



**Submission to Senate Rural, Regional Affairs &
Transport Committee**

**Inquiry into Generic Import Risk Analysis for Pig
Meat**

Australian Pork Limited

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Executive Summary

1. Australian Pork Limited (APL) is a significant stakeholder in the Import Risk Assessment for Pig Meat, representing the interests of Australian pork producers. APL members control approximately 77% of Australian pig meat production.
2. The pork industry generates substantial income and employment in rural and regional Australia producing over \$1.1 billion in household income and employing more than 33,000 people across Australia through the pork value chain. In recent years Australia's pork sector has evidenced one of the fastest rates of export growth for any agricultural industry with export revenue currently valued at \$228 million.
3. APL estimates that the ongoing combined direct and flow-on economic impacts of an exotic disease outbreak such as PMWS would result in the loss of almost 2,200 jobs, a \$188.9 million fall in gross domestic product and a \$76.3 million reduction in household income. Furthermore, it is estimated that within the pig production and processing sectors 250 full time jobs would be lost and industry output would be reduced by \$135 million.
4. APL has a number of significant concerns with respect to the methodology and resulting risk management measures proposed in the draft IRA for Pig Meat. The key areas of concern with respect to the draft IRA are:
 - Our concerns regarding the proposed risk management measures for addressing the diseases PMWS & PRRS. The risk management measures proposed for these diseases are inadequate and clearly fail to 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 substantial risk of introduction of PMWS to Australia in the context of the limited knowledge available about this disease and its current rapid and uncontrolled spread in Europe, North America, Asia and New Zealand.
 - The devastating impact of these diseases and no cure for PMWS. The lack 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.
 - Biosecurity Australia's (BA) advice during the public consultation process following the release of the draft IRA that the risk management measures proposed for the processing of pig meat (cooking or curing) from PMWS affected countries could be undertaken both onshore and offshore, which is contrary to the draft IRA which refers to offshore processing only. There is no justification in the draft IRA for onshore processing.
 - Loss of Australia's unique health status - our one clear competitive advantage over most of the other pork producing countries - and the subsequent loss of associated marketing advantages. APL estimates that a PMWS epidemic in Australia would add 15% to the cost of production resulting in a \$55.3 million loss in productivity.
 - The draft IRA report makes clear that BA is prepared to allow potentially virus affected meat to circulate within Australia having accepted that cooking will not appreciably inactivate the PCV2 virus.
 - Whilst WTO rules rightly insist on scientific evidence as the basis of risk management, they do not require Australia to rely on hope, assertion or speculation to manage the risks of a new disease with uncertain aetiology. Until the additional causative factors

are identified for PMWS, and control measures developed, BA would be justified in accordance with the Precautionary principle of the SPS Agreement (Article 5.7), in not allowing the importation of pork from PMWS affected countries while it conducted additional research regarding the aetiology of PMWS.

- BA proposes modifying the risk management measures for PRRS to also provide for offshore cooking but fails to provide sufficient comparative risk analysis or an explanation as to why on-shore processing is considered as safe as offshore. The draft IRA provides no basis to conclude that risks will be acceptably managed through on-shore cooking.
- The lack of transparency in the analysis procedures has led to an inability by APL and the Canadian Government to reach the same conclusions as BA. Biosecurity Australia has yet to clarify this possible deviation from process which might have involved the differential release of information about the methodology used.
- Specific methodological concerns include:
 - The quantitative approach applied to consequence assessment and risk estimation.
 - Unnecessary inaccuracies introduced into the annual likelihood of entry and exposure estimates resulting from converting R-tot to a semi-quantitative category.
 - 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 50th percentile instead of the 95th percentile. The effect of choosing the 50th 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 open to interpretation and therefore another assessor may not reach the same outcomes as those published by BA.
 - The consequences stage lacks mathematical rigour. Unlike the release and exposure risk assessments, APL contends that the methodology of the consequence assessment and risk estimation is unsound and unscientific.

5. The appropriate level of risk APL has sought throughout the IRA process is "very low" (or less), not "low". The industry does not advocate extremes in risk management such as a no risk policy or an open door policy but rather an 'Appropriate Level of Protection' – which is conservative for Australia.

6. The disease outbreak expectation results indicate that under the pig meat draft IRA Australia's existing quarantine measures will not meet Australia's Appropriate Level of Protection.

7. The above issues must be addressed if the industry is to have confidence that the estimates and calculations and resulting risk management measures used by BA will provide an appropriate level of protection to the Australian pork industry.

1 Introduction

The issue of food safety and animal health is equally 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 and quarantine systems are key strategic competitive advantages in our international markets and are vital to the competitiveness and growth of the industry. It is this health status that makes Australian pigs and pig products desirable. While the North America 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.

On the basis of the significant and ongoing economic impact that an exotic disease such as PMWS or PRRS can have on production, Australian Pork Limited (APL) advocates that the most responsible quarantine arrangements should involve a very low risk, conservative approach. We are very troubled by the fact that the draft IRA does not achieve this outcome.

APL has a number of concerns with respect to the methodology and resulting risk management measures proposed in the draft IRA for Pig Meat. APL does not believe that the risk management measures proposed by Biosecurity Australia in the draft IRA Report are adequate and thereby fail to reduce the risk to meet Australia's appropriate level of protection.

As a global player that both exports and imports, the Australian pig industry does not advocate extremes in risk management such as a no risk policy or an open door policy but rather an 'Appropriate Level of Protection' (ALOP) – which is conservative for Australia. The appropriate level of risk APL has sought throughout the IRA process is "very low".

Australia and the Australian pork industry is justified in expecting greater caution in applying adequate risk management to pig meat imports

2 The Australian Pork Industry

APL is the peak national body representing the interests of Australia's pork producers. It is a unique agricultural organization underpinned by legislation that enables the organization to combine the functions of marketing, research and strategic policy direction and implementation, supported by industry funds. There are currently 2,500 pork producers in Australia producing some 5 million pigs annually. APL's members own approximately 77% of the Australian pig production.

The Australian pork industry provides a significant positive impact to local, regional, state and national economies. The total value produced by the Australian pork industry is approximately \$2.6 billion. The majority of farms are small to medium sized, family owned and run operations. Despite the family orientated structure of the industry, pork represents 2.5% of total Australian farm production.

The pork industry generates substantial income and employment in rural and regional Australia. The industry generates over \$1.1 billion in household income. In 2002, the pork industry directly generated approximately 6,000 full time jobs with a further 33,863 jobs generated indirectly in other sectors of the national economy¹. The specific economic impacts at a national, state and regional level are documented below in Table 1.

