



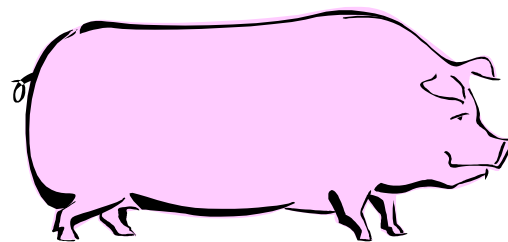
**Australian Government**

**Department of Agriculture, Fisheries and Forestry**

# Generic Import Risk Analysis (IRA) for Pig Meat

*Final Import Risk Analysis Report*

Annexes



February 2004



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*Final Import Risk Analysis Report*

Annexes

February 2004



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**Comments on the *Technical Issues Paper* (ABPM 2001/02)**

**Department of Primary Industries and Fisheries, Northern Territory**

The Northern Territory has considered the Issues Paper on Uncooked Pig Meat and found the paper to be technically comprehensive and provides the following comments for your information:

1. Section 3.2 Other pigs in Australia, page 22, 2nd paragraph – for several years there has not been any commercial harvesting of wild pigs in the NT due to the lack of markets.

***Response:*** *Noted.*

2. Section 5.7 Aujeszky's disease virus, page 50, last paragraph – cited reference, Banks et al, 1999 is not in reference list.

***Response:*** *Included in the reference list in the draft IRA report.*

3. Section 5.9 Bovine tuberculosis, page 53 world distribution – the first sentence states that “most European countries have achieved eradication” of bovine tuberculosis appears to be an over exaggeration as recent conference proceedings suggest only “some” European countries are free ie “Europe has had dramatic success in reducing [bovine] tuberculosis, but eradication from cattle remains elusive in most of its countries”.

***Response:*** *Noted.*

4. Section 5.20 Eperythrozoonosis page 73 – in the first week of March 2001 an organism morphologically consistent with Eperythrozoon suis was identified in domestic pigs from a Darwin piggery at the Berrimah Veterinary Laboratories. The pigs exhibited clinical signs (anaemia, jaundice, poor growth) consistent with eperythrozoonosis. This diagnosis has since been supported after preliminary electron microscopy investigations at AAHL.

***Response:*** *Eperythrozoon suis has been deleted from those hazards requiring risk assessment.*

### **Agriculture Western Australia**

Agwest notes the Issues Paper and I have no comment to add.

We have considered the Issue Paper for the IRA of pig meat and find it to be comprehensive and we have no issues to raise relevant to the IRA.

***Response: Noted.***

## **NSW Agriculture**

### **General comments**

It is stated on page 16 that the aim of this paper “is to document hazard *identification* relevant to the proposed importation of pig meat”. This is only the first of the five stages in the import risk analysis process outlined in the OIE Code (OIE, 1999). Given this, the present paper is quite exhaustive in its approach and one wonders why the aim and the above five stages of the OIE code were not succinctly stated much earlier and one questions the necessity for the detail of background information provided in the initial three sections.

The hazards which, were identified are often lost under the wealth of information for each particular agent given in Section 5. In Section 5, it may be worthwhile having a final paragraph, headed *Summary of hazards*, in each subsection to draw the information together.

*Response: Noted.*

### **SPECIFIC COMMENTS**

My specific comments on the paper are set out below:

#### **Section 3.1**

Paragraph 4 – presumably \$x million is meant.

*Response: The figure stated was \$633 million. This figure has been updated in the draft IRA report.*

#### **Section 3.2**

Paragraph 3 – the cause of melioidosis is now known as *Burkholderia pseudomallei*.

*Response: Amended in the draft IRA report.*

#### **Section 3.3.1**

Paragraph 3 – this is not entirely true. Victoria and South Australia do not have any government veterinary laboratories. With the advent of contracting out of laboratory services and full cost-recovery charging, field veterinarians are using laboratory services less and more veterinary diagnostic services are being undertaken by the private sector. Currently, there are no official reporting requirements placed upon private laboratories.

*Response: Noted.*

#### **Section 3.3.2**

Paragraph 3 – this is almost active surveillance in that the possibility of an exotic disease was specifically eliminated. However, in the present context, it would be more truthful to state the number of porcine cases, which were submitted for exotic disease exclusion.

