

# **Attachment F**



## **Generic Import Risk Analysis for Pig Meat**

### **Draft Import Risk Analysis Report**

**Second Submission**

**Australian Pork Limited**

**17<sup>th</sup> December 2003**

## Executive Summary

Australian Pork Limited (APL) is a significant stakeholder in the Import Risk Assessment for Pig Meat, representing the interests of Australian pork producers.

APL wish to re-affirm our position that there should be no watering down of current protocols with respect to PRRS. APL believe that Biosecurity Australia (BA) are justified in pursuing the proposed protocols, and suggest that many of the criticisms and proposed changes within stakeholder submissions responding to the Draft IRA are unsubstantiated.

Further, APL continues to oppose the importation of uncooked pig meat from PMWS and/or PRRS affected countries as these pose a significant threat to the future viability of the Australian pork industry due to the threat to the health status of the Australian pig herd. Given the lack of scientific understanding and agreement regarding PMWS, the only appropriate response is a conservative one.

APL propose that in accordance with the Precautionary Principle of the SPS Agreement (Article 5.7) the most appropriate course of action for preventing the spread of PMWS is for the IRA protocols to prohibit the importation of product from PMWS affected countries until additional research is conducted regarding the aetiology of PMWS including into virulence of different strains of PCV2.

APL advocates a strengthening of PMWS protocols requiring all imported product to be first cooked offshore as a necessary requirement to sufficiently minimise the risk to an appropriate level of protection.

APL has a number of concerns regarding particular points raised in the responses to the Draft IRA which include:

- The possibility that the Canadian Government was provided with different information from BA for the purposes of producing their submission, as compared to the other stakeholders.
- A lack of detail in the Canadian submission regarding claimed research findings that suggest isolated PRRS virus corresponds to a very low probability.
- The inaccurate assertion made by the National Pork Board (p2), US Animal and Plant Inspection Service (APHIS) (p7) and Danish Bacon and Meat Council (DBMC) (p1) that Australia has no proof that it is PMWS free.
- The premature conclusion that because Australia has evidence of PCV2 we consequently have PMWS, despite stakeholder's acknowledgement that co-factors are critically necessary for PMWS infection.
- The questionable APHIS suggestion that the IRA's reference to 'epidemiological characteristics' of a disease does not cover the 'triad of disease determinants'.

Also, APL is concerned with the failure of the Draft IRA to assess the rise of bio-terrorism, in light of the incident at Portland. The threat of bio-terrorism underlines the critical importance of effective risk management measures and the requirement for offshore and not onshore cooking. Consequently, the issue of bio-terrorism needs to be addressed by the draft IRA.

APL acknowledges and is appreciative of Biosecurity Australia's (BA) previous consultation with the industry and is keen to continue and build on this relationship. APL seeks assurance that it will be consulted before any major change to the final IRA Report is implemented, including BA's consideration of regional disease free status for diseases.

## **1. Introduction**

APL wishes to take this opportunity to correct certain information and data reported in the submission provided to BA by other stakeholders in response to the Draft IRA Report released in August 2003 as part of the generic Import Risk Assessment for Pig Meat. APL has focused our response on the key issues raised in these submissions with respect to PRRS and PMWS.

As a global player that both exports and imports the Australian pig industry through its representative body, APL, clearly does not support zero level risk management. Nor does APL support an open door policy. We do not believe it is reasonable for the EU to propose 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.

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' (ALOP) – which is conservative for Australia.

## **2. PRRS**

The position taken by BA on the measures to prevent the entry of PRRS virus is in general supported by APL. However, we do believe the prevention of the PRRS virus should be addressed through a requirement for off shore cooking. We refer to comments made in our previous submission that BA should require exporting countries to demonstrate that pig meat being sent to Australia is free from porcine circovirus and PRRS virus. The exporting country must show the cooking method will lead to the total inactivation of porcine circovirus. 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.