Table 1 Socio-Economic Impact of the Pork Value Chain

	Output (\$m)	Value Added (\$m)	Household Income (\$m)	Employment
Australia	6,199.90	2,576.00	1,109.78	33,863
States				
New South Wales	1,498.14	625.22	266.05	7,916
Victoria	1,359.76	550.05	242.38	7,732
Queensland	1,188.37	434.28	201.37	6,312
South Australia	539.65	219.53	85.70	3,121
Western Australia	469.24	183.47	78.16	2,380
Tasmania	87.39	35.07	16.09	488
Regions				
Central NSW	372.05	129.52	49.93	2,011
Southeast Qld	601.02	192.56	80.68	3,257
Southern NSW – Northern Victoria	615.20	212.25	88.80	3,348

Source: ‘Socio-Economic Impacts of the Australian Pork Industry’, Western Research Institute; 17 December 2002

The industry’s growing export markets are now valued at over \$228 million per year compared to \$24 million in 1997. Demand from overseas markets for Australian pork has increased substantially over the past four years, from just 2.6% of Australian pork production in 1997 to approximately 20% in 2003. Australia’s key markets are in Asia with Singapore and Japan providing export income of \$100 million and \$80 million per year respectively. Of major significance is the fact both these markets place a particularly high level of importance on food safety and animal health issues, as highlighted by Japan’s response to recent BSE outbreaks in Canada and the USA involving temporary bans on imports of beef from those countries.

The Australian pork industry is in the enviable position of having a national pig herd with a ‘world’s best’ health status, which underpins pork exports and is vital to the competitiveness and growth of the industry. It is this health status that makes Australian pigs and pig products desirable. With growing global consumer concern for food safety in the wake of increasing disease outbreaks, this highly regarded health status becomes even more desirable and an increasingly competitive advantage.

¹ ‘Socio-Economic Impacts of the Australian Pork Industry’, Western Research Institute; 17 December 2002

3 Key concerns with the draft IRA

In summary, APL has significant concerns about several aspects of the proposed importation of pig meat and the draft IRA:

- The substantial risk of introduction of PMWS in the context of the limited knowledge available about this disease and its current rapid and uncontrolled spread in Europe, North America, Asia and New Zealand.
- Inadequate risk management procedures proposed for the diseases PMWS & PRRS that do not reduce the risk posed by these diseases to the Australian pork industry to an appropriate level of protection i.e. Australia's low risk categorisation.
- Biosecurity Australia's (BA) advice at the public hearings following the release of the draft IRA that the risk management measures proposed for the processing of pig meat (cooking or curing) from PMWS affected countries could be undertaken both onshore and offshore appears contrary to the draft IRA which refers to offshore processing only. There is no justification in the draft IRA for onshore processing.
- The devastating impact of these diseases with no cure for PMWS. 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.
- Loss of Australia's unique health status – our one clear competitive advantage over most of the other pork producing countries - and the subsequent loss of associated marketing advantages.
- Until the additional causative factors are identified for PMWS, and in turn measures developed as to how to control it, BA would be justified in accordance with the Precautionary principle of the SPS Agreement (Article 5.7), in not allowing the importation of pork from PMWS affected countries while it conducted additional research regarding the aetiology of PMWS and the virulence of different strains of PCV2.
- BA proposes modifying the risk management measures for PRRS to also provide for offshore cooking but fails to provide sufficient comparative risk analysis or an explanation as to why on-shore processing is considered as safe as offshore. The draft IRA provides no basis to conclude that risks will be acceptably managed through on shore cooking.
- The lack of transparency in the analysis procedures has led to an inability by APL and the Canadian Government to reach the same conclusions as BA. Biosecurity Australia has yet to clarify this possible deviation from process which may have involved the differential release of information about the methodology used.
- Specific methodological concerns include:
 - The quantitative approach applied to consequence assessment and risk estimation.
 - Unnecessary inaccuracies introduced into the annual likelihood of entry and exposure estimates resulting from converting R-tot to a semi-quantitative category.
 - 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 50th percentile instead of the 95th percentile. The effect of choosing the 50th 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 open to interpretation and therefore another assessor may not reach the same outcomes as those published by BA.
 - The consequences stage lacks mathematical rigour. Unlike the release and exposure risk assessments, APL contends that the methodology of the consequence assessment and risk estimation is unsound and unscientific.
- The draft IRA also fails to document the appraisal techniques intended to be used to ensure proper execution of risk management procedures.

4 Appropriate Level of Protection

Under the current approach adopted by BA, the 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. This is especially so in a situation of scientific uncertainty as to aetiology and epidemiology of particular diseases. Australia has stated that its appropriate level of protection is 'very conservative'.² A qualitative risk assessment, by not taking into account variation and uncertainty, does not provide for a conservative approach to be adopted in the management of risk.³

As noted by APL in previous submissions on the draft IRA and as a matter of record, APL reiterates that the approach used in the draft IRA to setting the Appropriate Level of Protection (ALOP) is problematic. The draft IRA purports 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.

Under the current approach, it is almost impossible for stakeholders to determine what the ALOP actually is or means in concrete terms. Stakeholders are therefore prevented from being able to determine what the potential implications of the ALOP are for them. This also creates difficulty for stakeholders to respond effectively to the draft IRA. 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.

APL notes that the draft IRA attempts to be more quantitative in its approach to assessments than was the approach considered by the Senate Committee dealing with Fresh Apple Fruit

² Australia – salmon case.

³ Senate Rural and Regional Affairs and Transport Committee Interim Report on the Proposed Importation of Fresh Apple Fruit from New Zealand at 8.9

from New Zealand. However, as noted in the Section 6.2 below, this attempt breaks down in the consequence assessment which in turn impacts on the estimation of overall annual risk and the method of risk management proposed.

5 Risk Management for Exotic Diseases

5.1 Post Weaning Multisystemic Wasting Syndrome

Post Weaning Multisystemic Wasting Syndrome (PMWS) is a clinical syndrome of pigs that was first described in Canada in 1996 and has since been reported throughout the United States, Europe and Asia, despite the apparent presence of the virus in pig herds for long periods of time before the syndrome became a problem.

PMWS leads to significantly increased mortality rates, particularly on rearing and finishing units. The most obvious effect of this will be a decline in the number of pigs finished per sow per year. Mortality rates in PMWS affected herds are 15 to 20% on average and in contrast to most other diseases rates persist at these levels for prolonged periods of up to 3 years. The number of pigs affected in a herd can range from 3 to 50 per cent and it generally affects young pigs from 6-14 weeks of age, although it may affect pigs up to 20 weeks of age. Up to 80 per cent of affected pigs die.

5.1.1 Unknown cause of PMWS

The cause of PMWS remains controversial. Although the exact cause is uncertain, it is considered a multi-factorial disease that may be associated with at least (PCV2), porcine parvovirus or porcine reproductive and respiratory syndrome (PRRS) virus. A widely accepted hypothesis is that PMWS only occurs if some other triggering agent accompanies PCV2 infection, although this agent is yet to be identified. Co-infection with PRRS virus, or swine parvovirus, has been shown to increase the severity of the disease.

