined above. The risk management procedures proposed for the diseases PMWS & PRRS were inadequate and did not reduce the risk posed by these diseases to the Australian pork industry to an appropriate level of protection i.e. Australia's very low risk categorisation.

The Pigmeat IRA purported to define and derive the content of the term through the IRA process itself. It is suggested that this approach is inconsistent with Australian law – or at the very least results in procedural unfairness for parties who are affected by and may wish to challenge the setting of the ALOP.

Critically, APL does not believe that the ALOP is applied in a consistent manner or is well understood. Certainly our experience in the IRA for Pig Meat (2004) and as documented in our various submissions to the Import Risk Analysis Appeal Panel (IRAAP), Senate Rural and Regional Affairs Committee Inquiry into the Pig Meat IRA, (2004), and APL's legal challenge is testimony to this. APL contends that it still remains a critical problem which has not been adequately addressed by the various reforms, which were introduced to the IRA process and BA by the then Minister for Agriculture, Fisheries and Forestry, the Hon Warren Truss, on the 15 July 2004.

APL acknowledges that in respect of identifying ALOP there is an ever present challenge striking the balance between trying to acquire complete knowledge and obtaining a reasonable estimate on which predictions can be held with reasonable confidence. That said, there is no barrier to providing substantive explanation as to the judgments made during the IRA for Pigmeat by the respective IRA Panel, which formed the basis of these semi-qualitative analyses and figures.

## 5 Import Risk Assessment Framework and Process

Application of the ALOP begins with the IRA process – it affects the risk ranges and limitations in the methodology where the science is unknown. APL contends that the Pigmeat IRA did not competently and comprehensively assess risk and risk management issues. The methodology applied in assessing risk management procedures and unavailability of necessary scientific knowledge underpin APL’s ongoing concerns with the Pigmeat IRA, including the preference for quantitative risk assessment over a qualitative risk assessment.

APL does not believe that the risk management measures proposed by BA in the Pigmeat IRA Report were adequate and thereby failed to reduce the risk to meet an ALOP. Despite the review and strengthening of the IRA process, these issues remain and the principles raised in relation to ALOP, methodology and transparency are relevant to the IRA process in general.

Specific methodological flaws include:

- The quantitative approach applied to consequence assessment and risk estimation. It would have been beneficial for the Pigmeat IRA to explain why a qualitative assessment was chosen over a quantitative assessment, provide reasons for adopting this particular methodology and disclose the methodology used to undertake the qualitative risk assessment of the Pigmeat IRA.
- Unjustifiably low estimates of the likelihood of entry resulting from errors in the method used to calculate likelihood. There was an underestimation of the total impact of diseases due to the annualised calculation used to assess the likelihood of entry and exposure.
- The potential for serious distortion of the outcomes for risk assessment likelihood of “entry and exposure” resulting from the use of annualised calculation as opposed to consideration of an outbreak within a ten year period.
- Due to increased volumes of import trade above those used by BA in the draft IRA in its analysis, it follows there are substantial increased levels of disease risks which in turn raise the overall annual risk level but are not accounted for in the methodology.
- Insufficient explanation as to why likelihood models were based on the 50<sup>th</sup> percentile instead of the 95<sup>th</sup> percentile. The effect of choosing the 50<sup>th</sup> percentile is inappropriate and a deliberate move away from BA’s stated process of using conservative assumptions. The rules of the Impact Score Tables are arbitrary and

therefore it is not possible to reach the outcomes proposed by BA by actually applying these rules.

- The lack of transparency in the analysis procedures led to an inability by APL and the Canadian Government to reach the same conclusions as BA. It was difficult for stakeholders to logically follow the analysis procedure used by BA regarding custom distributions.
- BA initially proposed modifying the risk management measures for PRRS to also provide for offshore cooking but failed to provide sufficient comparative risk analysis or an explanation as to why on-shore processing is considered as safe as offshore. The IRA provided no basis to conclude that risks will be acceptably managed through on-shore cooking.
- The draft IRA also failed to document the appraisal techniques intended to be used to ensure proper execution of risk management procedures.

BA continually demonstrated a general unwillingness to either consider statistical analysis that APL's expert scientific panel had presented or to engage with APL to determine the validity of such analysis or the reasons why it was to be rejected. BA also provided an inadequate response and explanation to methodological flaws identified by APL, demonstrating that a consultation process in its own right does not necessarily bring about better outcomes.

APL was also greatly troubled by BA's lack of an adequate explanation in their response to CSIRO commissioned work proposing consideration be given to more than a one year period for the risk assessment. Similarly BA's inadequate explanation regarding the change in the likelihood distribution model which had the general effect of moving away from the general cautious approach used by BA in other import risk analyses. BA's lack of responsiveness resulted in there being a disturbing lack of transparency in the IRA process.

APL, a Senate Inquiry into the Pig Meat IRA and a Federal Court Judge all expressed great concern that BA had not undertaken the necessary scientific research to allow the IRA Panel to legitimately form a judgement that the assessed level of unrestricted risk would become 'very low', despite repeated requests from APL. This was inconsistent with how BA had addressed earlier concerns relating to the PRRS virus (1999) where like PMWS it was unknown as to what sort of cooking of pig meat would have the effect of reducing the risk of transmission of the virus through pigs eating infected pig meat. These concerns resulted in the commissioning of research into PRRS by BA. No such research was commissioned or apparently considered relevant by BA despite repeated requests from the industry and offers to

Government to co-fund such research. Nor was an adequate explanation was provided as to the reason on which this decision was based.

The IRA for Pimeat did not adequately address the substantial risk of a PMWS incursion in the context of the limited knowledge available about PMWS and its rapid and uncontrolled spread in Europe, North America, Asia and New Zealand. PMWS is without a cure and would have a significant impact on the Australian pork industry. The paucity of knowledge regarding PMWS makes eradication unfeasible and without a clear understanding of the factors involved with this disease, control measures are difficult to implement. A vaccine for PCV2 is not permitted to be imported into Australia. (Vaccine importation is dealt with in Section 7).

APL advocates that the precautionary approach should always be applied to managing risk in relation to any disease about which there is a great deal of unknown science. New diseases by their nature should require a cautious approach. Risk estimates, based on a qualitative assessment, should err on the side of caution.

### ***5.1 Appeals Process - Role of Import Risk Analysis Appeals Panel***

To enable greater procedural fairness for IRA stakeholders, it is essential that, amongst other things:

- a truly independent IRA Appeals Panel (IRAAP) is established, where required; and
- legitimate channels of appeal be available relating to the science.

#### **5.1.1 Independence and membership of the IRAAP**

The IRA Appeals Panel (IRAAP) is chaired by the Chairman of the Quarantine and Exports Advisory Council (QEAC). An IRAAP comprises three members:

- Chairman of QEAC
- One other member of QEAC
- A senior officer from the Department of Agriculture, Fisheries and Forestry.

The IRAAP Chairman nominates the QEAC member of an IRAAP. The Secretary of the Department nominates the senior Departmental member of an IRAAP. It also requires that membership of an IRAAP is subject to conflict of interest considerations. Each potential member of an IRAAP is required to declare any potential conflict of interest or any possible perception of bias that could prevent them from participating in a particular appeal. If this declaration raises concerns about whether the Chairman or a member should participate in the appeal, the Chairman, in consultation with the Secretary of the Department, nominates an alternative member.

Whilst the IRA Appeals Panel supposedly provides an ‘independent’ process of review for matters, APL seriously questions the IRAAP’s independence. Specifically, APL continues to be concerned by the fact that at least one of the appointed members of the Panel are employed by DAFF - a senior officer from the Department directly appointed by the Secretary of DAFF<sup>16</sup>. This brings into question the panels ‘independence’. Also noteworthy is the fact that the Secretary of Department of Agriculture, Fisheries and Forestry is also the Director of Animal and Plant Quarantine. As a starting point, it is essential that an IRA Appeal Panel must be truly independent representatives. DAFF could still provide secretariat services for the IRAAP, but the make-up of the Panel would be best served by non-DAFF or BA employees.

Under the current appeals process the decision as to whether to consider an appeal rests solely with the IRAAP Chairman, who will follow the Guidelines under the Import Risk Analysis Handbook 2007. It is the Chair who determines if the statement of reasons given by the Appellant provides evidence warranting consideration by an IRAAP. IRA claims of appeal are strictly confined to “*there having been a significant deviation from the regulated IRA process that adversely affected the interests of a stakeholder.*” The IRAAP does not consider matters relating to:

- The scientific merits of the IRA
- The merits of the recommendations made or the conclusions reached by BA or the Eminent Scientists Group.

The IRAAP's findings in relation to a claim are also confined to one or more of the following categories:

- Outside the ground for appeal
- Allowed
- Disallowed.