*Response: Noted.*

#### **Section 3.3.4**

The passive surveillance performed by the surviving veterinary laboratory network could be detailed in this section. Section 3.3.2 should list the porcine samples submitted to AAHL, whereas in this section, the routine porcine samples submitted to all laboratories could be explored. As examples, a competent pathologist will always eliminate the possibilities of transmissible gastroenteritis and swine fever in cases of neonatal diarrhoea and neurological disease, respectively, without taking the investigations one step further by the submission of samples to the AAHL.

**Response:** *Noted.*

#### **Section 4.1**

Should the other lyssaviruses, such as Australian bat lyssavirus be listed here?

**Response:** *Australian bat lyssavirus and other lyssaviruses have been included in the draft IRA report.*

*Serpulina pilosicoli* is now known as *Brachyspira pilosicoli* and don't overlook the *Burkholderia*!

**Response:** *Amended in draft IRA report.*

#### **Section 4.2**

Table 1 – *Salmonella typhimurium* should be *Salmonella* Typhimurium; it is a serovar of *Salmonella enteritica*. *Salmonella Choleraesuis* could possibly be added to this list, as it has not been recovered in New South Wales for many years and causes economically important disease in North America.

**Response:** *Noted –the full name has been referred to initially in the draft IRA report i.e. Salmonella enterica subspecies enterica serovar Typhimurium variant Definitive Type 104 R-ACSSuT then referred to as S. typhimurium DT104.*

*Salmonella choleraesuis* was not included as a hazard as in the absence of any official control program, endemic diseases are not considered by the OIE and Biosecurity Australia to be hazards.

#### **Section 5.1**

Although of undoubted importance, this seems to be a rather lengthy discussion of the issues; perhaps it could be shortened by removing much of the information relative to ruminants.

**Response:** *Noted.*

#### **Section 5.2**

Paragraph 3 – although *it* survives in soil----. Be consistent with the use of abbreviation, VS.

**Response:** *Noted*

#### **Section 5.3**

Paragraph 1 – genus enterovirus.

**Response:** *Amended in the draft IRA report.*

Paragraph 4 – remove the subsequent “ins”.

Paragraph 6 - ---massive and leads to infection of herd mates via the gastrointestinal tract, particularly the tonsils, and skin abrasions.

**Response:** *Noted.*

#### **Section 5.4**

Relatively long dissertation considering the likely risk.

Paragraph 9 – “at when raised”?

**Response:** *Noted.*

### **Section 5.5**

African swine fever virus appears to be classified in the family *Asfviridae*.

Paragraph 4 – If the last outbreak was reported in December 1993, how can the most recent one be reported in November 1999?

Paragraph 6 – infarcts not infarctions. Reticular cells are fixed macrophages, better to say, has a significant effect on members of the mononuclear macrophage system.

*Response: Amended in the draft IRA report.*

Paragraph 12 – I am not familiar with the term “Kilograys”.

*Response: Noted.*

### **Section 5.6**

Should there be mention of the previous outbreaks in Australia?

Paragraph 5 – oral and nasal secretions are a means not a route of transmission.

Paragraph 9 – there are only two not three processing protocols described.

*Response: Previous outbreak of CSF included in the draft IRA report and report amended.*

### **Section 5.7**

Paragraph 1 – it should be herpesvirus.

Paragraph 2 – there should be a full stop at the end.

Paragraph 3 – contradictory, it states that the virus is rapidly inactivated away from the host at 4-13<sup>0</sup> C, but in the next few sentences goes on to prove that this is not the case.

Paragraph 5 – change primary to natural host. The evidence that the virus infects domestic poultry is not overwhelming. All I could find is that experimentally, the virus has infected chicken embryos, 2-day-old chickens and pigeons.

Paragraph 6 – this is not entirely true. A better summary of the pathogenesis can be found on page 313 of the latest edition of *Veterinary Virology*, Murphy *et al.* They are dendrites not dendrites.

Paragraph 7 – natural host again.

*Response: Noted, the draft IRA report amended.*

### **Section 5.8**

Paragraph 5 – remove “other”. Mention Australian bat lyssavirus?