It is clear that the cause of PMWS is still not completely understood. There is limited scientific knowledge as to the cause or how it is transmitted. This lack of knowledge has been highlighted in the recent outbreak of PMWS in New Zealand. The New Zealand Director of Animal Biosecurity, Derek Belton, stated in November 2003, that "This has been an extremely difficult investigation because of the lack of knowledge of what causes the disease, how it could have arisen in New Zealand and its association with two pig viruses already well established here." In its submission in response to draft Pig Meat IRA the Danish Bacon and Meat Council (DBMC) Veterinary and Food Advisory Service also acknowledged that the exact cause of PMWS was unknown.⁴

5.1.2 No Known Cure

International experts (Stevenson 2003⁵; Madec et al 2002⁶) and opinion (Derek Armstrong, MLC Veterinary Scientist for the United Kingdom's Meat and Livestock Commission (*personal*

⁴ P.4 Danish Bacon and Meat Council, Response to Biosecurity Australia Draft Pig Meat IRA

⁵ Stevenson G. Porcine circovirus type 2: A critical appraisal of its role in PMWS. Proceedings of the 2003 Allen D Lemans Swine Conference, Minneapolis, 117-121.

⁶ Madec F, Waddilove J 2002. Control PCV2 or control other factors? Several approaches to a complex problem. PMWS and PCV2 disease: beyond debate, Merial Symposium, Ames, IA, USA: 45-53.

communication 2003), advise that there is no known cure or vaccine, although changes in management practices have been shown to help alleviate the problems caused by PMWS. However, in most EU member states even when PMWS is brought under control, overall mortality rates remain 1-2% higher than before the infection emerged on the farm.

Without a clear understanding of the factors involved with this disease, control measures will be difficult to implement. Consequently, there is little that can be done to reduce the cost of an outbreak. All these factors underscore the need to manage risk to very low levels and to take every precaution to ensure that PMWS does not enter Australia.

5.1.3 Unable to Eradicate

Overseas experience indicates it is not feasible to eradicate PMWS and this is confirmed in the recent outbreak of PMWS in New Zealand in September 2003. By late 2003 following a review of the response options available, the New Zealand Director of Animal Biosecurity, Derek Belton, stated that the New Zealand Ministry of Agriculture and Forestry (MAF), did 'not believe it is possible to eradicate post-weaning multisystemic wasting syndrome (PMWS)'⁷. This view was formed from two months of MAF investigations into the possible spread and cause of the syndrome confirmed on a Waikato piggery. Belton further commented that:

"Attempts to destroy PMWS in other parts of the world through slaughter of affected pig herds have failed. No country in the world is adopting either a regional or national program of depopulation of affected piggeries to either manage or control the disease, in fact options of depopulation have been looked at and rejected,"⁸.

One of the options that the NZ MAF is exploring is the potential implementation of a control program in the hope of slowing its spread as opposed to completely halting the disease.

5.1.4 Australia's PMWS Status

Australia is one of the few countries that remains free of PMWS as are Finland and Belgium. The Australian pork industry via APL has actively looked for clinical cases of PMWS in Australia with research to date not having found any clinical evidence of its presence.

APL has funded research at Murdoch University⁹ for the past 3 years and also at Elizabeth Macarthur Agricultural Institute (EMAI)¹⁰ - for the past 12 months with neither of these having found any clinical cases that fulfill the criteria for PMWS as set down by Sorden (2001) and Segales (2003). Significantly, to date the Murdoch findings have not found any evidence of causality with research highlighting the importance of cofactors with this disease.

⁷ 'Eradication of Pig Disease May Not be Feasible' Media Release 19 November 2003, New Zealand Ministry of Agriculture and Forestry <http://www.maf.govt.nz/mafnet/press/191103pig.htm>

⁸ Ibid

⁹ APL Project # 1538 & # 1824 - projects into porcine circovirus

¹⁰ APL Project # 1840 'Survey for PMWS in NSW Piggeries', NSW Agriculture, Nov. 2003 (Attachment D).

It has been inaccurately asserted by the US National Pork Board ¹¹, US Animal and Plant Inspection Service (APHIS)¹² and Danish Bacon and Meat Council ¹³ that Australia has no proof that it is PMWS free. APHIS has questioned the value of clinical surveys and suggests serological surveys are of greater significance. In both cases the search for clinical cases has been an important component of the research protocols. Whilst both the Murdoch and EMAI research found evidence of infection of PCV2 (i.e. positive serological results and positive PCR results for the presence of the PCV2 virus) we highlight the fact that infection with PCV2 and presence of disease (PMWS) are NOT interchangeable terms.

Recent history demonstrates that clinical signs remain the first important step in the recognition of exotic diseases. Australia's recognition of a new disease with the experience of Menangle virus, and New Zealand's in the case of PMWS, are cases in point. The absence of clinical signs in Australia justifies Australia's claim of freedom from PMWS. This has been confirmed by the recent study conducted by EMAI in which use of the three criteria, acknowledged by Danish Bacon and Meat Council to be necessary for PMWS diagnosis, failed to produce evidence for the disease.

APL also challenges the validity of the claim made by our competitor countries that because Australia has PCV2 we must have PMWS. This argument is a very simplistic view of PMWS. Whilst recent reports indicate that PCV2 is a necessary component of the syndrome there are other factors involved. In accordance with the three criteria laid down by Sorden (2001), in addition to wasting and presence of PCV2, microscopic lesions and evidence of the virus in lesions are also necessary factors. Dr Greg Stevenson has also commented that "PCV2 is the essential infectious cause of PMWS, but is not likely a primary pathogen in the conventional sense"¹⁴. In addition, John Deen states the infectious agent in the spread of the PMWS is not Circovirus. "Circovirus already exist in the populations that are becoming infected, so it is simply not the causative agent"¹⁵. Roger Morris of Massey University has also questioned claims about PCV2 being the primary causal agent of PCV2. Morris has commented that:

....(a) growing body of epidemiological experience with PMWS in Europe and now in New Zealand has made the view that PCV2 is the primary causal agent of the disease very much more difficult to sustain, and there is rapidly growing acceptance even among former strong proponents of the PCV2 hypothesis that there is another underlying primary causal agent which initiates the disease, and stimulates the massive amplification of PCV2 virus in cells, which then kills the pigs¹⁶.

¹¹ National Pork Board p.2 - Comments on Draft Generic Import Risk Analysis (IRA) for Pig Meat

¹² Animal and Plant Health Inspection Service (APHIS) 'Comments on Australia's Draft Generic Import Risk Analysis (IRA) for Pig Meat'; August 2003.

¹³ Danish Bacon and Meat Council (Veterinary and Food Advisory Service) 'Main reservations regarding the Draft Import Analysis for pig meat released by the Australian Government Department of Agriculture, Fisheries and Forestry' 10/10/2003

¹⁴ Proceedings of 2003 Leman Conference; pg. 118

¹⁵ John Deen, 'What's New with Circovirus?' International Pigletter, October 20, Vol. 23, No. 8a

¹⁶ Morris R. 'Epidemiology of Post-Weaning Multi-Systemic Wasting Syndrome in Pigs' Epicentre Institute of Veterinary, Animal and Biomedical Sciences, 03/02/04

PCV2 is best viewed as a ubiquitous secondary pathogen that can cause disease **given adequate co-factors and susceptible hosts**. **The problem is, we do not yet recognize all possible co-factors nor do we understand the determinant of host susceptibility** (Stevenson 2003). It appears that PRRS virus is more important than porcine parvovirus (which exists in Australia). **Given that the definitive cause of PMWS is not known we would suggest that the only recourse is not to allow the importation of uncooked pork.**

Whilst WTO rules rightly insist on scientific evidence as the basis of risk management, they do not require Australia to rely on hope, assertion or speculation to manage the risks of a new disease with uncertain aetiology. **The mechanisms by which the virus results in a syndrome are largely unknown and therefore scientifically rigorous and effective control measures are not available. In light of this, the most responsible quarantine arrangements should involve a very low risk, conservative approach.**

5.1.5 PMWS Measures

While PCV2 is present in Australia, and PMWS is absent, there are three possible causes of PMWS – none of which is exclusive of either or both of the other two.