APL believes that this process is seriously deficient and the Terms of Reference (ToR) of the Panel significantly narrow. Appeals can only be heard if stakeholders considered that the IRA process was not conducted according to the IRA Handbook or that a significant body of scientific information relevant to the outcome of the IRA was not considered. APL’s experience of the Appeal is that it appeared to be a simple rubber stamping of BA’s previously inadequately argued positions. There was no adequate explanation provided as to why the Panel reached its findings other than to state that a claim was disallowed or outside the ground for appeal. The ToR constrained the Panel’s examination of all of the factors impacting on the levels

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<sup>16</sup> In the case of the IRAAP for Pigmeat, there were five panel members, two of which were employees of the Department.

of risk associated with an exotic disease outbreak, which APL, a Senate Inquiry, and the Federal Court had consistently highlighted.

APL believes that the poor analysis undertaken and response of the IRAAP, even to those issues relevant to the terms of reference of the IRAAP process, also diminished the credibility of their findings. For example, in response to the APL assertion that the 'very low risk' status had not been met, it appears that the IRAAP took on face value the IRA's assertion that for PMWS the required 'very low risk' necessary to meet Australia's ALOP had been fulfilled, simply because the IRA claimed that to be the case. This was hardly investigative. IRAAP stated that:

*"The Panel noted that the Final IRA Report states, on page 747, that the risk management measures proposed for PMWS reduce the risk to 'very low', which satisfies Australia's ALOP. The Panel agreed unanimously to disallow this aspect of the appeal on the ground that APL had not established that there had been a significant deviation from the IRA process."<sup>17</sup>*

Yet page 747 did not provide a sufficient explanation to the concerns raised by APL (nor for a Senate Inquiry or the Federal Court.) Hence the Panel was unable to in anyway review the 'basis' for which BA reached its 'very low' risk assessment and merely concurred that the answer provided by BA was sufficient.

Similarly, the ToR lessened the transparency of the IRA process in relation to APL seeking further substantiation from BA regarding their decision not to consider risk beyond one year. Whilst BA might have simply demonstrated to the IRAAP that they had 'considered' the document that APL provided, and hence claim that the 'significant body of scientific information relevant to the outcome of the IRA in question had been considered', the IRAAP Panel ToR did not enable them to request that BA provide a robust reasoning as to why BA chose to restrict the analysis to only a one year time frame.

The industry has not, at any time during or post the IRA and the IRAAP had its questions and significant concerns addressed adequately. Indeed industry's right to appeal or at the very least have some recourse to ensure that its claims are effectively answered is severely reduced and for all intent and purposes non-existent when compared to the rights of our trading partners. This issue is covered further in Section 5.2.

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<sup>17</sup> Import Risk Analysis Appeal Panel, Importation of Pig Meat, Findings – Pig Meat Import Risk Analysis Appeals 10 May 2004 p1

### 5.1.2 Eminent Scientists Group

Certainly the addition of the Eminent Scientists Group (ESG) in July 2004<sup>18</sup> has gone some way to strengthen the IRA process, particularly in relation to some of the concerns raised by APL in the Pig Meat IRA process, given its role is independent of BA and that is tasked with providing external scientific scrutiny of import risk analyses. It is APL's opinion that the ESG provides a critical and necessary function by reviewing the drafts of IRA reports, as revised by BA, after consideration of stakeholder comments, that have been through the expanded IRA process and prior to their release. Also welcomed is the widening of the ESG's role in 2007<sup>19</sup> to take account of relevant new information brought to its attention, including assessing conflicting scientific views provided to it.

It is difficult to comment on the merits of the ESG's role and reports in relation to IRA's since its inception given the one report it has made (the draft Final Import Risk Analysis Report for Apples from New Zealand) and we understand there have been none since its role was expanded in September 2007. APL has examined the ESG Report<sup>20</sup> and believes that it still does not provide sufficient substance or give adequate explanation concerning their assessment. While we respect the qualifications of the ESG members, the report does not appear to have robust justification for the assessment and the concerns raised by APL in regard to the IRAAP report are relevant here.

APL is also concerned that the independence of the ESG may be compromised (even with the extensive precautions taken concerning the appointment of its members<sup>21</sup> while the Secretary of the Department of Agriculture, Fisheries and Forestry continues to also act as the Director of Animal and Plant Quarantine and it remains as an agency within the auspices of the DAFF. In particular, APL believes that the potential for conflict of interest, transparency of process and the influence of politics and pressing trade concerns, whether intentional or indirect, is still not easily separated under the current system.

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<sup>18</sup> ANIMAL BIOSECURITY POLICY MEMORANDUM 2004/15 - NEW ARRANGEMENTS TO STRENGTHEN IMPORT RISK ANALYSIS. The changes outlined in this memorandum were introduced by Minister Truss boost confidence in the rigour of the Import Risk Analysis (IRA) process and address perceptions that trade considerations, rather than scientific analysis, were influencing the IRA process.

<sup>19</sup> The ESG's role was strengthened to include: all submissions received from stakeholders in response to the draft IRA report have been properly considered; and, the conclusions of draft IRA report are scientifically reasonable, based on the material presented.

<sup>20</sup> Eminent Scientists Group. Report of the Eminent Scientists Group on the Import of Apples from New Zealand to the Director of Animal and Plant Quarantine. October 2006

<sup>21</sup> Members of the ESG will be selected by the Director of Animal and Plant Quarantine in consultation with the Chief Scientist and chief executive officers of state and territory departments responsible for primary industries. Each member selected will have a proven record of scientific leadership, have made significant contribution to science and be well respected in the broad scientific community. The Director of Animal and Plant Quarantine will select one member of the ESG as Chairman. The Chairman of the ESG will appoint no less than two members of the ESG to undertake the review of each draft final IRA report referred to the ESG and will nominate one of those members to lead the review in circumstances where the ESG Chairman is unable to undertake this role for particular reviews. The Chairman of the ESG may also co-opt additional expertise or seek advice to assist the ESG in meeting its terms of reference.

The IRAAP terms of reference, its processes and membership must ensure at the very least its complete independence of the IRAAP from BA and DAFF and that a proper appeal process to be undertaken. This assertion is also true of the ESG; while ever the appointment of members of the ESG are made by the Director of Animal and Plant Quarantine and BA sits within DAFF there is likely to be potential conflicts and concerns relating to transparency of issues.

## ***5.2 Australian Pork's Legal Challenge to the Pig Meat Quarantine Decision***

APL had raised its concerns regarding the Import Risk Analysis for Pigmear and faithfully followed all procedural processes allowed to it including:

- Active involvement during the drafting of the IRA, including submissions after the methodology paper and draft IRA.
- The Senate Rural Regional Affairs and Transport Committee conducted an Inquiry into the IRA. APL made a submission and gave oral statements, as did BA and the CSIRO.
- Appeal to the IRA Appeals Tribunal.

APL contributed to the drafting of the IRA process. It expressed its concerns about methodology at an early stage; however this was neither reflected in the final IRA nor in fact ever sufficiently addressed. APL's concerns included the 'quantitative' approach applied to consequence assessment and risk estimation and also the apparent underestimation of the total impact of diseases due to the annualised calculation used to assess the likelihood of entry and exposure.

Indeed BA in its Generic IRA for Pig Meat Final Report <sup>22</sup> did provide a response to the concerns raised by APL. This position was supported by the IRAAP stating that *"in particular, mathematical modelling conducted by CSIRO and emerging scientific information from New Zealand scientists had been considered by the IRA team."*<sup>23</sup> However, APL contended that BA (and the IRAAP as raised in the previous sections) failed to provide sufficient documentation or justification explaining how these decisions and conclusions were reached.

The Australian pork industry's concerns in relation to the new quarantine regime for imported pig meat were vindicated in a report from the Senate Standing Committee on Rural and Regional Affairs and Transport. The Report recommended that:

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<sup>22</sup> Department of Agriculture, Fisheries & Forestry Generic Import Risk Analysis for Pig Meat Final Risk Analysis Report Annex February 2004

<sup>23</sup> Import Risk Analysis Appeal Panel, Importation of Pig Meat, Findings – Pig Meat Import Risk Analysis Appeals 10 May 2004 p1

- “the Director of Animal and Plant Quarantine withdraw the new quarantine regime for imported pig meat on the basis of inadequate methodology, as well as inadequate risk assessment and risk management strategies”; and
- “Biosecurity Australia (BA) invokes the precautionary principle contained in article 5.7 of the SPS Agreement in relation to PMWS.”<sup>24</sup>

However, although the Senate Committee vindicated APL’s concerns about the serious failings in the IRA the Government did not accept the recommendations.

The only remaining recourse available to APL following the IRAAP decision was litigation. This decision was not taken lightly by the APL Board but was seen as a last (but necessary) resort to protect the health status of the Australian pig herd; to ensure that the quarantine risk measures proposed by BA were indeed sufficient to reduce the risk to an appropriate level of protection i.e. very low as required by our Quarantine Act.