*Response: Australian bat lyssavirus included in the draft IRA report.*

### **Section 5.9**

Paragraph 5 – calcification does not progress to the pathognomonic tubercle. The tubercle is a granuloma, sometimes with mineralised caseous contents.

*Response: Noted.*

Paragraph 7 – what about muscle associated tissue such as lymph nodes?

*Response: Included in the draft IRA report.*

### **Section 5.10**

Paragraph 4 – add “Haemorrhagic septicaemia-like disease, caused by types B:2 or E:2, has been reported in pigs in close contact with diseased cattle “to make the section relevant or remove the entire section.

**Response:** Amended in the draft IRA report.

### **Section 5.12**

Paragraph 5 – may be seen, while adult pigs may exhibit -----.

**Response:** Amended in the draft IRA report.

### **Section 5.18**

Paragraph 8 – the mature parasites cannot be intracellular, as mature males are 1.4 to 1.6mm and mature females 3 to 4mm.

**Response:** Statement from *Diseases of Swine (1999)*.

Paragraph 14 – it is now considered that nematodes infect rather infest their hosts.

**Response:** Noted.

### **Section 5.19**

The larval stage is known as *Cysticercus cellulosae* and this would be better stated in the opening paragraph.

**Response:** Amended in the draft IRA report.

Paragraph 4 – delete the particular reference to Muslim countries. It may be worthwhile highlighting its occurrence in Irian Jaya.

**Response:** Noted.

### **Section 5.20**

Paragraph 3 – punctuation in the first sentence.

Paragraph 6 – in heavily parasitised animals, the organism is likely to be present with the blood vessels in skeletal muscle; the temperature sensitivity of the organism would be important in this regard.

**Response:** *Eperythrozoon suis* has been removed as an identified hazard following the detection in Australia.

### **Section 5.21**

Paragraph 4 – cats, horses, goats and bats.

Paragraph 6 – requires rewriting. It is stated that the kidney is a major organ but it does not rate another mention. It may be preferable to commence the paragraph with the sentence “Generalised vasculitis ---. Suppurative not suppurative.

Paragraph 9 - ---, and by analogy, transmission from pigs to humans most ---.

**Response:** Noted, amended in IRA.

### **Section 5.22**

Paragraph 1 – it would be better to state that: Porcine circovirus type 2 (PCV2) has been associated with wasting, interstitial pneumonia and dermatitis nephropathy syndrome. PMWS has been successfully experimentally reproduced using PCV2. No agent characteristics are listed.

**Response:** Noted, agent characteristics included in the draft IRA report.

**Section 5.24**

Paragraph 1 – delete either tract or tissue from the last sentence.

*Response: Noted.*

**Section 5.25**

Paragraph 5 – the fact that muscle lesions are not described is irrelevant, as viraemic animals will have plenty of virus in their muscles.

*Response: Considered in the draft IRA report.*

**Section 5.26**

Remember *Salmonella* Choleraesuis and consider whether this section should focus on this serovar more.

*Response: Not exotic to Australia.*

Paragraph 3 - ----similar manner to that in the UK not EU.

*Response: Noted.*

Paragraph 5 – needs substantial revision. Malabsorption only occurs in the later stages of the enteric disease; early diarrhoea is associated with hypersecretion and inflammatory leakage. The pathogenesis of septicaemia has nothing to do with the mechanisms, which cause diarrhoea. Endotoxaemia is not necessarily associated with bacterial dissemination; it is a systemic condition, which can be associated with a localised Gram negative bacterial infection.

*Response: Amended in the draft IRA report. Reference provided for these statements.*

**Section 5.28**

Paragraph 8 – Is there any information on the effects of cooking and curing processes?

*Response: A risk assessment was not undertaken on vesicular exanthema as no longer present in any country – certification of country or zone freedom required*

**CONCLUSION**

The issues paper, “Generic Import Risk Analysis (IRA) for Uncooked Pig Meat”, meets its stated aims adequately but could be improved by the consideration of the above comments and suggestions.

**Dr Jack Reddin, Murray Bridge Veterinary Clinic**

Gentlemen

I sit here with a strong sense of foreboding responding to yet another I.R.A. for the pig industry.

The foreboding comes from the fact that the list of pig diseases put up for this I.R.A. contains new ones not on the list 5 years ago. Similarly the 1990 pig I.R.A. disease list is deficient on the 1995 list by 5 diseases. And the 1985 list is deficient of 5 more.