1. PMWS may be caused by a PCV2 strain or PCV2 strains which is or are not present in Australia;
2. PMWS may be caused by an unknown organism which is not present in Australian pigs but is present in the herds of PMWS affected countries; or
3. PMWS may be caused by environmental factors (eg immunisation practices).

The first possibility is that the PCV2 serotypes present in Australia are non-pathogenic. The second possibility is that other unknown agents are involved, in which case it can be argued that the appropriate response, until the disease is better understood, is that risk management should be sufficient to kill most or all pathogens, eg protracted heat treatment at high temperatures.

Taking the example of Newcastle Disease Virus (NDV), a one base pair difference separates the virulent form from the non-virulent form. The strains of PCV2 present in Australia do not cause any symptoms or clinical signs consistent with PMWS. The virus was first identified less than 10 years ago. There is no work of which APL is aware which provides any basis for concluding that the PCV2 strains isolated in Australia are identical to those isolated in PMWS affected countries.

The first possibility provides ample justification for the measures proposed in the draft IRA for control of PMWS – all of which are directed to managing the risk of introduction, establishment or spread of PCV2 from a PMWS affected country.

The second possibility is that PMWS is caused, in whole or in part, by an organism that is currently unknown. That possibility is confirmed by the submission of Danish Bacon and Meat Council (DBMC) to BA in response to the draft IRA and the comments of Roger Morris (see

attached paper)¹⁷. The freedom of Australia from PMWS provides cogent evidence that such an organism is not present in Australia. If that organism were to establish in the Australian pig herd it is likely that PMWS would establish in Australia.

The role of such unidentified organisms might also be indicated by evidence which is emerging that the types of PMWS apparent in the US and EU have different virulence¹⁸. This might be due to different strains of PCV2 or might be due to other unknown factors contributing to PMWS. **Nevertheless the draft IRA addresses only the first possibility of the cause of PMWS (i.e. that there are pathogenic strains of PCV2 which are absent from Australia) but fails to address the second possibility that PCV2 operates in conjunction with an unknown essential pathogen.**

APL submits that the appropriate response to this second possibility is, pursuant to Article 5.7 of the SPS Agreement, to ban importation of pork products from PMWS affected countries. That ban would apply until the necessary research is done to either identify the causative agents or confirm that the cause of PMWS is found in differing strains of PCV2. The measure could be relaxed to an appropriate off shore cooking regime if it can be established that all strains of PCV2 and all other identifiable organisms in pork meat would be inactivated by such a cooking regime.

APL contends that a temporary ban should be placed on importations from PMWS affected countries pending further investigation; and that in the longer term cooking regimes in addition to the measures outlined in the draft IRA should be required for importation from PMWS affected countries.

5.1.6 Impact of PMWS on industry

PMWS has had a devastating economic impact on the North American and European pork industries. In the European Union PMWS is responsible for a reduction of 8 million pigs and a loss of €900 million (\$A1.471 billion)¹⁹. APL estimates that an epidemic of PMWS in Australia of similar proportion to our northern counterparts would add 15% to the cost of pig meat production in affected herds²⁰.

The experience of the Netherlands and Britain highlights the extent of the substantial economic damage PMWS could potentially inflict on the Australian pork industry. Having first appeared in the Netherlands in 1998, the total estimated cost of PMWS is €30 - €35 million per year (\$A49-\$A57 million)²¹ with 70-80% of pig farms having been affected.

¹⁷ Morris R. 'Epidemiology of Post-Weaning Multi-Systemic Wasting Syndrome in Pigs' Epicentre Institute of Veterinary, Animal and Biomedical Sciences, 03/02/04

¹⁸ John Deen, 'What's New with Circovirus?' International Pigletter, October 20, Vol. 23, No. 8a

¹⁹ Correspondence with Derek Armstrong - MLC Veterinary Scientist, Veterinary Department, Meat and Livestock Commission, December 2003.

²⁰ Based on the UK experience as detailed by Derek Armstrong, APL has estimated equivalent impact on Australia

²¹ Correspondence with Derek Armstrong - MLC Veterinary Scientist, Veterinary Department, Meat and Livestock Commission, December 2003.

In the case of Britain, the UK Meat and Livestock Commission estimates that PMWS has reduced sow productivity by 6-7%. In production terms this equates to 600,000 pigs per annum which is the equivalent to 45,000 tonnes of pig meat production²². Since the disease was first diagnosed in 1999, PMWS has resulted in mortality rates of 10-15% of stock²³:

The recent NZ outbreak of PMWS also indicates the potential damage that could be inflicted on the Australian pork industry. The New Zealand Ministry for Agriculture and Forestry (MAF) has estimated that the cost to the NZ pork industry to date resulting from the PMWS outbreak has been \$3.3 million, whilst Professor Roger Morris from the Massey University EpiCentre in NZ put the cost at \$4.5 million²⁴. Furthermore, the NZ MAF has estimated that to depopulate and decontaminate affected herds would cost up to NZ\$174,000 for the owner of and NZ\$134,000 to MAF for each affected 100 sow finishing enterprise²⁵. (These figures however exclude potential compensation costs as well as further research and surveillance costs. These are provided in Attachment B 'NZ Options Paper'.)

In respect of the direct impact an outbreak of PMWS disease could inflict on the Australian pork production and processing sector, APL estimates that it would result in the loss of approximately 250 full time jobs, with an estimated 155 of these coming from the pig production sector. The industry would also be expected to lose approximately \$81 million in sales revenue, \$6.4 million in household income and forego almost \$17.6million in value adding. These figures do not include surveillance and/or control costs if the disease was to occur here.

The ongoing direct and flow-on economic impacts of an PMWS exotic disease outbreak on the *Australian economy* is estimated to be in the order of 2,200 lost jobs, a \$188.9 million fall in gross domestic product and a \$76.3 million reduction in household income.

5.1.7 Managing Risk to an Appropriate Level of Protection

APL interprets the risk management measure proposed for the processing of pig meat (cooking or curing) from PMWS affected countries as being undertaken solely offshore. This interpretation is sustained in the Executive Summary (p6) and in the draft Report (pp743-744) where references to the cooking or curing process fail to distinguish between onshore and offshore, especially when compared to the explicit statements made by BA with respect to PRRS, that "imported pig meat may be cooked off-shore or in Australia on shore..." Executive Summary (p5).