In late July 2004 APL filed a legal challenge in the Federal Court to have the IRA set aside on administrative law grounds. APL’s primary concern centred on the rules proposed to be applied for Post Weaning Multi-systemic Wasting Syndrome (PMWS). PMWS is a syndrome which causes death and failure to thrive among weaner piglets. The issues around PMWS are complex – because scientists still do not know what causes PMWS.<sup>25</sup> The challenge in a quarantine setting is how to design rules to control for the risk of that unknown infective agent – when it is not known what it is. APL has argued consistently from 1999 that the best way to do that was to undertake research (as was done in the case of PRRS virus) as detailed at the beginning of Section 5.

APL argued that the process used was not in accordance with the science-based process required. On May 27 2005, Justice Wilcox delivered his judgement, agreeing with APL and holding the IRA invalid on the ground of unreasonableness. That is, it was an illegal exercise of power because the decision was so unreasonable that no reasonable person would have made it.

In reaching this conclusion Justice Wilcox accepted evidence that there was a 96-99 percent chance of a PMWS outbreak in the next 10 years. This figure was based on modelling done by the CSIRO. Justice Wilcox said (at pp 306, 316) it was not reasonable for a body who sought to minimise disease risk to say that a 96-99 percent chance was ‘low risk’. He found that ‘the Panel’s reasoning was unsupported by any fact, scientific evidence or scientific expertise.’

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<sup>24</sup> Senate Standing Committee on Rural and Regional Affairs and Transport General Inquiry Biosecurity Australia’s Import Risk Analysis for Pigmeat 14 May 2004

<sup>25</sup> A virus, PCV2 is associated with the expression of the syndrome but scientists agree there may be some other, unknown infective agent involved as well. PCV2 is present in Australia, but PMWS is not.

Such an outcome totally validated APL's position and long struggle to achieve a scientific import risk assessment. However, the Government appealed the decision. The Full Court of the Federal Court overturned that decision on 16 September 2005 finding in a 2-1 majority that the decision to permit the import permit was legal because there was no legal invalidity in any part of the process:

*"The majority said that even though the IRA involved "weighing imponderables", making value judgements, and engaging in speculation that did not make it unlawful. They said: "One can legitimately argue that this was not an ideal process as a matter of scientific method. Perhaps, as was suggested in argument, some experiments might have been conducted."*

Nevertheless the majority found that the law permitted this approach – because, in their opinion, all that the law required was that the level of quarantine risk be “acceptably low” – and that was an “imponderable standard.”

While APL failed on a technicality of law, many of the issues we raised remain relevant to the current IRA process.

The ruling of the Federal Court has broader and important repercussions for Australian stakeholders in general. Indeed an industry's right to appeal, or at the very least to have some recourse to ensure that its claims are effectively answered, is severely reduced and for all intent purposes non-existent when compared to the rights of our trading partners.

Australia's trading partners have recourse to challenge the import protocols through the IRA process and via the WTO. However, following the ruling of the High Court, no such challenges are available to domestic industries through law. We are reduced to, and at the mercy of, the IRAAP panel (and to some degree the Eminent Scientists Group.) The effect of the Full Court of the Federal Court's decision is that it would be extraordinary for any domestic producer to be able to challenge an IRA outcome because of the content of quarantine measures (as opposed to the process for making it.)

On the other hand, each of the successful WTO challenges under the SPS agreement has been on the basis of some aspect of the content of quarantine measures – so trading partners can challenge on content, but domestic industries cannot.

### ***5.3 Improving the IRA Process***

APL does not believe that the issues raised concerning the IRA process have been satisfactorily addressed, even with the recent strengthening of the IRA process and the establishment of the Eminent Scientist Group. While it can be argued that BA as

an agency has been formally separated from DAFF, this has still not addressed the fundamental problems.

APL subsequently sees merit in the idea of establishing BA as an independent authority as an effective means for addressing the major problems that have occurred with IRAs. This will help ensure that the resulting IRA quarantine proposals relating to imports are science based and developed in a manner clearly distinct from any broader policy considerations such as trade, the socio-economic impacts and political influences.

Trade and quarantine issues are separate and the administration of these issues should be separate and distinct functions. The Director of Animal and Plant Quarantine should be separated from the role of the Secretary of the Department. There is some concern that foreign trade considerations may affect decisions on quarantine measures to control a risk from imports and realistically these are always ever present in the background. The IRA handbook says that Australia seeks to comply with the WTO requirements that quarantine measures should, “minimise negative trade effects”. Exporters of processed food have frequently expressed concern about the potential for ‘retaliatory’ action by our trading partners for Australian quarantine protocols or prohibition on some imports. APL strongly believes that an essential requirement to improve Australia’s biosecurity and quarantine system is establishing BA as independent of DAFF. APL believes that AQIS is able to perform its functions effectively within DAFF and that there is no substantive reason to remove it from the Department although there is an urgent need to improved transparency, consultation and accountability to industry in its enforcement of quarantine (as explained in detail in Section 6).

Of great concern to APL is the lack of opportunity in the appeals process to legitimately challenge the veracity of the scientific data used by BA in the IRA process. Under the current IRA process there is no body at all to adjudicate on the quality of the work done in the IRA (outside of the SEG), unlike other segments of the law involving regulations determined by public agencies. In other fields involving complex science, such as decisions on the registration of medicines by the Therapeutic Goods Administration or regulations from the Fisheries Management Authority, decisions can be questioned in the Administrative Appeals Tribunal.

APL had stated in numerous submissions to the Government that there is an ongoing need for improved Government funding and resourcing of BA’s activities if BA is to undertake the type of rigorous assessments and consultations required of them. This will greatly assist the organisation to more expeditiously complete the IRAs, whilst at the same time help ensure that BA is able to fund any necessary

additional research which may required for certain aspects of the IRA's investigation.

## 6 Risk Management Measures and Quarantine: Compliance

It is equally important that the execution of risk management measures pre-border and at the border are adequate in practice. There is a natural tendency to focus on the principles of risk management and then to assume that the finalised principles will be competently observed. There have been examples in recent years where countries with supposedly advanced veterinary services have failed in some of these respects, for varying reasons. This system places heavy reliance on the veterinary standards and surveillance of exporting countries, official notifications and public statements and the ability of AQIS to monitor and audit regularly.

Appraisal of risk management measures in practice is as important as the design and should be addressed in the IRA so that sufficient resources are made available by AQIS to ensure that the proposed protocols are effective in minimising the identified risk.

Transparency and effectiveness of the application of quarantine measures at the border, including offshore inspection and certification has also been of concern. APL believes that in the interests of equivalency, standards the same as, or procedures shown to be in practice equivalent to current Australian standards, must be in place in establishments approved to export to Australia. APL has sought verification from both BA (during the IRA process) and AQIS as to how it satisfies itself that overseas abattoirs and processing plants conform to Australian standards, that audits by Australian authorities are of an equivalence and intensity expected of Australia by its competitors and how it intends to address the issues of identification and segregation. APL's efforts to verify the process for AQIS accreditation and the frequency and general outcomes (including corrective action) of audits, both overseas and to some extent in Australia, of exporting and processing establishments has been met with resistance and limited information.

Though similar, there are different trade requirements that have been developed by the Australian Government for Canada, Denmark and the U.S. AQIS' Import Conditions (ICON) Database lists in brief what requirements the country must comply with in order to import cooked and uncooked pork meat into Australia. The Canadian CFIA and the U.S. FSIS<sup>26</sup> listed additional requirements such as labelling and application issues as required by AQIS. There are approval processes for:

- Establishments which include transport and handling of meats
- Approved chemicals on use at the establishments

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<sup>26</sup> <http://www.fsis.usda.gov/OFO/export/australia.htm>

- Cooking and cutting requirements for foreign establishments.

Australian Agricultural Counsellors posted in key overseas locations conduct the audit process for slaughter, cutting/boning and further processing establishments prior to export to Australia. Overseas agricultural counsellors come from both DAFF and from DFAT and are the responsibility of the International Unit of AQIS.<sup>27</sup>The Import Conditions Database prepared by AQIS did not detail for Canada, Denmark or the U.S., the process for ongoing audits for compliance to Australian requirements, re-certification for facilities or for regular reviews of establishment processes and allowable compounds to be used at facilities. (This may be at the discretion of the Australian Government, but this is unconfirmed.)

While AQIS is to be acknowledged for its reinstatement of its annual summary reports to APL on overall compliance across all establishments (although reports received now are of such a broad and general nature that they are of little value to industry), APL remains concerned that it is still not notified in a timely manner when AQIS has identified potential and actual *major* breaches in compliance to the quarantine protocols. Based on past experience, APL has not been alerted to these incidents until long after the fact and not until they have been almost resolved. This raises serious questions about the timeliness of advice provided by AQIS to industry. In fact often it is information from the industry itself which provides APL with the first alert to a problem.