How then, can anyone (without a crystal ball in working order) sit down in 2000 or 2001 and do an I.R.A. for the next 1, 2 or even 3 years given the experience of the last two decades?

Is the position of the goal posts of the I.R.A. that you have been asked to assess fixed? Certainly.

Is the position of those accursed posts fixed relative to the world's pig diseases? Certainly not!

So what then of your I.R.A? Well in my view it is little more than an historical document given the evident flux of the world's pig disease status.

In my view you have the unenviable job of presiding over an 'Uncertainty Principle' that takes you well outside the I.R.A. guidelines.

In my view your role is to keep Australia's pig herds as clean and green as possible. Send those intending exporting countries photos of the imported frozen pig meat spilling into our rivers.

Send them 'I told you so' telegrams each time a new syndrome rears its head.

My perspective as a veterinarian and producer is that you must do all in your power to keep Australian free of disease, both old and impending and do not allow yourselves to be dragged down to other countries' disease levels.

To do otherwise is unthinkable.

***Response: Noted.***

**Department of Natural Resources and Environment, Victoria**

I refer to the above memorandum seeking comment on the above issues paper.

Victoria considers that the issues paper provides a thorough and comprehensive coverage of all relevant disease agents of concern.

I trust these comments will receive your serious consideration.

***Response: Noted.***

## **Pork Council of Australia (now Australian Pork Limited)**

### **Re: Import Risk Analysis on Pig Meat – Comments on Technical Issues Paper**

I write on behalf of the Pork Council of Australia (PCA) to provide comments on the Technical Issues Paper for the Generic IRA on Pig Meat.

The Technical Issues Paper is comprehensive and deals effectively with diseases and hazards that are well known and understood. The discussion of hazards also appears exhaustive. Further, the public hearing on the Technical Issues Paper – an initiative welcomed by PCA – was a useful forum as it provided the industry with the opportunity to directly communicate its concerns and to better understand the IRA process.

I would like to reiterate the points raised by PCA in this forum (and in our accompanying paper) which require further consideration to ensure that the analysis is comprehensive.

- Maintaining Australia's current quarantine status (as one of the cleanest in the world) is vital to the future competitiveness and development of the Australian pork industry. The decision and conditions for imports of animal products such as pig meat are made after considering the Appropriate Level of Protection (ALOP) required by Australia. While the determinants of Australia's ALOP are based on its conservative approach to risk management, this can vary with each IRA. There are no formal benchmarks of the ALOP allowing comparisons of risk management and consistency of application.
- As the ALOP is not defined quantitatively, the IRA panel is in the position of making a subjective decision on the level of acceptable risk to be applied to pig meat. Many factors can therefore influence the outcomes of an IRA including political and trade influences.
- Pork Council continues to be concerned with the absence of sufficient information to clarify the ALOP and how this is used in the IRA process. PCA requests that this issue is given further consideration in the forthcoming IRA document.

***Response:*** *The draft IRA report discusses Australia's ALOP. The ALOP is expressed using a risk estimation matrix to ensure consistency between different IRAs. IRAs are based on science and outcomes are not influenced by political and trade issues.*

- Biosecurity Australia is to be commended for commissioning the preliminary research into the oral transmission of PRRS. The findings of this research indicate that oral transmission of virus by way of infected meat is possible. The outcome illustrates the potential errors entailed in making assumptions about epidemiology. It also casts doubt on the adequacy of the current protocols in minimising risk to the Australian pork industry and safeguarding the health of the pig herd, particularly in light of the truck accident involving frozen pork imports last year.
- It is therefore imperative that further research be conducted on the effectiveness of heat treatment on virus transmission and that this research should be conducted under commercial conditions, or at the very least, conditions which mimic as closely as possible commercial operations to ensure practice follows principle.

**Response:** Biosecurity Australia has currently commissioned further research into the thermal stability of PRRS virus. Preliminary results indicate that the virus (in medium) was not detectable following heating at 56°C for 60 minutes.