However when the issue was raised at the IRA public meetings conducted by Biosecurity Australia following the release of the draft IRA Report, BA expressed an entirely different opinion stating that the risk management measure proposed can also be undertaken onshore. As stated above there is no justification provided in the draft IRA for on-shore processing. The key

²² Fowler, Tony; MLC Planning and Forecasting Group; 6 February 2003.

²³ Correspondence with Derek Armstrong - MLC Veterinary Scientist, Veterinary Department, Meat and Livestock Commission, December 2003.

²⁴ Professor Roger Morris; Massey University Epicentre Institute of Veterinary, Animal and Biomedical Sciences.

²⁵ Post Weaning Multisystemic Wasting Syndrome Response Options Analysis New Zealand Ministry of Agriculture and Forestry 7 November 2003.

risk modification sought to be achieved through deboning and cooking is a reduction of waste in the Australian environment. That impact cannot be achieved as effectively if the deboning and cooking occurs in Australia. Cooking and deboning on shore are not equivalent to off shore processing. Without express consideration of on shore cooking as a control measure separate from off shore cooking and deboning, the draft IRA provides no basis to conclude that risks will be acceptably managed through on shore cooking.

Further, the draft IRA makes clear that cooking will not appreciably inactivate the PCV2 virus. Although a cooking schedule is defined for the disease PRRS, there is no definition of the cooking schedule stated for the risk management of PMWS. It is not sufficient, nor acceptable as argued by the draft IRA Risk Analysis Panel that, "the direct effect of processing PCV2 was not examined, however, it was recognised that there may be some reduction in virus titre after curing for long periods or cooking"²⁶.

APL requests that BA provide a definition of the cooking schedule required for risk management of PMWS. APL contends that if the cooking process is to be 70C for 11 minutes (based on the recommendation for the PRRS virus), then this does nothing to inactivate PCV2 virus, and consequently R4 for PMWS (where R4 is the likelihood that a pathogenic agent is present in the meat harvested from an infected pig) should be "moderate" rather than "low" (as argued by APL in section 6.1 "Likelihood of Entry.")

The draft IRA report makes clear that BA is prepared to allow potentially virus affected meat to circulate within Australia having accepted that cooking will not appreciably inactivate the PCV2 virus. A study carried out in Ireland in 1994 (GM Allan et al)²⁷ has shown that porcine circovirus is extremely resistant to the effects of high temperatures. No reduction of infective titers was shown after a 15 minute period at 70C. Personal communications from researchers at Murdoch University and the Elizabeth Macarthur Agricultural Institute indicate that this class of virus is very heat resistant and able to withstand prolonged periods of temperatures in excess of 70C.

The level of heat treatment required to inactivate PCV2 is unknown. **APL propose that for any cooking process short of 100C, experimental work will need to be undertaken to establish what is required.** A method of assessment that incorporates more than just culture of the virus and includes some transmission experiments with live pigs is required. **Transmission experiments are valuable, as there have been viruses, which have been unapparent in meat when cultured, but present in sufficient quantity to produce infection when fed to live pigs.** As an alternative to transmission experiments, PCR testing could also be considered.

The recent NZ outbreak would appear to underline these concerns. Morris observed that in 1999 the requirement for cooking such material before feeding it to pigs was removed, and in 2001 a requirement for cooking imported pig meat on arrival in New Zealand was introduced. He notes that:

²⁶ Draft Import Risk Analysis Report IRA p743

²⁷ Allan G.M. et al; J.Vet. Med. B 41 (1) 17-26

Between those dates appears from the evidence to be when the disease first developed in New Zealand, and circumstantial support has been accumulated through our investigations for the hypothesis that some of the farmers concerned used feed materials during this period which are likely to have contained uncooked or inadequately cooked pig meat of imported origin²⁸.

APL believes that there is too high a risk involved in allowing onshore transportation and processing of PMWS infected product. Australia and the Australian pork industry is justified in expecting greater caution in applying adequate risk management to pig meat imports to ensure that highly pathogenic strains of PCV2 are not introduced.

The draft Report also fails to address a number of critical issues that will impact on how these proposed risk management measures will operate in practice. The draft IRA fails to provide advice and/or recommendations on how to address this problem, in particular:

- How BA plans to identify PMWS affected countries?
- How BA will ensure that Australia is immediately notified of a PMWS outbreak?
- What constitutes freedom from PMWS?
- What guidelines does BA plan to put in place to demonstrate area freedom from PMWS?

5.2 Porcine Reproductive and Respiratory Syndrome

The Porcine Reproductive and Respiratory Syndrome (PRRS) virus causes late term abortions which typically occur in the last 10 days of pregnancy. In naïve herds (those herds which have never been exposed to the disease) these losses can be substantial with up to 20% of the pregnant sow aborting. PRRS typically also results in an increase in the number of stillborn piglets, and mummified foetuses, whilst pigs that are born alive may show reduced viability with an increase in pre-weaning mortality.

In the respiratory component of the syndrome there is an increase in the number of weaned pigs that show respiratory signs such as difficult breathing and coughing. These animals fail to grow as a result of reduced feed intake and in the presence of other respiratory bacteria or viruses often die. The virulence of the virus is variable and in some infected herds not all clinical signs are present.

Serological surveys have confirmed that PRRS has not been identified in Australia.

5.2.2 Impact on industry

Losses from PRRS result from increases in reproductive failure and increased costs associated with attempts to control the condition by vaccination and medication to control secondary respiratory disease. A survey conducted by Garner *et al* on the expected economic impact of selected exotic diseases on the pig industry estimated that the introduction and proportionate opportunity lost from a PRRS epidemic would result in \$39 million reduction (6% fall) in gross

²⁸ Morris R. 'Epidemiology of Post-Weaning Multi-Systemic Wasting Syndrome in Pigs' Epicentre Institute of Veterinary, Animal and Biomedical Sciences, 03/02/04

income²⁹. Similarly, the expected fall in gross income in the Darling Downs region alone from a PRRS epidemic was estimated at \$13 million, which equates to a 21% drop³⁰.

At present effective measures to eradicate the disease from an infected herd are extremely expensive. National and regional attempts to control the spread of the disease in affected countries have been largely unsuccessful³¹.

5.2.3 PRRS Protocols

As freedom from PRRS is important for the industry's future, APL feels justified in asking for an explanation as to why on-shore processing is considered as safe as offshore. The draft IRA provides no justification for onshore processing. APL contends from these first principles that cooking and deboning on shore cannot be equivalent to off shore processing. As with PMWS, the key PRRS risk modification sought to be achieved through deboning and cooking is a reduction of waste in the Australian environment. **Without express consideration of on shore cooking as a control measure separate from off shore cooking and deboning, the draft IRA provides no basis to conclude that risks will be acceptably managed through on shore cooking.**

We contend that the prevention of PRRS should be addressed through a requirement for off shore cooking, particularly from countries which are both PRRS and PMWS affected. Current import protocol procedures enable the transportation of untreated pork imports from the port of entry to the processors' site. The pork industry is being asked to bear a risk that is not only unacceptable but also inconsistent with the nation's approach to other quarantine import protocols such as for maize. The proposed conditions for the import of maize require that it be treated at the point of export so as to provide a high degree of confidence that disease risks are managed offshore. The same principle should apply to pork imports.