Recent industry developments, in particular the NSW Food Authority's ongoing investigation of a complaint from an individual about imported pork being processed locally and sold as "Product of Australia" bacon, combined with persistent industry rumours of the importation of sow meat, the sale of imported pork as fresh (such as sausages) continue to reinforce these concerns. However, while APL has in the past dismissed such industry rumours (following confirmation and advice from AQIS concerning audit processes in general), APL has now formed the view that it may in fact reflect a much broader and significant problem: it may be indicative of a system flaw and weakness due to an outdated reporting and compliance system which has not kept pace or reflects changes in technology, product development and market changes, despite AQIS's best of intentions and the restrictions it faces under the authority invested in it under the Quarantine Act.

APL is seriously concerned with the weaknesses and flaws in the current audit and compliance system which is used to ensure that the quarantine conditions required for imported pigmeat are being effectively complied with. We believe that it is open to misuse and deception, either intentionally or indirectly. Significant areas of concern relate to the post border use of quarantine material (i.e. imported pigmeat)

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<sup>27</sup> Personal communication, AQIS.

following receipt of this material at the AQIS registered warehouse and within the manufacturing plant itself, in particular:

- i. The possible substitution of imported pork for domestic pork post border within the manufacturing system
  - a. Tariff statistical codes: an Achilles heel potentially contributing to misuse
  - b. Auditing and compliance post border reveals a flawed system: compliance within manufacturing plants requires the reconciling of imported product and intended use; and the opportunity exists for the illegal transport of quarantine material
- ii. Waste treatment and disposal – the opportunity to take short cuts.

This is explored in detail below.

## ***6.1 Possible substitution of imported pork for domestic pork***

### **6.1.1 Tariff Classification: an Achilles heel**

The current tariff statistical codes for imports of meat of swine, frozen falling under tariff subheading 0203.29 of the Australian Customs Tariff is inadequate and obscures the industry's and AQIS ability to identify and track product through the manufacturing system once it has cleared Customs. An examination of pigmeat import volumes entering Australia over the 12 months to December 2007 against the tariff statistical code for which they are recorded raises serious questions concerning the adequacy of the Australian Customs Tariff Classification; and, potentially its indirect role in facilitating the possible substitution of imported pork with domestic pork in the manufacturing system. This alone is serious in the potential quarantine risk to the Australian pork industry because of the need to ensure that *all* imported pork is cooked to precise cooking and time temperature controls as specified in the quarantine protocols for imported pigmeat.

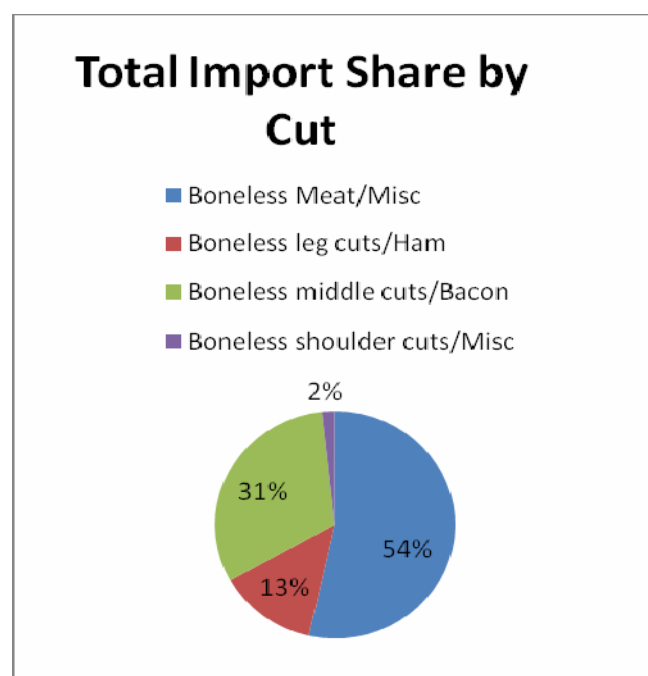
According to the current tariff statistical codes, total pork imports can be classified into three main types of cuts as described in the Table 3 and Chart 4 below.

**Table 3 Import Shares by Cut**

Harmonised Tariff Import Statistical Code		Description	Total Import Share by Cut %
203290045	Boneless Frozen Swine Meat	Meat of swine (excl. boneless leg cuts, middle cuts and shoulder cuts) frozen and boneless	54%
203290040	Boneless Frozen Swine Meat, leg cuts	Meat of swine, frozen, boneless, leg cuts (exc. Salted dried or smoked jam)	13%
203290041	Boneless Frozen Swine Meat, middle cuts	Meat of swine, frozen, boneless, middle cuts	31%
203290042	Boneless Frozen Swine Meat, shoulder cuts	Meat of swine, frozen, boneless, shoulder cuts	2%

Source: ABS 2007

**Chart 4 Total Import Share by Cut**

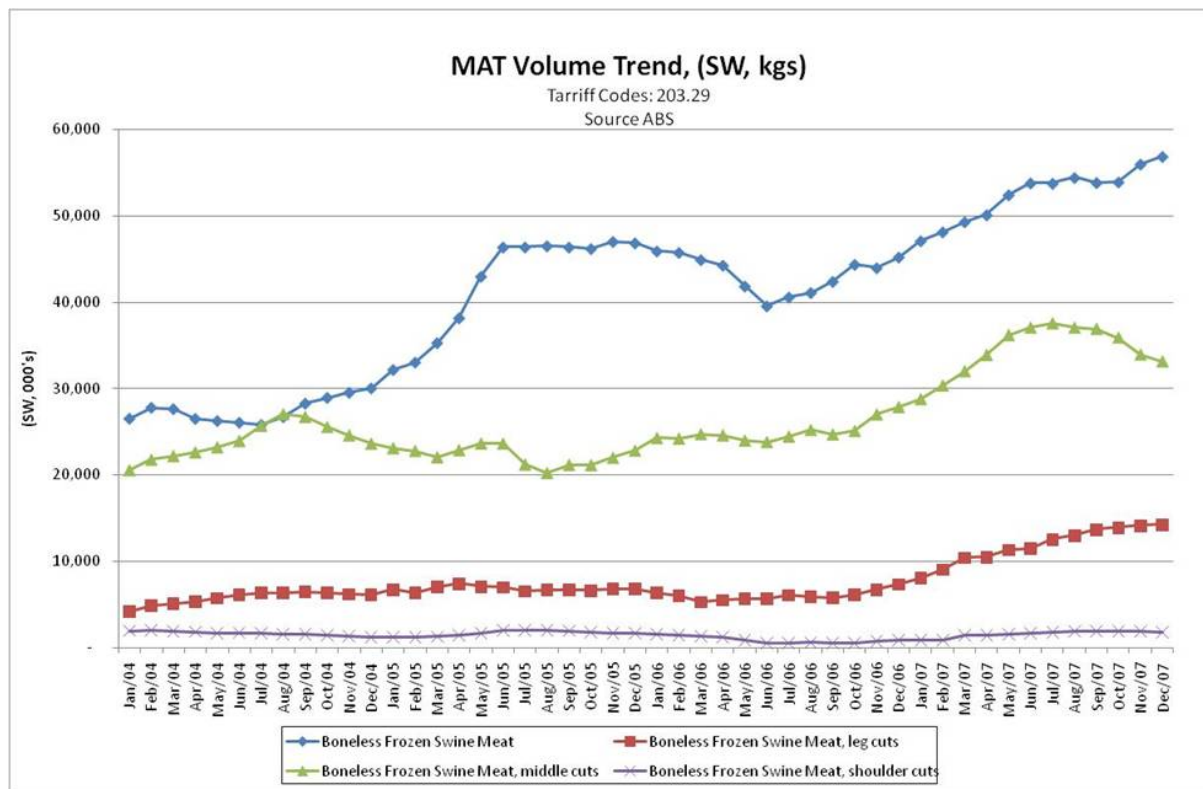


Source: ABS 2007

Clearly boneless, frozen swine meat, leg cuts, middle cuts and shoulder cuts account for over 97 percent of total imports into Australia, of which the ‘catch all’ tariff statistical code frozen boneless meat (excluding leg, shoulder or middle cuts) was the largest of all imported cuts at 63,380 tonnes i.e. some 54 percent in 2007. Chart 5 below clearly shows the phenomenal growth in import pigmeat volumes, nearly tripling in just three years, which are largely being classified in this ‘catchall’ tariff statistical code “boneless frozen swine meat”. It is obvious that there is significant

misreporting occurring; these products should be either reported as middles, legs or shoulders since most are destined for manufacturing into specific smallgoods.