### **2.1. US Animal and Plant Health Inspection Service (APHIS) Submission**

#### **2.1.1 Tissue Culture Infected Dose (TCID<sub>50</sub>)**

APL notes that APHIS (p6) criticises the Tissue Culture Infected Dose (TCID<sub>50</sub>) figure used in the Lelystad study. However the accuracy of the data used by APHIS is highly questionable:

- The information is in the first instance dated as it refers to data collected in 2000.
- The cited 21.4% of sites in the US that had breeding females with PRRS in the last 12 months is not evidential as it is an estimate only.

- The cited figures of 17.5% of nursery sites and 16.6% of finisher sites with PRRS in the last 12 months as well as the 21.4% figure referenced above do not refer to serological presence in these sites and yet the probability of this being the case (i.e. sero presence) is in fact very high.

Therefore the estimates of PRRS infectivity in US swine herds provided by APHIS in fact underestimate the prevalence. As such APL contends that the conclusions reached by BA remain relevant.

APHIS notes that infection in Australia would require an oral dose (waste unit) and that the minimum oral infectious dose has not been determined in any referred study outside the Lelystad project. It then goes on to quote related work with Lactate Dehydrogenase Elevating Virus3 (LDV) in mice and quotes ID<sub>50</sub> for LDV and for PRRS in the range <10<sup>1.8</sup> to 10<sup>5.3</sup> APHIS subsequently infers that doses greater than those established in the Lelystad study (<10<sup>1.8</sup> ID<sub>50</sub>/gm x 500 grams) may be required to predictably infect swine with PRRS.

However CSIRO statisticians maintain that in order to determine the likelihood of infection involved in an import risk analysis, a level lower than the 50 percent infectious dose (ID<sub>50</sub>) needs to be considered. Cafruny and Hovinen (1988) referred to in the APHIS submission studied LDV and noted that while the particle/infectivity ratio for LDV had not been established it was likely to be low (1-10 particles/ID<sub>50</sub>). In addition their work noted that minimum infectious dose (MID) is poorly understood for most viruses and varies considerably depending on type and strain of the virus and the route of infection. It is therefore difficult to draw conclusions from LDV and apply the information to PRRS.

Australia wants to prevent the disease entering Australia and therefore is interested in a much lower chance of infection; say the 1% infectious dose (ID<sub>01</sub>). Even one pig infected within a herd of 100 is unacceptable. The TCID<sub>50</sub> does not adequately reflect the minimum level of infective dose. A 1% infectious dose (TCID<sub>01</sub>) more adequately reflects the minimum infective dose pertinent for use in the Australian generic IRA. TCID<sub>01</sub> would be substantially less than TCID<sub>50</sub>.

There are difficulties working with ID<sub>50</sub> information:

- It is not clear that infection of a small percentage (or a single pig in a herd) is related to body weight in the same way as a TCID<sub>50</sub>.
- The research work fails to consider the time factor involved in a commercial piggery, which is absent from the research work. It is assumed that there is no cross infection in the research to establish a TCID<sub>50</sub>. However, over time PRRS *will* be transferred between pigs within a herd to infect virtually all pigs.

Therefore it is not possible to determine the TCID<sub>01</sub> from information about the TCID<sub>50</sub>. APHIS choice of ID<sub>50</sub> highlights the difficulty in accurately predicting outcomes and the need to be more cautious. More importantly it is likely that the Lelystad study in fact will lead to an underestimate of L2 (the likelihood a waste unit would contain sufficient dose of disease agent to initiate infection).

APL concurs with APHIS (p6) that peer reviewed research material may assist in clarifying issues raised with respect to the Lelystad study. However, APL notes that APHIS has readily cited *non-peer* reviewed material in the form of a personal communication with Zimmerman (p12 footnote ii) to advocate their case.

APL also suggests that additional research should include greater examination of the respiratory route of infection versus the oral route to better determine the likelihood of rapid spread of PRRS from a single infected pig.