If there is to be any on shore processing it will be essential that there be protocols such as incineration and covered drains which ensure waste from the onshore processing plants is not disposed into areas where establishment of disease could occur. We request that access by birds and insects to waste from onshore processing be restricted by such measures as incineration and covered drains that cannot be accessed by feral pigs, birds, insects, rodents or other animals.

Further research work also needs to be undertaken if we are to have assurance and confidence that the risk management procedures proposed by BA are effective in reducing the risk of this disease to the industry.

²⁹ Garner M.G. et al. 'The expected economic impact of selected exotic diseases on the pig industry of Australia'; Rev. Sci Tech 2001 December 20(3); Australian Department of Agriculture, Fisheries and Forestry.

³⁰ Garner M.G. et al. 'The expected economic impact of selected exotic diseases on the pig industry of Australia'; Rev. Sci Tech 2001 December 20(3); Australian Department of Agriculture, Fisheries and Forestry.

³¹ Ibid

6. Methodological problems

There are a number of methodological problems with the draft IRA which impact on the outcome of the risks assessed. APL has already identified many of these in its submissions to Biosecurity Australia on the Issues Paper and draft Methods Paper. In particular, there are numerous instances where the draft IRA has failed sufficiently to adequately address specific points raised in APL's submissions leading APL to question whether those points have been considered by BA. The principle concerns are:

- The volume of pathogenic agent (e.g. the number of pathogens in the carcass) is not adequately incorporated in the risk assessment method.
- Confusion between the roles of R4 (the likelihood that a pathogenic agent is present in the meat harvested from an infected pig) and L2 (the likelihood of a sufficient dose to initiate infection) in risk management.
- Unnecessary inaccuracy introduced into the annual likelihood of entry and exposure estimates resulting from converting R-tot to a semi-quantitative category.
- 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.
- Insufficient explanation as to why likelihood models were based on the 50th percentile instead of the 95th percentile. The effect of choosing the 50th 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 open to interpretation and therefore another assessor may not reach the same outcomes as those published by BA.
- The lack of transparency in the analysis procedures has led to an inability by APL and the Canadian Government to reach the same conclusions as BA.
- As a result of increased volumes of import trade above those used by BA in the draft IRA, 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.
- The consequences stage lacks mathematical rigour. Unlike the release and exposure risk assessments, APL contends that the methodology of the consequence assessment and risk estimation is unsound and unscientific.

6.1 Likelihood of entry

APL's analysis indicates that within the draft IRA Report there are errors in respect of the estimates of R4 (where R4 is the likelihood that a pathogenic agent is present in the meat harvested from an infected pig). Nowhere in this definition is there any reference to the volume of pathogenic agent (e.g. the number of pathogens in the carcass). R4 is simply the likelihood that some units of the pathogen, no matter how few, are present in an infected carcass.

Using this definition, it is generally invalid to apply factors such as carcass bleeding or removal of the respiratory tract to reduce R4. These processes reduce the volume of the pathogen, but do not eliminate it. Consequently they do not significantly reduce the probability that a small

volume of pathogen remains in a carcass. The only parameter that can be modified by the application of these processes is L2, the likelihood of a sufficient dose to initiate infection. It appears that for the risk analysis of some diseases, this error has led to R4 estimates at a lower than justified level. For example in the risk analysis for swine influenza it is stated that removal of the respiratory tract and “bleeding the carcass should remove, to a large extent, the virus contaminating muscle due to viraemic pigs (ie. reduce R4)” (p.456 & 532 Draft IRA). It is therefore questionable whether BA’s assessment of “extremely low” (less than 1:1000) for R4 is reasonable for this disease.

Of even more concern to APL are R4 errors relating to risk management. We question the estimate of the impact of removing lymphatic tissue on R4 for PMWS and PRRS, whereby R4 is reduced from “moderate” to “low”. We believe this measure does not reduce R4, although it does reduce L2.

On this basis APL argues that the estimates for R4 must be reviewed, particularly in respect of risk management.

More generally, regarding the total release likelihood (R_tot) distribution, APL has difficulty in identifying the scientific justification for building a model to make precise estimates, then introducing inaccuracies by converting them to semi-qualitative figures and in turn feeding them back into the model to produce more precise estimates.

APL believes that there has been an introduction of the inaccuracy in the methodology in calculating total release likelihood. In the draft Report, a quantitative estimate of the total release likelihood (R-tot) distribution using @Risk software has been carefully obtained. **However, following from this BA only use the semi-quantitative category (for example 'low') into which this quantitative 50th percentile calculation of R-tot falls in subsequent annual likelihood calculations. In so doing, they lose both accuracy and information about the spread of the distribution around the R_tot likelihood.**

APL argues that all simulations should be performed using the 95th percentile calculated R_tot. This calculated R_tot, with its associated expected value and distribution resulting from the simulation, can then be carried through to the risk assessment for the three exposure groups (i.e. feral pigs, backyard pigs and small commercial piggeries).

6.2 Calculation of ‘annual’ likelihood of entry and exposure

The likelihood of ‘entry and exposure’ calculated in the draft IRA are annualised. APL’s submission in response to the draft Methods Paper drew attention to the fact that this has the potential to seriously distort the outcome of the risk assessment. APL argues that both logically and statistically this can have a significant and major impact on the likelihood and subsequently consequence assessments. It fails to consider the totality of the impact of diseases.

The Quarantine Act and the Quarantine Proclamation do not confine any likelihoods or risks to an annual basis. Consideration of the requirements of section 5D of the Quarantine Act does not limit the estimation of likelihood in this way, further reinforcing APL’s position on this point. Section 5D of the Quarantine Act 1908 defines a “level of quarantine risk” as:

- (a) the probability of:
 - (i) a disease or pest being introduced, established or spread in Australia or the Cocos Islands; and
 - (ii) the disease or pest causing harm to human beings, animals, plants, other aspect of the environment, or economic activities.
- (b) The probable extent of harm.

Consideration of annual likelihoods of exposure or uncontained outbreaks can convey a false sense of security, and that Australia should be thinking of the risks entailed in decades rather than a year of imports. The methodology is flawed in failing to extrapolate annual exposure or outbreak risks to the risks attendant over longer periods of imports. Instead, the approach of the draft IRA is to immediately directly combine annual exposures with a qualitative methodology of consequence assessment. **It follows that the draft IRA has not, and could not consider the risk implications of the implementation of the quarantine measures beyond a time frame of one year.**

There is a failure in the draft IRA Report to take the next logical step forward from an estimate of annual risk. As an example, an annual likelihood of exposure of 0.027 is categorised as “very low”. This looks disarmingly reassuring until one considers the likelihood of an uncontained outbreak over time. With that likelihood, over a period of 10 years the likelihood of at least one incursion is 0.24 (low), over a period of 15 years the likelihood is 0.34 (moderate) and over a period of 50 years the likelihood is 0.75 (high).