**Chart 5 Pork Import Volumes Jan 04 – Dec 07 period (MAT)**



Source: ABS 2007

Data from Ibis World<sup>28</sup> reports that ham makes up 60 percent of smallgoods in Australia. Yet imports of leg meat in 2007 destined for ham was only 13 percent of total imports (15,346 tonnes). Most of the remaining 47 percent of the Australian ham market can be assumed to be distributed<sup>29</sup> in some proportion between:

- bone-in ham which can only be supplied by Australian pork (due to quarantine conditions which require imported pork to be deboned amongst other conditions); and
- processed ham (i.e. lower value, non whole muscle) and smallgoods<sup>30</sup> (i.e. frankfurts, devon, mortadella etc).

APL contends that the bone-in ham market is relatively small in comparison to the processed ham market. Demand for bone in ham tends to reflect the Christmas seasonal demand. Bone-in ham and leg ham are also priced higher than the

<sup>28</sup> IBIS World Industry Report 25 May 2007. Bacon, Ham and Smallgoods Manufacturing in Australia C2113

<sup>29</sup> Figures for this breakdown are not available.

<sup>30</sup> Smallgoods can be classified into several categories, depending upon their processing methods but it is generally a term referring to manufacturing meat products including sausages, salamis, pates and smoked meat products. Not all smallgoods require cooking; some are produced by a fermentation process.

processed ham market. Importantly, with increasing imported pigmeat capturing more and more of the processed market, Australian producers over the last few years have shifted their production from producing a large (baconer) pig for the processed market to a smaller (porker) pig for the fresh meat market<sup>31</sup>. It is also significant that unlike imported legs and the 'catch all' tariff statistical code frozen boneless meat (excluding leg, shoulder or middle cuts) that imported middle cuts have a very limited end use i.e. the production of bacon. Even accounting for the fact that some parts of the Australian porker and baconer pig would end up in the lower processed ham market, the current volume of frozen boneless meat (excluding leg, shoulder or middle cuts) again raises the question as to whether all the imported pork in this 'catchall' tariff code is actually being used for either processed ham and/or that part of the smallgoods market where the manufacturing of the final product is subject to the required quarantine cooking and temperature controls.

Given the increasing volumes of pigmeat imports, the ability to monitor and track imports post Customs is paramount and requires:

- The tariff statistical codes to accurately reflect the type of cut entering Australia and therefore need to be refined to reflect changes in that have occurred in the global market, consumer preferences and technological advances.
- Australian Customs to verify/provide confidence that the information provided to them regarding the type of import is accurate i.e. that certain tariff subheading are not being abused as a catchall for imports.

It is difficult enough to trace back product without it being thwarted by the ongoing flaws in tariff classification. Australia's animal health and food safety record are at risk of being compromised.

Refining the tariff statistical code for pigmeat imports would provide valuable information and a trigger for AQIS on where it should be focusing its audits. There would be efficiency gains from focusing scarce resources to high risk areas, not to mention the proactive management and minimisation of these risks. It would also enable to industry and AQIS to identify the types of end products which can be made from this cut, opportunities for substitution and feed into the mass balance reconciliation advocated earlier.

To appreciate the importance of this issue, particularly in terms of proactively managing our quarantine risks via compliance, it is important to understand the

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<sup>31</sup> Imports continue to reduce the opportunity for Australian producers to produce the heavier weight carcasses required by the manufacturing sector. Instead producers are focusing on producing pigs for the fresh pork market which requires a lighter carcasse as a result of market specifications from domestic retailers. It is also difficult for producers to switch from production for one market to another in terms of additional housing needed for different size pigs. For producers to provide a heavier pit, one of the following needs to occur: reduced imports so we can access a proportion of the domestic processing market at least at a viable price; changes to market specifications from domestic retailers; or a drop in the AUD so we can export viably.

drivers for the use of imported or domestic pork in the processing sector: essentially it is an economic decision based on price. Currently, there are too many smallgoods manufacturers for too little market share. Margins are therefore tight and competition fierce between businesses for customers and market share. Demand and price for processed pork goods is primarily driven by the two major supermarkets<sup>32</sup>.

There are further pressures arising from unexpected demand from retailers/customers in different markets and/or states, which need to be met immediately and can potentially lead to short cuts being taken by the manufacturer in order to retain their market share/customer. There are opportunities to misuse the current system, particularly when businesses are under severe financial pressure. At such times it should not be unexpected that such businesses will seek to minimise their losses. For some businesses within the smallgoods industry, it is not so much about profit but their very survival, and there are opportunities to misuse the current system.

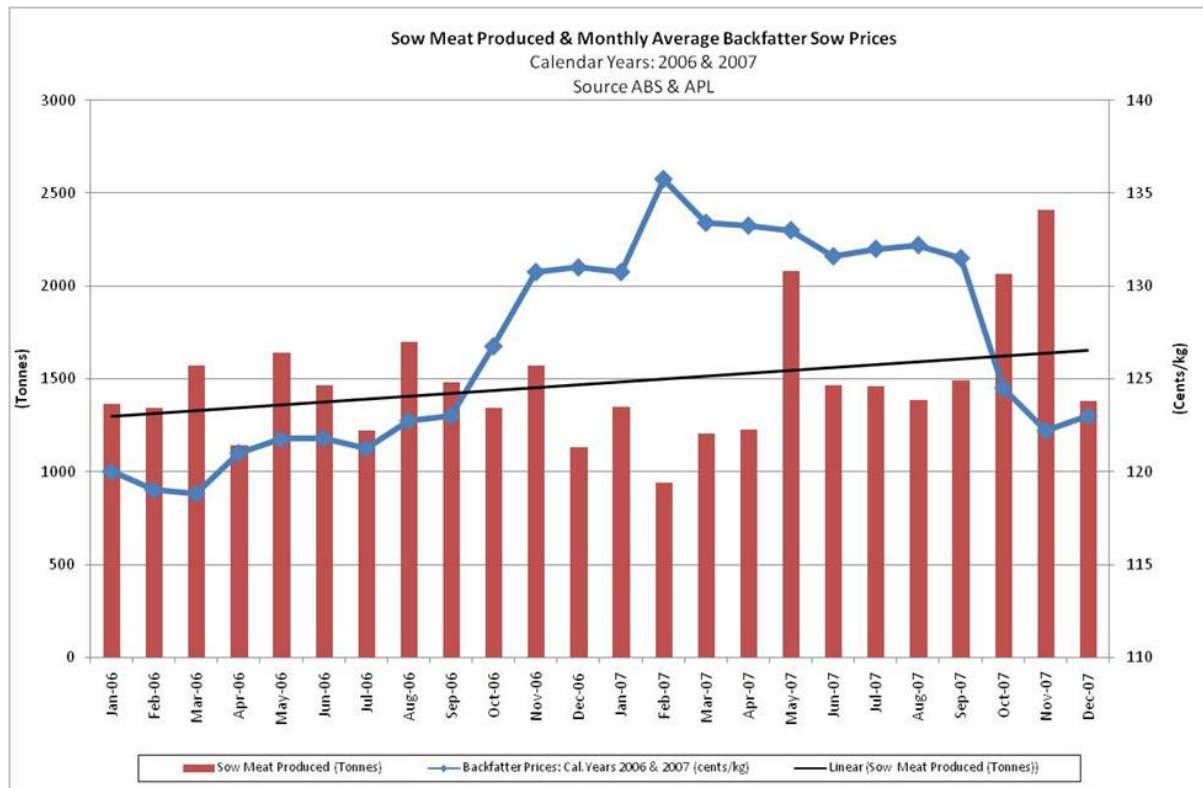
Last year APL received reports from the market that sow pigmeat was being imported. It is not possible to verify through the current tariff statistical code whether sow pigmeat in fact was being imported. But why would sow pigmeat imports be of concern given that they would also be required to meet the same quarantine protocols as other imported pigmeat cuts? The fact is that sow meat has a very particular dark red colour, distinct taste and flavour. Its strong flavour greatly restricts its use: it can only be really used in the production of salami or potentially in fresh meat such as sausages. Salami is a fermented ham i.e. it does not require cooking. (While it can be argued that it undergoes an accelerated fermentation process to elevate temperature, these temperatures are insufficient to meet the required quarantine protocols). Sow meat is therefore a high risk import to the industry, to our industry's health status and to Australia's biosecurity.

The scenario concerning sow meat is not improbable. Industry information puts the import orders for sow meat at around September 2007. An examination of Chart 6 shows rising Australian sow meat prices from October 2006 to September 2007 with a decline in sow meat supply over a corresponding period (set against a rising trend line for demand in sow meat.)

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<sup>32</sup> For example, Australian supermarkets have traditionally utilised the sale of bacon as a means to generate customer traffic through their stores, since bacon has always been one of the top three to four items purchased by consumers. This practice is eroding margins down the supply chain to a level that is unsustainable in terms of pricing; it has the effect of has had the effect of commoditising bacon sales. Competing suppliers of bacon face mounting pressure to continue to reduce the price points they have offered to the retailers in order to maintain market share.