APHIS (p7) also seeks to draw parallels between New Zealand and Australia to highlight why they view BA's requirements for PRRS as unnecessarily restrictive. APHIS base this view on an *incorrect* assumption that New Zealand and Australia have similar patterns of feral/domestic swine exposure, garbage feeding etc. The recently confirmed incidence of PMWS in New Zealand in fact emphasizes the value of Australia having different import protocols, which reflect Australia's appropriate level of protection.

## **2.2 Government of Canada Submission**

### **2.2.1 Truncated Log Logistic Distribution**

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 more detail on the custom distribution used. Even with that further information, APL deduced from the Canadian submission that the Panel chose a Custom distribution to best represent the distribution of the size of the waste unit described in the Draft Methods Paper using @ Risk Best Fit utility (LogLogistic (0.01,0.55, 1.68) Trunc (0.01,5.0).

However, 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 submission should be rejected as based on falsehoods and BA should make that clear.

Second, the Government of Canada may 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 would suggest the potential existence of two different Draft IRA documents or at least 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 along with BA's ability to manage a transparent and scientifically rigorous analysis. Further, the differential release of information about the methodology used would limit the Australian pork industry's ability to comment effectively.

Biosecurity Australia should publicly confirm as early as possible the status of any dealings with Canada on this issue.

### **2.2.2 Release Assessments**

The Canadian submission refers to research undertaken recently in Canada confirming that PRRS virus could be isolated from the meat but that it corresponds to a "very low probability."

Canada however fails to provide greater details of this research to substantiate this claim or whether it has been peer reviewed.

The Canadian submission argues that the likelihood that meat from an infected pig will harbour the virus is substantially lower than the likelihood for oropharyngeal/tonsillar tissue and that this has not been considered by BA. On the contrary the Draft IRA appears to accept that the virus will be present in regional lymphoid tissues and that these will not be completely removed from pig meat during processing.

### **2.2.3 Exposure Assessment**

The Canadian submission challenges the assumptions made in BA's Exposure Assessment which they argue results in a number of important likelihood estimates being excluded from the risk assessment, in particular production, processing and handling, as detailed in points 2a to 2d. However, the Canadians fail to provide, or reference, the information necessary to substantiate these claims. APL also contends that the appropriate place to examine and assess these claims is in the 'Release Assessment' not the 'Exposure Assessment'.

### **2.2.4 Annual Likelihood of Entry And Exposure**

The Canadian submission challenges the calculations of the annual likelihood of entry and exposure for each exposure group as being unrealistic and constituting a worst case scenario. The Canadian's argue that a two-step process is applicable i.e. the chances of the pig eating the discarded material and then the chance it will go undetected as problematic. It is assumed that BA has treated each exposure group as a discrete unit on the basis of the potential for cross infection. APL accepts that waste units consumed by a backyard or small commercial piggery exposure group will not be distributed evenly. However, the assumption that this constitutes a 'simplistic worst case scenario' is not correct as the calculation is based on the annual likelihood. The rate of transmission within a herd would be expected to result in most if not all pigs becoming infected within the period of a year.

APL believes that BA's assessment of PRRS is appropriate in this context.

- *'cooked and processed pig meat scraps were included in the analysis because cooking and processing may not have been carried out to a level sufficient to inactivate the pathogenic agents under consideration.'* The Canadian submission misquotes the Draft IRA. The statement is an explanation about why cooked and processed scraps were included in the step not a judgement about the likelihood they will be infected.
- Contrary to the suggestion in the Canadian submission, BA *does* make an assessment of the likelihood a waste unit will contain sufficient dose to initiate infection (L2). The assessment does not differentiate cooked and uncooked waste units but makes an overall assessment of the likelihood.
- BA has assumed that all food service establishments and all households will discard some pig meat as waste. This is reasonable when it is assumed that packaging, washing down wastewater and actual waste are all sources of meat scraps and therefore sources of infection.
- BA has assumed all waste units will contain sufficient virus to initiate infection as the oral minimum infectious dose (MID) is unknown.