In the case of the major diseases of pigs, expectations of acceptable low risk over time frames of 50 to 100 years are quite justifiable historically. Australia freed itself of FMD in the 19th century and classical swine fever for some 50 years or so, without reinfection. **It would therefore compromise historical norms of ALOP if pig meat were allowed entry without assurance that risk still remains acceptably low after similar long periods of imports.** To achieve this, calculated annual likelihoods of uncontained outbreaks for the major diseases over a 50 year period should fall into the “very low” range. That would require that the calculated annual likelihoods should fall into the “extremely low” or “negligible categories”.

Analysis conducted by the CSIRO highlights our concerns regarding the potential longer-term risks. Taking the example of PMWS, the CSIRO analysis has shown that with the measures proposed in the draft IRA the likelihood of there being one or more outbreaks (considering the median predicted values) over the next ten years as being 99%, with the corresponding figure for 25 years or more approaching 100%. (Refer to Attachment E - APL Submission to Biosecurity Australia, October 2003 Table 1 in Appendix A).

The disease outbreak expectation results indicate that under the pig meat draft IRA Australia's existing quarantine measures will not meet Australia's Appropriate Level of Protection (ALOP). The simulation shows that on the balance of probability there will be one or more outbreaks within the next two years under the proposed protocols. In fact the preferred approach would be to express the outcomes of the simulation in terms of the expected number of outbreaks that would occur over a ten year period.

6.3 Likelihood distribution models based on 50th percentile instead of 95th percentile

It is unclear from the draft IRA Report as to why the approach stated in the drafts Methods Paper (p18) which adopts “a conservative (95th) percentile “ is changed to the “median value (50th) percentile” in the draft IRA Report (p30). APL argues that the explanation provided by Biosecurity Australia (BA) in “Annex B (p59) is inadequate. The explanation is not clear as to why it was decided to reconsider this approach. No explicit explanation has been provided by BA as to why this approach was reconsidered.

APL also contends that at least **where considering a disease in respect of which there is substantial uncertainty as to aetiology and epidemiology the effect of choosing the 50th percentile has been to move away from “the use of conservative assumptions” and that that is inappropriate.**

APL’s own analysis with regard to the draft IRA demonstrates that use of the 50th percentile as opposed to the 95th percentile in the case of PRRS had the effect of reducing the assessment of overall annual risk from ‘Low’ to ‘Very Low’. (Refer to the attached APL October 13th 2003 Submission - Table 2 and Table 3 in Appendix A).

6.4 Impact Score Tables

The Impact Score Table attempts to “quantify” the combined local, district, state and national consequences of scores as illustrated in Table 12 (p63) in the Guidelines, and Table 8 (p63) in the draft IRA (with rules on p66).

APL continues to maintain and as originally stated in its response to the draft Methods Paper that the rules of the Impact Score Tables are arbitrary and therefore it is not possible *objectively* to reach the outcomes proposed by BA from applying the ‘rules’.

This raises serious doubts about the methodology generally which must be addressed if APL and other stakeholders are to have confidence in the risk measures proposed.

6.5 Effect of multiple diseases on quarantine risk

The draft IRA and indeed the IRA guidelines, consider diseases one at a time. However, in practice, there are often several diseases. BA documented risk assessments for some 26 diseases. The import risk is typically defined by only one disease that presents the greatest risk. For APL there are two diseases of particular concern, namely PRRS and PWMS. The probability of an incursion from at least one disease is greater than the probability from a single disease. For small probabilities these probabilities are additive.

While the probabilities of an incursion of some of the diseases are small, their combined risk may be significant. The current IRA and indeed the guidelines are silent on this matter.

6.6 Transparency of analysis procedures

In our submission on the draft Methods Paper APL raised the issue of the use of custom distributions. In response the draft IRA provided some detail on the custom distribution used. The lack of transparency in the analysis procedures has led to an inability by APL and the Canadian Government to reach the same conclusions as BA.

The Canadian Government appear to have information that a specific distribution, namely the 'truncated log logistic' distribution, has been used to model the size of an infected waste unit. In addition Canada has used a coefficient of variation (cv) of 38% on this 'truncated log logistic distribution'.

Two possibilities arise from this. First, the Government of Canada's submission is based on a probability distribution it has selected without reference to the work published by BA. If that is the case the Canadian submission should be rejected as based on falsehoods.

Second, the Government of Canada might be specifically aware that the 'truncated log logistic distribution' with a cv of 38% was used rather than a 'custom' distribution as the question is specifically asked in their submission. **This potentially suggests the apparent withholding of essential information from the Australian pork industry and other stakeholders. It would call into question the entire import risk analysis process.**

In its previous submission to Biosecurity Australia APL has requested urgent clarification of this issue but has yet to receive any written advice (refer to Attachment F).

6.7 Consequences stage lacks mathematical rigour

APL is of the view that in relation to consequence assessment there is a lack of mathematical rigour in the alphabetical rating system used. CSIRO statisticians have added uncertainty to the consequences ratings to enable the simulations to assist in understanding the effect of uncertainty in the likelihood component as well as in the consequences.

Unlike the release and exposure risk assessments, the methodology of the consequence assessment and risk estimation is unsound and unscientific on the following grounds:

- The complex and contrived nature of the rules and matrices obscures comprehension and transparency.
- There is a failure to provide rationale for the impact estimates, classification rules and look-up tables.
- The use of rules and a table to pseudo-mathematically derive abstract constructs to apply to a further table to develop constructs that are even more abstract, is intuitively, logically and scientifically suspect.
- There is a consequent compromise of the absolute accuracy of the estimates, but a failure to match the objectivity of the earlier quantitative assessment.
- There is a particular failure of the methodology to enable verification, checking or challenge of any of the estimates. The impact estimates, the classification rules and the table look-up outcomes cannot be assessed in terms of some external standard, so that it is impossible to

verify or challenge them except by reference to one's own subjective opinions. This further renders the process unscientific.

- There is no provision of uncertainty estimates to be included in the estimation of consequences.

Accordingly these sections of the methodology are considered unsatisfactory. The Committee dealt with generally analogous issues in its inquiry into Fresh Apples from New Zealand. The Committee's conclusions and government response were as follows.