**Chart 6 Sow Meat Produced vs. Monthly Average Backfatter Sow Prices (Jan 06- Dec 07)**



Source: ABS & APL

Again APL asks how can AQIS be confident that all of the “miscellaneous” boneless frozen swine meat (including shoulder cuts) – the largest single tariff statistical code - being imported into Australia, i.e. some 54 percent of imports, is destined for ham and smallgoods production? How is AQIS able to track and verify compliance with this through its currently designed audit system (and within the remit of its responsibilities as defined by the Quarantine Act)? It is *not improbable* that this product could end up as a salami (which requires a dry fermentation **uncooked** process) or as fresh meat in the form of sausages.

Clearly the tariff statistical codes do provide sufficient information to allow imported product to be tracked post border through processing and thereby minimise potential misuse and abuse of the system and reduce high risk areas. There is a disconnect between the domestic market and the imported products and its end use: the two are intertwined and are not separate processes. The codes fail to reflect advances in technology and how meat is traded and cut. With increasing diversity of differing types of the cuts being traded globally and entering the Australian market the potential for substitution or misuse of the system increases. There is mutual benefit to AQIS and industry of improving this classification system.

### **6.1.2 Compliance within manufacturing plants -reconciling imported product and intended use**

Within the manufacturing plant, there are a number of steps involved in the production of the finished processed product, namely:

1. Receival
2. Storage
3. Thawing
4. Injection
5. Massaging
6. Cooking or fermenting
7. Chilling
8. Slicing
9. Storage of finished product

Once the product is in the processing facility and moves to the thawing room, there is the potential for substitution of domestic pork for imported pork. During thawing, domestic and imported product are processed (either independently or combined) through the same production line. This product then proceeds through the manufacturing process to ultimately produce a volume of smallgoods ranging from bacon, hams, salami, sausages etc. At this point, AQIS is unable to effectively and reliably trace this imported product (other than to verify that a given tonnage of pigmeat - as specified on the paperwork received from the registered warehouse where the imported product was stored - was cooked). Instead AQIS inspectors must rely on paper work and QA to verify compliance. It is not unreasonable to suggest that this cooked pigmeat *is assumed* to be imported.

Further complicating this issue is a widely used imported product known in the industry as 'C105'. C105 is an imported leg meat available from either the USA or Canada. C105 meets AQIS quarantine requirements i.e. boned out, lymph out etc leaving a product of muscle, fat, sinew and membrane. C105 tends to be used for the production of leg ham since it can be provided in three different types of cut depending on the customer's specification. The C105 may be trimmed to meet these specifications. The trim removed from this imported product is also a useful and a cheap by-product which can be used in the production of other lower value smallgoods including continental sausages.

Imported trim is also available to importers but like sow meat it is not picked up under the current tariff statistical codes. Trim significantly reduces the total cost of raw material and therefore the cost of the finished product<sup>33</sup>. However there is also the potential opportunity to use 'imported trim' as a fresh meat component of

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<sup>33</sup> A common practice in the manufacturing process in producing lower grade bacon is to cook the eye from imported pigmeat combined with a tail made from 'trim' (referred to as bog). The trim is a low cost way of increasing the size of the bacon's tail.

sausages. Smallgoods manufacturers may substitute because of cost and/or availability as occasionally there is a shortage of trim supply. Such opportunities give strength to persistent industry rumours that sausages (uncooked meat) have at times contained imported trim mixed with domestic meat/trim which is not cooked. The industry has raised this issue with AQIS many times seeking assurance and verification that all parts of the imported pigmeat have met the required the quarantine protocols.

Despite the assurances given (which are essentially based on AQIS's current and somewhat flawed auditing system), it is APL's strong belief that it is only possible to verify this by undertaking a mass balance reconciliation of domestic and imported product to guarantee compliance within the quarantine protocols. Currently there appears no mechanism to enable AQIS to conduct at the manufacturing plant a mass reconciliation of imported pork with the processed pork produced from using both imported and domestic product.<sup>34</sup>

### **6.1.3 The potential for illegal transport of quarantine material**

When placing an import order, importers are required under the quarantine conditions to nominate the closest port of entry for delivery to the nearest production destination. Processors would provide this information based on data in relation to customer orders e.g. processed product type, volume, market destination etc. However even the best laid plans can go wrong; short term high volume demands are disengaged from the supply and demand material required for finished products, which in turn, may cause a shortage of raw materials out of one of location. For example:

- Processors can be requested by a customer to fill an order at short notice. The required imported product would take a minimum of six to eight weeks from order to delivery; or
- There is an order cancellation, freeing up product i.e. quarantine material at a registered warehouse or processing plant in a location which is *not the nearest production destination* and in fact may be interstate.

While AQIS would argue that the current audit arrangements should be sufficient to deter processors from either accidentally or deliberately doing wrong, as well as an inherent and reasonable expectation of the general good will of processors, again it is

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<sup>34</sup> Following a meeting with APL in February 2008, AQIS agreed to review the AQIS audit procedures to determine whether such a mecha<sup>35</sup> The IRA for Pig Meat in Annex C states that: "The Company will describe how waste disposal is to be controlled and managed for the three types of waste products. (Liquid waste, meat scraps or spoiled meat, packaging. Specific details will be provided in relation to: management of wastewater, wash down and water associated with thawing, washing or processing of pig meat product; collection and storage of waste product and associated packaging; and the collection and disposal of waste. In relation to the collection and disposal of waste the Company will identify either the contractor or means by which waste is to be disposed of."

important to consider the current market environment and the financial pressures facing processors as explained previously. Although APL believes that most processors are endeavouring to do the right thing, the practices of perhaps a few are questionable, which is in itself is a quarantine risk. As shown in the U.K. FMD outbreak in 2001 it only takes the illegal practices of one to impact and cause devastation to the many.

This risk becomes apparent if we develop the examples provided above. On delivery of a shipment of imported pork, the quarantine material once cleared by Customs and AQIS, must then be stored in an AQIS registered warehouse until it can be received by the smallgoods manufacturer. The smallgoods manufacturer may then decide to move this product to another plant located in another state, for example, in order to meet an unexpected order (or perhaps because of capacity issues within the local plant – this particular circumstance is explored later). In order to meet the quarantine protocols, the quarantine material must be moved by ship which may take up to three weeks. Despite this quarantine requirement, the opportunity exists for illegal transport of quarantine material.

Paperwork can be manipulated to show that an imported product has been issued out of the registered warehouse, processed at the local manufacturing plant X and then transported as a finished product to the interstate manufacturing plant Y. Plant Y would record receiving this material as a smallgood e.g. bacon finished at the original plant. In fact what may have happened is that the imported material, despite quarantine protocols, is transported directly interstate to the manufacturing plant Y as a thawed product. Since the receiving plant Y records the material as finished processed goods, there is no audit trail or compliance requirement for AQIS to follow within plant Y. Plant Y is then free to use this quarantine material to produce smallgoods, including fermented smallgoods which do not require cooking such as salami, or possibly as fresh meat in the manufacture of sausages. At a later time when they are able, Plant Y may also replace Plant X's 'thawed product' again by the same process.

In fact it is possible for two completely independent manufacturing companies to bypass the system using the same process. In times of high demand and when raw material is in short supply in a particular location (but can be sourced from another location) and/or due to capacity constraints in the manufacturing site, this risk becomes greater. There is an opportunity for registered manufacturers to barter frozen imported material during peak times (particularly around Christmas).

In the end, the question remains as to the effectiveness and reliability of AQIS's current audit and compliance system in securing compliance with our quarantine requirements and protecting the Australian pork industry. APL is seriously

concerned with the system's apparent failings which leave it open to misuse and deception, either intentionally or indirectly. It is a flawed system, essentially outdated, which fails to reflect changes in technology, product development and market changes, despite AQIS's best of intentions and the restrictions it faces under the authority invested in it under the Quarantine Act.

## **6.2 Waste Treatment and Disposal**

Another potential high risk area is the treatment of waste, both packaging and liquid, within the processing sector. While quarantine protocols specify requirements in relation to waste treatment (liquid and packaging) and these are audited by AQIS, the financial pressures facing some processors makes this area potentially vulnerable to short cuts to reduce the costs of disposal. AQIS import conditions require:

*"All solid waste associated with imported pig meat, including trimmings, wrapping, cartons, waste water and sludge is now considered quarantinable waste and must be treated by incineration, autoclaving, deep burial, heat treatment on-site to a minimum core temperature of 100°C for 30 minutes, or other method approved in writing by AQIS<sup>35</sup>."*

APL is confident that such conditions are being met for the waste disposal of packaging. However, treatment of liquid and sludge waste are susceptible to shortcuts and there have been technological advancements in relation to the thawing process which are being progressively adopted by the manufacturing sector.