- It is critical that any quarantine protocols governing the treatment of pig meat offshore require treatment procedures and infrastructure that are equivalent to Australian standards. Also wherever imported pigmeat is to be heat treated, a comprehensive auditing system is required. Protocols for independent random and scheduled auditing should be developed and approved by AQIS. These protocols should be part of an overall QA system and have tough sanctions policies for non-compliance.

**Response:** Noted. AQIS currently has in place an auditing system to ensure compliance for those processors using imported product.

- Further information on the current quarantine procedures for pigmeat entering the country including the adequacy of quarantine observance and prevalence of breaches (including swill feeding) is important to developing risk management. Information on the volumes of imported product by type, processing plants per country, number of exporting herds etc would also be useful. If protocols were to change then the possible expansion of import volumes and the subsequent effect on risk management should also be reviewed.

**Response:** Annual volume of trade has been incorporated in the simulation model for the disease risk assessments, up to a maximum of 151,160 tonnes shipped weight. Swill feeding has been examined in the context of the exposure assessment. In this IRA meat from the carcass of a single infected pig was chosen to be the unit for assessments. As such information on number of exporting herds was not required, nor processing plants per country.

- In light of the recent outbreaks of FMD in Europe and its rapid spread, risk management should incorporate a system of traceability for imported pig meat.

**Response:** Under the Food Standards, for traceability purposes, it is a requirement that imported food has to be labelled either with the vendor or the Australian importer's details. AQIS has also to be advised of the manufacturer or packer in Australia.

- An omission in the hazard review concerning the transmission of disease from pig meat via vectors and to meat handlers requires further review.

**Response:** Where applicable this is discussed in the risk assessments.

- Finally given recent concerns arising from BSE and cross species infectivity this disease should also be given consideration in the IRA, particularly since aspects of this disease remain elusive.

**Response:** BSE was included in the hazard identification table but has not been considered further as experimentally pigs were unable to be infected orally with high doses nor is there epidemiological evidence of infection in the field.

Further technical comments are included in the attached paper prepared by Dr Eric Thornton on behalf of the industry. Please contact me if I can provide further information.

**Response to the Issues Paper for the Import Risk Analysis of Pigmeat**

**3 April 2001**

**On behalf of the Pork Council of Australia**

*Eric Thornton*  
*Amulet Veterinary Consultancy*

**PO Box 518**  
**Beechworth Vic 3747**

**Phone/Fax 03 5728 2487**  
**Mobile 0417 490 525**

**Email: [thorntonerich@hotmail.com](mailto:thorntonerich@hotmail.com)**

## **1) SUMMARY**

This document addresses the AFFA Issues Paper for the Import Risk Analysis of Piguemeat (Jan 2001). The Issues Paper is in two parts, first an introductory and background section, and then a detailed technical discussion of the hazards to be addressed in the risk analysis.

The discussion of hazards is exhaustive, derived from detailed reviews of the scientific literature. It is uncontroversial, though inevitably there are some omissions or knowledge gaps. The diseases transmissible by consumption of pigumeat are of the highest priority for risk management, specifically FMD and the vesicular diseases, classical and African swine fever, PRRS, Aujeszky's disease and TGE. Current events internationally are highlighting the importance of swill feeding and livestock movement as risk management issues. Transmission of disease from pigumeat via vectors, and transmission to meat handlers, should not be overlooked. There are three hazards which have not been listed.

Arguably there are some omissions from the background section, relating to risk management. There is only passing reference to appropriate level of protection, current quarantine procedures for pigumeat entering Australia, and the volume of pigumeat now entering Australia (or might enter Australia if import protocols were to change). It is expected that these issues will be addressed more fully in the eventual IRA document.

*Response: Noted. These issues are addressed in the draft IRA report.*

## **2) INTRODUCTION**

On behalf of the Pork Council of Australia (PCA), this paper addresses the Issues Paper for the Import Risk Analysis of Piguemeat, released by Agriculture, Fisheries and Forestry Australia (AFFA) on January 8<sup>th</sup>, 2001.

The Issues Paper is exhaustive, running to 100 pages or so including references. It is divided into sections addressing the background of the IRA, the policy environment in which the IRA is being conducted, pig production in Australia, the determination and description of hazards to be addressed, and lists of references, annexes and abbreviations.