**2.2.5 Consequence Assessment – Estimating the likelihood of each outbreak scenario**

The Canadians have used very different outbreak scenario probabilities than those advocated by BA. Table 1 in the Canadian document, however, is not a table of results; it simply shows the probabilities that the Canadians have decided to use for the likelihood that the outbreak scenario would occur.

On page 9 of the Canadian submission they rightly state that the sum of outbreak scenario probabilities should sum to one (assuming the probabilities are mutually exclusive). In our previous submission dated 13 October 2003, APL acknowledged the shortcomings of grouping probabilities.

The interchange between qualitative and semi-quantitative likelihood calculations has inherent problems when trying to work from qualitative statements of likelihood (high, moderate, low) back to assumptions about semi-quantitative medians (0.85, 0.5 and 0.175 respectively). It is not correct to assume that a statement that a particular scenario has a ‘moderate’ likelihood means it has a likelihood of 0.5. There is a uniform likelihood that any value between 0.3 and 0.7 will occur and any likelihood value in this range would be described as ‘moderate’. A wide range of possible quantitative likelihoods for the four outbreak scenarios is consistent with the statements made on pages 282-284 of the Draft IRA. These include, for example:

**Table 1 Likelihood of each outbreak scenario**

Scenario	Feral pigs		Backyard Piggeries		Small commercial Piggeries	
	Likelihood (example)	Qualitative description	Likelihood (example)	Qualitative description	Likelihood (example)	Qualitative description
Scenario 1	0.026	Very low	0.175	Low	0.175	Low
Scenario 2	0.307	Moderate	0.217	Low	0.144	Low
Scenario 3	0.117	Low	0.106	Low	0.340	Moderate
Scenario 4	0.550	Moderate	0.502	Moderate	0.341	Moderate

In each case the sum of likelihoods for the various scenarios is equal to one.

It is interesting to note that Figures 6-8 of the Canadian submission have avoided using the nomenclature set out in Table 2 of the Draft IRA and have reached unity (sum of probabilities equal to one) by the use of ‘P(spread...)’ and ‘P(NOT spread...)’ to describe the likelihood and its alternative outcome at each scenario branch. This approach effectively distributes the likelihoods in Table 2 of the Draft IRA evenly around ‘moderate’; an approach advocated by APL in an earlier submission.

APL questions Canada’s suggestion that there is a problem with the outbreak scenario model and any suggestion that there are significant changes required to the outbreak scenario probabilities detailed in Table 1 above.

### 3. PMWS

APL wishes to reaffirm our position that the proposed protocols for PMWS need tightening due to the fact the science of this disease is largely unknown. APL is of the view that there needs to be more research into this disease and the required cooking regimes.

#### 3.1 Australia's PMWS Status

APL questions the assertion made by the National Pork Board (p2) and APHIS (p7) that Australia has no proof that it is PMWS free. Australia (via APL) has actively looked for clinical cases of PMWS with research to date not having found any clinical evidence of its presence.

APL has funded research at Murdoch University<sup>1</sup> for the past 3 years and also at Elizabeth Macarthur Agricultural Institute (EMAI)<sup>2</sup> - for the past 12 months with neither of these having found any clinical cases of PMWS that fulfill the criteria 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.

We note that APHIS questions the value of clinical surveys and suggests serological surveys are of greater significance, an assertion APL questions. In both cases the search for clinical cases has been an implicit part of the research protocols. Whilst both the Murdoch and EMAI research found evidence of infection (i.e. positive serological results and positive PCR results for the presence of the PCV2 virus) we highlight the fact that infection and disease are NOT interchangeable terms. In addition to this, a country is not required to satisfy serological surveys.

Recent history demonstrates that clinical signs remain the first important step in the recognition of exotic diseases. Australia's recognition of a new disease in the case 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 Denmark in their submission to BA to be necessary for PMWS diagnosis, failed to produce evidence for the disease.

APL also challenges the validity of the claim made in the submissions of NPB, APHIS, and DBMC (Veterinary and Food Advisory Service), that because Australia has PCV2 we must have PMWS. We believe this argument is a very simplistic view of PMWS. Whilst recent reports still 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"<sup>3</sup>. 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"<sup>4</sup>.