As described previously, the production cycle within a plant requires the thawing of imported pigmeat. Processing plants use either air thawing or water thawing. The major operators appear to have moved to air thawing, with the injection of high pressure steam to shorten the thawing process. This process is used for both imported and domestic frozen meats. APL questions whether existing safeguards remain appropriate for the removal and treatment of waste material (juice/blood), cleaning of the cabinets and the prevention of cross contamination of imported and domestic meat given this move by the industry to use air thawing combined with high pressure steam injection.

Water thawing is the other thawing method used by the majority of smaller processors (although the larger processors also use water thawing when faced with capacity constraints). Water thawing requires a constant flow of chilled water across the meat surface. Large quantities of water are used and significantly higher levels of juice are extracted from the meat. These large volumes of liquid are then required to be treated through an approved wastewater treatment plant. What does AQIS require and how does it ensure compliance on the treatment of this wastewater?

The wastewater treatment process is a major concern to APL. What science has been undertaken to confirm that anaerobic waste water treatment eliminates the risk of exotic disease outbreaks? Smaller operators may also use systems as simple as a grease trap, with the sludge being collected and the wastewater transferred to the sewer. How does AQIS monitor these waste streams?

## **7 Facilitating Biosecurity and Risk Management on Farm: Vaccines**

Vaccines commonly available abroad for use in the pig industry to control endemic disease and prevent exotic disease have been slow to be produced in Australia or very difficult to import into Australia. While vaccination use is necessary as a control tool in the case of an exotic disease outbreak, (such as the Equine Influenza vaccine that was strategically used during the 2007 EI outbreak), vaccines also play an important role in the better management of certain endemic diseases in growing pigs now prevented by antibiotics (for example ileitis). AQIS risk assessments for the importation of vaccines are complex and timeframes for completion do vary. APL also recommends that Emergency Permits for vaccines be developed prior to any disease outbreak as a significant step in an emergency disease response plan. As a guide, emergency permits should be developed for those diseases identified in the IRA and which are therefore a high risk to the industry.

### **7.1 Vaccine Import Permits: the process**

The process for importation of vaccines may take up to three to four years. Before any vaccine can be used routinely in Australia, the manufacturer must seek to have the product registered with the Australian Pesticides and Veterinary Medicines Authority (APVMA), have the appropriate import approvals from the AQIS and, if the vaccine is based on genetically modified organism, be authorised under the *Gene Technology Act 2000*.

An AQIS risk assessment is required for consideration of an application to import vaccines. This is to ensure that the quarantine risk associated with importation and use of the vaccine in Australia has been mitigated to a level that is considered acceptably low. As part of this risk assessment, AQIS would take into consideration the potential for the introduction of diseases/pathogens (endemic or exotic) into Australia. The risk assessment takes the form of a review of manufacturer's documentation to ensure compliance with BA's vaccine policies.

The APVMA would also require and assess efficacy data, safety in the animal, use guidelines, environmental and human safety risks, etc before approving registration of the product. In many cases the APVMA is unlikely to accept vaccine efficacy data that has not been generated in Australia. This is problematic for small industries such as Australian pork where it is financially unattractive for commercial suppliers to undertake this work due to the small size of the market. It is also financially impossible for APL to fund the development of Australian generated efficacy data.

APL has sought clarification from APVMA regarding the acceptance of 'overseas-generated' efficacy data but has not received information at this stage. The APVMA's refusal to consider overseas efficacy data is impede biosecurity on farm, the pro-active management of endemic diseases and the improvement and management of animal health. It also impedes the industry's & Government's ability to move quickly to contain a disease and successfully eradicate it. It is hoped that the review of the EI disease outbreak will facilitate the necessary changes to address these issues.

## 8 Harmonisation and Consistency in Approach: Cross Jurisdictional Issues

### 8.1 Consistency in the Imported Food Inspection Process

Food imported from other countries must be subject to the food safety standards applied to Australian produced food, which is enshrined in the Food Standards Code under the directive of Food Standards Australia New Zealand.

However APL as well as the Queensland Farmer's Federation and the Virginia Horticulture Centre in their submissions to the *Productivity Commission Review into the Regulatory Burdens on the Primary Sector (2007)*<sup>36</sup>, have sought consistent testing of imported and domestic produce and for standards harmonisation between import and export products. While the Commission admits that AQIS officers inspect imported food to the same standards applied to domestic food under the Imported Food Control Act 1992, APL believes that food imports do not undergo the same treatment for domestic food.

For example, certain chemicals used in overseas production which are not allowed in Australia are not necessarily tested at the border. Recently AQIS removed Carbadox testing for food imports, based on an internal review in 2006 of the testing regime for food imports. There was no consultation or notification to industry and demonstrates the problem of transparency when managing food safety protocols and its impact on Australian industry. As Carbadox use is legal in the U.S., the removal of import testing on Carbadox potentially allows U.S. imports of pigmeat to enter the Australian food chain. There is a two-tier system in relation to food safety and also impacts on industry competitiveness.

APL wishes to see greater transparency in the AQIS Meat Notice process. These notices detail the changes to meat legislation in relation to food and meat imports. There also needs to be greater industry and timely consultation into the rationale and decisions made for changing food import testing requirements in the *active surveillance*, *random surveillance* and *risk surveillance* categories. As part of post-border import audits, AQIS conducts on a regular basis, testing of meat and meat products in accordance with their current testing categories. *The Imported Food Control Order 2001* specifies what foods are considered active, risk and random surveillance foods.

In a recent review of the ICON Database and Imported Food Notice, APL noted a critical inconsistency and has sought advice and clarification from AQIS in relation to this matter. On the AQIS ICON database it appears that all imported "Pig (pork) meat - uncooked" from various countries must be heat treated. However there

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<sup>36</sup> [http://www.pc.gov.au/\\_\\_data/assets/pdf\\_file/0010/68338/subdr066.pdf](http://www.pc.gov.au/__data/assets/pdf_file/0010/68338/subdr066.pdf)

appears to be a discrepancy and inconsistency on the Imported Food Notice 09/07. This Notice states that when an additive is added to "meat" it may become a "processed meat". As already explained some smallgoods are not cooked but fermented. If the food category clarification and definition as noted by the Imported Food Notice in relation to "Processed meat (uncooked)" is taken as stated, there may be possibility for an additive to be added to this meat and as such it may not require heat treatment as per the import protocols.<sup>37</sup>

## **8.2 NRS and AQIS' PESTICID screen**

The AQIS Food Import Inspection Program tests for a limited number of pesticides and antibiotics in its PESTICID screen. It tests for 49 chemicals in the fat component of pig meat imports. It is less stringent than the National Residue Survey (NRS) Pig Monitoring Scheme which is applied only to domestically produced pig meat for export certification. Comparatively, the NRS Pig Monitoring Scheme, which screens domestic produce for export requirements, has listed a total of 96 possible contaminants in pig meat. There are more MRLs set in the NRS by DAFF<sup>38</sup>, than in the AQIS Imported Food Inspection Program, set by FSANZ. This is a regulatory loophole which can impact on consumer health. This deficiency also enhances the competitive advantage of imports compared to local produce.

Australia does not permit over thirty substances for use in Australian pig meat production; however these substances are permitted in the U.S. for any food producing animal. Some of these substances, for example Carbadox as mentioned previously, have been banned in Australia and also in the EU and Canada as a carcinogen, are no longer tested for on import to Australia. What is not registered for use in Australian domestic meat or pig production should also apply to food and meat imports. APL believes that there is rationale for a strengthening of import protocols to ensure that Australian food safety standards apply equally to Australian and imported food produce.

There is a cross-over between AQIS' Food Inspection Program, the National Residue Survey and the Food Standards Code in setting three different standards for imports, exports and food for human consumption. APL recommends a review of the AQIS' Imported Food Inspection Program and the AQIS' Export Meat Program, to ascertain whether Australian exporters are unduly disadvantaged in any way and to advance an agenda for regulation harmonisation across these two programs.

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<sup>37</sup> This is different from the issue of fermented products which is provided for in the Food Category Meat – uncooked and processed/manufactured meat (ready for consumption which specifically mentions "including matured/dried cured and fermented products e.g. Parma hams, Iberian hams". The treatment of these hams is clearly specified in the import protocols.

<sup>38</sup> The National Residue Survey (NRS) is an operational unit of the Product Safety and Integrity Branch of the Product Integrity, Animal and Plant Health Division within the Australian Government Department of Agriculture, Fisheries and Forestry (DAFF). Link: <http://www.daff.gov.au/agriculture-food/nrs/about>

### **8.3 Traceability**

Animal feed safety has now become one of the priority areas for international organizations such as the Food and Agriculture Organization of the United Nations (FAO) as well as many overseas countries, particularly in Western Europe. Animal feeds are routinely subject to contamination from diverse sources including pesticides, antimicrobials, bacteria, industrial pollutants, mycotoxins, weed seeds, animal toxins as well as plant toxins. Some of these contaminants in feed ingredients are unlikely to be metabolised and are deposited in animal tissue, which may then become a potential risk to human health.