The Committee said:

...the Committee is highly critical of the decision by BA to utilise a qualitative risk assessment in the draft IRA, as opposed to a quantitative risk assessment. Fundamentally, this is because of the complexity of the risk evaluation task in the draft IRA, the scarcity of data on some issues, the lack of knowledge in certain areas and the need for transparency in the risk assessment. These factors are precisely the reasons for favouring a quantitative analysis over a qualitative analysis.³²

...a quantitative measure of probability has certain definite advantages over a qualitative measure:

- (a) A qualitative approach assigns a single probability to an event (ie the location), and does not take account of the variation or uncertainty of that value (ie the spread). That is to say, in the above example, a qualitative measure of probability based on a location of 10 does not take into account the fact that the outcome can potentially be as low as 3/100 or as high as 17/100.
- (b) Because a qualitative approach cannot take into account the variations in the spread of outcomes (ie 3/100 to 17/100 in the above example), the user of the qualitative approach cannot adopt alternative measures of risk by adopting either the most optimistic (ie a probability of 3/100) or pessimistic (ie a probability of 17/100) outcome.³³

From this the Committee commented with respect to the draft IRA on New Zealand Apples:

... the qualitative risk evaluation matrix used by BA in the Draft IRA does not allow a conservative approach to be adopted to the management of risk. Rather, the risks associated with New Zealand apples are simply what the authors state them to be, and as such cannot be tested. By contrast, a quantitative risk is ideally suited to such an analysis. It allows the user to break the risk down into constituent parts, and where necessary adopt alternative measurements of risk.³⁴

³² Senate Rural and Regional Affairs and Transport Legislation Committee (July 2001): para 8.4

³³ *ibid*: para 8.8

³⁴ Senate Rural and Regional Affairs and Transport Legislation Committee (July 2001): para 8.9

At Recommendation 6 the Committee recommended:

... that Biosecurity Australia incorporate a full quantitative risk evaluation in the final IRA on the possible importation of New Zealand apples, in preference to the current unsatisfactory qualitative *risk evaluation used in the draft IRA*.³⁵

The Government responded:

International consensus is that both quantitative and qualitative approaches to quarantine risk analysis are valid, with the circumstances of the individual analysis determining the appropriate approach in each case. Quarantine risk analyses are commonly qualitative and have traditionally been presented in a narrative form. Analyses presented in such a way have been criticised for a lack of objectivity.

...

The Government recognises that the discipline of applying quantitative risk assessment to quarantine is evolving and notes that international risk analysts understand these methodologies better than they did several years ago. However, the use of quantitative risk assessment in certain situations does not necessarily have a significant advantage over qualitative or semi-quantitative techniques. Quantitative risk assessment requires more resources and is problematic when the data are of poor quality. Therefore, judgments on the efficient and effective use of resources, and the applicability of the various methodologies, need to be made case by case.

...

Biosecurity Australia will continue to use quantitative risk assessment methodology when feasible and appropriate. The risk assessment panel is investigating options for doing a more quantitative analysis of *Erwinia amylovora* than for the original draft IRA.

In the context of a generic IRA, APL cannot identify any reason why the resources necessary to extend the quantitative analysis to consequences would not be made available in accordance with the Government's response to the Committee.

³⁵ *ibid*: para Recommendations

7. Risk management in practice

APL remains concerned that if the protocols proposed in the draft IRA come into effect that the execution of risk management is 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 in the veterinary standards and surveillance of exporting countries, official notifications and public statements and the ability of AQIS to monitor and audit regularly.

Australia needs to guard against the non-general or unusual situation. The emergence of PMWS in New Zealand is a case in point. As previously discussed in 5.1.7, there was a period between 1998 and 2001 in which regulations were not in place to prevent the potential feeding of pigs with materials that may have contained uncooked or inadequately cooked pig meat of imported origin³⁶. APL understands that while the New Zealand MAF intended to reintroduce regulations for feeding of food waste to pigs it to pigs post the FMD crisis in Europe in 2002; the implementation of the regulations was to be on a voluntary basis with penalties for non-compliance. In early 2003 APL wrote to Biosecurity Australia detailing our concerns with regard to this practice, stating that as food waste or swill feeding is not permitted (and is illegal) within Australia, the proposed New Zealand regulations may present an unacceptable risk to the Australian pork industry. The reintroduction of these regulations has yet to occur.

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 risk to the Australian pig herd.

APL believes that in the interests of equivalency, standards the same as, or procedures shown to be equivalent to current Australian standards must be in place in establishments approved to export to Australia. APL seeks verification from the draft IRA on how Biosecurity Australia will satisfy itself that overseas abattoirs and processing plants conform to Australian standards and that audits by Australian authorities are of an equivalence and intensity expected of Australia by its competitors, especially Canada, the US and the EC, and how it intends to address the issues of identification and segregation.

³⁶ Morris R. 'Epidemiology of Post-Weaning Multi-Systemic Wasting Syndrome in Pigs' Epicentre Institute of Veterinary, Animal and Biomedical Sciences, 03/02/04

8. Conclusion

APL has detailed a number of significant concerns with respect to the methodology and resulting risk management measures proposed in the draft IRA for Pig Meat. One of our primary concerns regarding the proposed risk measures for addressing the diseases PMWS & PRRS.

We wish to re-iterate our view that risk management measures proposed for PMWS and PRRS are inadequate and fail to reduce the risk that these diseases pose to the Australian pork industry to an appropriate level of protection ie. Australia's very low risk categorisation. In respect of PMWS, the mechanisms by which the virus results in a syndrome are largely unknown and therefore scientifically rigorous and effective control measures are not available. In light of this, the most responsible quarantine arrangements should involve a very low risk, conservative approach. Throughout the whole IRA process the appropriate level of risk APL has sought is "very low" (or less), not "low".

Specifically, the disease outbreak expectation results within draft IRA indicate that under the pig meat Australia's existing quarantine measures will not meet Australia's ALOP.

An increasing amount of scientific opinion is emerging that concludes that PMWS may be caused by an unknown organism that is not present in Australian pigs, but is present in the herds of PMWS affected countries. On this basis APL submits that the appropriate response to this possibility, pursuant to Article 5.7 of the SPS Agreement, is to ban importation of pork products from PMWS affected countries, until more conclusive research is completed.

In the longer term APL propose that cooking regimes, in addition to the measures outlined in the draft IRA, should be required for importation from PMWS affected countries. We maintain that off-shore cooking is still the only appropriate measure for addressing the threat posed by PMWS.

APL also has a number of key methodological concerns which include:

- The quantitative approach applied to consequence assessment and risk estimation.
- Unnecessary inaccuracy introduced into the annual likelihood of entry and exposure estimates resulting from converting R-tot to a semi-quantitative category.
- The volume of pathogenic agent (e.g. the number of pathogens in the carcass) is not adequately incorporated in the risk assessment method.
- Confusion between the roles of R4 (the likelihood that a pathogenic agent is present in the meat harvested from an infected pig) and L2 (the likelihood of a sufficient dose to initiate infection) in risk management.
- 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.

- No consideration in the methodology of the substantial increased levels of disease risks, and in turn overall annual risk level, resulting from increased volumes of import trade above those amounts used by BA in the draft IRA.
- A lack of explanation as to why likelihood models were based on the 50th percentile instead of the 95th percentile that results in an inappropriate move away from BA's stated process of using conservative assumptions.
- A lack of mathematical rigour regarding the consequences stage. The rules of the Impact Score Tables are open to interpretation and therefore another assessor may not reach the same outcomes as those published by BA

APL is extremely concerned as to the potential damage that an outbreak of PMWS or PRRS could have on Australia's unique animal health status and quarantine systems as these are key strategic competitive advantages in our international markets. We subsequently strongly urge the Senate RRAT Committee to give due regard to the science we have detailed in our submission in its recommendations.