---

<sup>1</sup> APL Project # 1538 & # 1824 - projects into porcine circovirus

<sup>2</sup> APL Project # 1840.

<sup>3</sup> Proceedings of 2003 Leman Conference; pg. 118)

<sup>4</sup> John Deen, 'What's New with Circovirus?' International Pigletter, October 20, Vol. 23, No. 8a



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 is applicable to Australia. 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.

Furthermore the DBMC (Veterinary and Food Advisory Service) arguments regarding PMWS appear selective and at times quite contradictory. On the one hand there is the repeated claim that PCV2 is the causal agent of PMWS, and therefore Australia's requirement for risk management for PMWS is a violation of the SPS agreement since PCV2 is present in Australia. On the other hand it is admitted that the exact cause of PMWS is unknown, and that unknown factors are involved.

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 is 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 low risk, conservative approach.

APL questions the argument put forward by the DBMC (Veterinary and Food Advisory Service) submission (p4) that it is impossible to have a surveillance program on PMWS. Using the same reasoning it would be impossible to have a surveillance program for any disease where clinical signs may be ambiguous, eg CSF, or FMD in sheep; or for any new emerging disease where the aetiological agent is uncertain. Experience suggests this is not the case.

### **3.2 PMWS Measures**

In the absence of clinical PMWS, and the presence of PCV2, 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; this is countered simply and inadequately in the Danish submissions by no more than a simple assertion that they are pathogenic, hardly a scientific argument. 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 heat treatment at 100 C. Evidently further research needs to be undertaken on PMWS.

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.

There is an argument advanced that PCV2 cannot be meat borne. Certainly the virus can be present in meat, since it is a pathogen of lymphatic tissue, which is an intrinsic component of muscle and associated tissue. If it is meant that the virus cannot be transmitted in meat, then this is another unsupported assertion until the relevant experimental work is done. Likewise the claim that PMWS cannot under any circumstances be meat borne is not a scientific argument, merely an assertion.

The first possibility (which is the more likely of the three possibilities) 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 DBMC. 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 virulence<sup>5</sup>. This might be due to different strains of PCV2 or might be due to other unknown factors contributing to PMWS.

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.

There is nothing other than hope, assertion or speculation, which could support a conclusion that the third possibility – environmental factors – is the exclusive cause of PMWS. However it is only if the third factor were the exclusive cause for the difference in PMWS status of Australia and PMWS affected countries that the submissions of Canada, Denmark and the United States on this issue could be accepted.

The SPS Agreement does not require Australia to rely on such unscientific bases as hope, assertion or speculation in order to protect its environment and industries. For these reasons 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

---

<sup>5</sup> John Deen, 'What's New with Circovirus?' International Pigletter, October 20, Vol. 23, No. 8a

measures outlined in the Draft IRA should be required for importation from PMWS affected countries.

#### **4. *S typhimurium* DT104**

The APHIS submission references declining global outbreaks of *S typhimurium* DT104. APL suggests that this is Americo-centric in the extreme, particularly when the evidence for global decline is sourced from a US National study.

APHIS also draws on the Draft IRA Report noting that Australia has reported cases of DT104, which were attributed to foreign travel or consumption of infected foreign foods. APHIS then implies that human-to-human spread or human-to-animal spread is higher than through the importation of meat. There is no information provided by APHIS to support this suggestion. A foreign traveller eating infected food overseas or infected food being imported and eaten in Australia are equivalent events affected by the volume of travellers (and their eating habits) and the volume of trade. No inference can be drawn about human-to-human or human-to-animal spread.

Finally APL agrees with the issue raised by the New Zealand Ministry of Agriculture and Forestry (p3) in that the measures proposed in the Draft IRA Report to control the infection of DT104 can only be taken after the disease has become established in Australia and those measures, in turn, are likely to force importers to import uncooked meat and cook it in Australia. The Report fails to consider the sale of fresh (uncooked) Australian pig meat after the establishment of the infection in Australia.