However, of much greater importance, particularly in recent years, is the risk to trade and market access rather than any genuine health concerns of chemical residues in pig tissues. To mitigate trade risks, the Australian pork industry has developed the Australian Pork Industry Quality (APIQ) Program under the auspices of APL. The program is HACCP based and a section is devoted to chemical residues and feed mixing.

Additionally, the Stockfeed Manufacturers Council of Australia has an accredited FeedSafe Quality Assurance program. This program provides a minimum set of standards with which members of the SFMCA adhere.

State authorities are responsible for control and use of pesticides and chemicals used in crop production and there is a comprehensive system of controls regarding the use of restricted agricultural products. However, there is little control over imported feed ingredients and as a consequence there are ongoing minor residue detections through the National Residue Survey.

Industry and government members are regularly involved in investigations into the causes of these residues and the pork industry is required to fund residue monitoring in addition to the agreed annual program. This puts significant pressure on the industry and causes planning and funding difficulties.

The Australian pork industry is concerned at the diversity of State legislation relating to various aspects of stockfeeds and the lack of a national stockfeed standard. This means that there is no effective control over contaminants in imported stockfeed and feed ingredients, resulting in a significant food safety risk for consumers of meat products. It also presents a significant trade risk for the Australian pork industry.

The current gaps and lack of consistency between the States presents significant difficulties in tracing and resolving residue and contamination issues identified through the National Residue Survey and other programs. APL recommends that work on development and implementation of an Australian Stockfeed Standard,

incorporated in Commonwealth and State legislation, be accelerated to ungently address the current food safety and trade risks associated with imported stockfeed and feed ingredients.

## 9 Conclusion

Quarantine is a high priority for all Australian farmers for the protection of agricultural production from exotic pests and diseases, but is of particular concern for the Australian pig industry, which has the uncommon status in the Australian agricultural sector of being one of the few food producing industries to operate in a global market in the true sense. Effective quarantine must be delivered through a combination of border, pre-border and post-border activities. It must be based on strong scientific principles combined with effective execution of risk management measures that will minimise the possibility of an incursion of an exotic human, plant or animal pest or disease.

Quarantine processes should operate within a regulatory framework and within a structure where there is effective governance processes in place to ensure quarantine and IRA activities and outcomes are managed independently and with minimal political interference.

Some of the key issues raised and recommendations made by APL in this submission include:

- **The setting of the Australia's appropriate level of protection:** Under the current approach adopted by BA, Australia's ALOP is defined as very low risk and is set by a reference to a semi-qualitative, and in some respects arbitrary, risk analysis – rather than by an identifiable objective standard. However, a qualitative risk assessment cannot effectively take account of variation or uncertainty in the probability it assigns to an event and therefore does not provide for a conservative approach to be adopted in the management of risk. This is especially so in a situation of scientific uncertainty as to aetiology and epidemiology of diseases where the science is relatively unknown. APL does not believe that the risk management measures proposed by BA in the Pigmear IRA Report were adequate and thereby failed to reduce the risk to meet an ALOP.
- **The import risk assessment framework, methodology and process:** Application of the ALOP begins with the IRA process – it affects the risk ranges and limitations in the methodology where the science is unknown. APL contends that the Pigmear IRA did not competently and comprehensively assess risk and risk management issues. The methodology applied in assessing risk management procedures and unavailability of necessary scientific knowledge underpin APL's ongoing concerns with the Pigmear IRA, including the preference for quantitative risk assessment over a qualitative risk assessment. Despite the review and strengthening of the IRA process post 2004, these issues remain and the

principles raised in relation to ALOP, methodology and transparency are relevant to the IRA process in general. In particular, APL advocates that the precautionary approach should always be applied to managing risk in relation to any disease about which there is a great deal of unknown science. Risk estimates, based on a qualitative assessment, should err on the side of caution.

- **Strengthening the independence and resourcing of BA:** Quarantine processes should operate within a regulatory framework and within a structure where there is effective governance processes in place to ensure quarantine and IRA activities and outcomes are managed independently and with minimal political interference. To enable greater procedural fairness for IRA stakeholders, it is essential that, amongst other things; a truly independent IRA Appeals Panel (IRAAP) is established, where required, and legitimate channels of appeal be available relating to the science.

This issue is of critical importance to all Australian stakeholders following the ruling of the Full Court of the Federal Court in 2005 when APL mounted a legal challenge to have the IRA for Pigmeat set aside. An industry's right to appeal, or at the very least to have some recourse to ensure that its claims are effectively answered, is now severely reduced and for all intent purposes non-existent when compared to the rights of our trading partners. Australia's trading partners have recourse to challenge the import protocols through the IRA process and also through the WTO. The effect of the Federal Court's decision is that it would be extraordinary for any domestic producer to be able to challenge an IRA outcome because of the content of quarantine measures (as opposed to the process for making it). On the other hand, each of the successful WTO challenges under the SPS agreement has been on the basis of some aspect of the content of quarantine measures - so trading partners can challenge on content, but domestic industries cannot.

APL sees merit in the idea of establishing BA as an independent authority as an effective means for addressing the major problems that have occurred with IRAs. This will help ensure that the resulting IRA quarantine proposals relating to imports are science based and are developed in a manner clearly distinct from any broader policy considerations such as trade, the socio-economic impacts and political influences. While it can be argued that BA as an agency has been formally separated from DAFF, this has still not addressed the fundamental problems.

- **The jurisdictional authority of AQIS and its ability to enforce and provide confidence in compliance with import protocols:** It is equally important that the execution of risk management measures pre-border and at the border, are

adequate in practice. There is a natural tendency to focus on the principles of risk management and then to assume that the finalised principles will be competently observed. Appraisal of risk management measures in practice is as important as the design and should be addressed in the IRA so that sufficient resources are made available by AQIS to ensure that the proposed protocols are effective in minimising the identified risk.

APL is seriously concerned with the weaknesses and flaws in the current audit and compliance system undertaken by AQIS. It seems to be an outdated system which has not kept pace or reflects changes in technology, product development and market changes, despite AQIS's best of intentions and the restrictions it faces under the authority invested in it under the Quarantine Act. We believe that it is open to misuse and deception, either intentionally or indirectly which puts the industry at risk of an exotic disease incursion. APL shows that in the absence of mass balance reconciliation of imports and their intended use, as well as a robust audit process, there is the potential for substitution of imported pork with domestic post border within the manufacturing process. The generality of the Tariff Statistical Codes is an issue to the pork industry and is potentially contributing to misuse of product in the processing of pigmeat products. Treatment of waste products, specifically liquid from the thawing process and 'trim' from imported meat, is an area that requires closer scrutiny. The treatment and disposal of waste products is potentially vulnerable to short cuts to reduce the costs of disposal.

In addition to this, APL remains concerned that it is still not notified in a timely manner when AQIS has identified potential and actual *major* breaches in compliance to the quarantine protocols. Based on past experience, APL is not been not alerted to these incidents until long after the fact and not until they have been almost resolved. This raises serious questions about the timeliness of advice provided by AQIS to industry. APL recommends that AQIS notification processes to industry are improved.

- **The Food Import Inspection Process:** APL believes that food imports do not undergo the same treatment as domestic food in that certain chemicals used in overseas production, which are not allowed to be used in Australia, are not necessarily tested at the border. There is a cross-over between AQIS' Food Inspection Program, the National Residue Survey and the Food Standards Code in setting three different standards for imports, exports and food for human consumption. APL recommends a review of the AQIS' Imported Food Inspection Program, and AQIS' Export Meat Program, to ascertain whether Australian exporters are unduly disadvantaged in any way and to advance an agenda for regulation harmonisation across these two programs.

- **Australian Stockfeed Standard:** APL recommends that work on development and implementation of an Australian Stockfeed Standard, incorporated in Commonwealth and State legislation, be accelerated to urgently address the current food safety and trade risks associated with imported stockfeed and feed ingredients.
- **Fast-tracking of Vaccination Imports and Emergency Import Permits:** The process for importation of vaccines for use in prevention of exotic and endemic animal diseases is complicated and stifled by the fact that the APVMA will not accept vaccine efficacy data that has not been generated in Australia. APL recommends that the acceptance of overseas generated efficacy data for vaccines be considered for importation of vaccine for use in animal health. APL also recommends that Emergency Permits for vaccines be developed prior to any disease outbreak as a significant step in an emergency disease response plan.

APL contends that it is essential that these matters be satisfactorily addressed in order for the pork industry to retain confidence in the ability of Australia's quarantine system to deliver protection for Australia's animal, plant, human health and the environment.