#### **5. Methodological problems**

In respect of the IRA methodology, APL questions a number of the criticisms made by the National Pork Board (NPB). Firstly, APL challenges the NPB assertion on page 1 that a worst case situation rather than most likely situation results in accumulative effect that leads to overestimates of risk for each disease. This is very much a matter of opinion, which can best be resolved by improving the quality of data used in the analysis.

APL also questions the NPB assertion (p. 2) that the travel time required to transport meat from Midwestern U.S. is effectively a form of risk mitigation. APL suggests that this is irrelevant with respect to PRRS since this virus is sensitive to temperature and that under the proposed protocols there would be no change to temperature because product from the US will be required to be frozen during transportation. Consequently, the transit time would not be a risk mitigation measure.

NPB also charges on page 2 that risk mitigation measure such as commercial slaughtering processes were not assessed in the IRA. APL wishes to reiterate the comments we made in our previous submission regarding L2/R4 factors. APL highlighted that, *within the Draft IRA Report R4 is defined as the likelihood that a “pathogenic agent is present in the meat harvested from an infected pig” where 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.*

The APHIS submission (p.3) suggests that that the IRA's reference to 'epidemiological characteristics' of a disease does not cover the triad of disease determinants – (host-agent-environment). APHIS is critical of the primary assumption on which an Australian 'generic risk analysis' is based. BA states (p.25) '*That if a disease were present in a country, it would be present at a sustainable herd level... ..prevalence. This assumption was based on the premise that prevalence: (a) would be dictated by epidemiological characteristics of the disease, and (b) is by nature, dynamic and thus may not remain at the level cited....*' In addition APHIS claims that the above assumption is '*contrary to the most fundamental of all concepts of epidemiology, namely the concept of a "triad of disease determinants" (i.e. host-agent-environment).*' APHIS also suggests that BA's assumption indicates that the disease agent is the sole determining factor.

To the contrary, the BA assumption appears to be sound since it is dealing with a *generic* pig meat IRA. This assessment obviously assumes that there is at least a host, namely a pig. In stating this assumption, BA readily agrees that the level of disease therefore will be dictated by epidemiological factors, will be dynamic and will vary depending on the time an assessment is made. Clearly BA is acknowledging that there are environmental influences on the prevalence of the particular disease agent.

The key to BA's assumption is that it is assumed that there will be a sustainable presence. APL contends that this is a reasonable assumption in order to satisfy 'Australia's appropriate level of protection' and does not in any way contradict the fundamentals of epidemiological science; rather it confirms them.

APL also suggests that the APHIS criticism regarding disease prevalence of *Trichinella spiralis* arises due to the inherently difficult task of categorising widely different prevalence levels using the Draft IRA nomenclature. Disease prevalence studies conducted in the European Union have reported prevalence levels of less than 0.001% while China reports sero-prevalence between 0.0001% and 34.2%. This data suggests likelihood ranges from 'very low' to 'moderate' but can be broadly described as 'low'. This category underestimates risk when dealing with some countries and overestimates risk in others.

## **6. Other comments**

### **6.1 Sanitary & Phytosanitary Agreement of the WTO**

Contrary to the comments made by APHIS, the Danish Veterinary and Food Administration and the EU, APL suggest that the measures proposed for the control of PMWS in the Draft IRA do not constitute a contravention of the Sanitary and Phytosanitary Agreement (SPS) of the World Trade Organisation (WTO). APL do however believe the IRA's treatment of the issue needs to be more extensive than in the Draft.

### **6.1.1 Precautionary Principle - Article 5.7**

APL propose that in accordance with the Precautionary Principle of the SPS Agreement (Article 5.7) the most appropriate course of action for preventing the spread of PMWS is for the IRA protocols to prohibit importation from PMWS affected countries until additional research is conducted to explore the differences in strains of PCV2.

Furthermore, due to the fact evidence is emerging that the types of PMWS apparent in the US and EU have different virulence, the legitimate question arises as whether there may be other unknown factors contributing to PMWS. APL suggests that until such additional factors are identified, and in turn measures developed as to how to control it, under Article 5.7 of the SPS Agreement, BA would be justified in not allowing the importation of pork from PMWS affected countries.

### **6.1.2 Risk Assessment - Article 5.1**

We are concerned that some other submissions evidence a narrow, legalistic approach to the risk assessment in relation to PMWS and in doing so seek to ignore the science or to deflect attention from the scientific conclusions. We suggest that BA may be able to bolster the IRA against these legalistic attacks by adding material to the risk assessment to make explicit what is currently implicit in the Draft IRA.

In *Japan – Measures Affecting the Importation of Apples* the appellate body said

Members are free to consider in their risk analysis multiple agents in relation to one disease, provided that the risk assessment attributes a likelihood of entry, establishment or spread of the disease to each agent specifically.

It would be helpful if BA expanded the release and exposure assessments found at pages 387 to 399 of the Draft IRA to deal with the other factors considered as possible causes of PMWS.

We recognise that, given the paucity of scientific knowledge on the role of those other factors, little of substance will be added to the IRA by this exercise but urge BA to take this step to forestall unwarranted legalistic challenges.

## **6.2 Third Country Certification**

We note enquiries regarding finishing pigs originating from Canada (p12) with respect to third country certification. APL strongly opposes third country certification as suggested by APHIS. Canada's trade arrangements with the US through NAFTA, and subsequent acceptance of US animal health status, is a matter of concern between those two countries. They are unrelated to this process since Australia is not a party to this agreement.

## **6.3 Risk Management Measures in Practice**

As indicated in APL's previous submission the Draft Report fails to address a number of crucial issues that will impact on how the proposed risk management measures will operate in practice, including:

- BA's assessment of what constitutes disease freedom,
- BA's recognitions of zoning and regional disease free regions
- The guidelines that BA plans to put in place to demonstrate area freedom.

APL requests that it be consulted in the consideration of these issues.

## **7. Conclusion**

In the main APL is of the opinion that BA is justified in pursuing the proposed protocols, and suggest that many of the criticisms and proposed changes within stakeholder submissions responding to the Draft IRA are not substantiated. APL does however wish to emphasize that we believe there should be no watering down of the current Draft protocols with respect to PMWS and PRRS.

APL continues to oppose the importation of uncooked pig meat from PMWS and/or PRRS affected countries as these pose a significant threat to the future viability of the Australian pork industry due to its threat to the health status of the Australian pig herd. APL advocates a strengthening of PMWS protocols requiring initially a ban on importation of meat product from PMWS affected countries pending further research and subsequent consideration of a requirement that all product imported from a PMWS affected country be first cooked offshore.

APL has highlighted a number of concerns in relation to particular points raised in response to the Draft IRA Report. Key concerns are:

- Possibility that BA may have provided different information to the Canadian Government for the purposes of their submission, as compared to that received by the other stakeholders or that the Canadian submission is based on falsehoods.
- Their lack of detail regarding claimed research findings that suggest isolated PRRS virus corresponds to a very low probability.
- The assertion made by the NPB, APHIS and DBMC that Australia has no proof that it is PMWS free is inaccurate

Several submissions also appear to have prematurely concluded that because Australia has evidence of PCV2 we consequently have PMWS, despite the fact stakeholders are aware that clinical signs, microscopic lesions and evidence of the virus in lesions are also necessary factors.

In responding to the various stakeholders submissions we urge BA to remain focused on the need to ensure the necessary protocols are in place to effectively minimise risk to the Australian pig industry to an acceptably low and 'very conservative' level, as defined by Australia's appropriate level of protection<sup>6</sup>. APL wishes to emphasize that we will continue to oppose changes to the risk management measures as they relate to PMWS and PRRS, other than a temporary ban and to secure cooking of product offshore.

---

<sup>5</sup> Australia – salmon case