## **3) BACKGROUND**

### **a) History**

The History of this IRA begins in 1998 after requests to AQIS to develop import protocols for pigumeat from 9 countries, encompassing Europe (one of which, the EU, includes several member states), North America, Korea and South Africa. In May 1998 AQIS issued a proposal to conduct a non-routine risk analysis with a view to developing generic import protocols for pigumeat, and a Risk Analysis Panel was established.

### **b) Piguemeat as a commodity**

For the purposes of the IRA, pigumeat is defined as "porcine muscle tissue, blood...and any other tissues (eg lymph nodes) that may be considered from muscle". The Panel has made the important distinction between muscle and meat, and recognised that what is occurring in muscle may not be relevant for other tissues inseparable from muscle.

Following this definition are conditions necessary for meat to act as a vehicle for the transmission of a pathogen. Again the distinction is made that conditions such as temperature and pH which affect muscle, may not have the same effect on other elements of meat.

### **Methods of preservation**

There is a section of several pages on the preservation of meat products, taken from a review by the NZ Ministry of Agriculture and Forestry. Methods addressed include refrigeration, heat,

dehydration, irradiation and chemical, including traditional curing methods. The review is a useful introduction to the subject, though lacking quantitative detail. For example, while it is known that organic acids lower the pH of meat and so may inactivate pathogens, there is no information in the review of the proportional reduction of pathogens by increments of acidity, nor any information on the probability that a pH reduction may eliminate a proportion of pathogens, or all pathogens, nor how long such inactivation may take. All methods of processing in the review are addressed in a similar descriptive manner, with the exception of thermal processing.

There is more detailed quantitative information on pathogen survival in the later sections on specific hazards, in some cases quite detailed and useful.

### **c) IRA policy environment**

#### **Outline of IRA process**

It is explained how the need for IRA's arises from Australia's obligations through the World Trade Organisation (WTO) Agreement, including the Sanitary and Phytosanitary (SPS) Agreement. Under the SPS Agreement, a country's restrictions on imports on animal disease grounds must be based upon an international standard **or** a scientific risk analysis. The WTO grounds must be based upon an international standard or a scientific risk analysis. The WTO looks to the Office International des Epizooties (OIE) for international standards, but these are developed in terms of "minimum health guarantees". It is therefore appropriate for a country with a high animal health status and a conservative approach to risk management, such as Australia, to prefer the alternative of a scientific risk analysis to OIE minimal standards.

For the purpose of sound risk analysis, there are requirements for exporting countries, under the OIE Code, to provide information on a range of animal health matters to importing countries on request.

Under the SPS Agreement, there should be 5 steps in the risk analysis process: hazard identification, likelihood evaluation, consequence assessment, risk estimation and risk management. The purpose of the Issues Paper is to address hazard identification principally; the remaining steps of the process are to be addressed in more detail in the IRA paper itself.

It is explained that the SPS Agreement allows that a country is entitled to apply to imports a level of protection which it deems appropriate for human or animal health, and that this level should be consistent across all (animal) industries and species. This is termed appropriate level of protection (ALOP).

More detail could have been provided about how quarantine issues are addressed in terms of ALOP. My understanding is that this matter will be addressed more fully in the eventual IRA document.

**Response:** *The ALOP is explained in the draft IRA report, together with the risk estimation matrix.*

#### **Quarantine in Australia**

In this section the powers of government relating to quarantine are explained.

More specifically, there is brief reference to current quarantine policy for pigmeat. This section could have been expanded to provide detail of the current cooking and canning protocols, together with some information explaining their efficiency. However I now understand that this information is publicly available on the Internet.

The adequacy of quarantine observance, and prevalence of breaches, including swill feeding, are matters which should be addressed in the IRA document.

*Response: Further details on current pig meat import policy and illegal swill feeding are provided in the draft IRA report.*

#### **d) Pig production in Australia**

This section contains information on the Australian pig industry, feral pigs, and pig health in Australia.

At this point it might have been appropriate to provide more information on the volumes of imported product, both canned and subject to cooking, currently entering Australia, by country. Further breakdown into processing plants per country, and estimates of the average number of farms supplying plants, would be useful. Certainly this information would need to be applied to risk management in the draft IRA, given that risk is proportional to the volume of imports, and that import volumes need to be addressed not only in terms of tonnages, but also in terms of the number of exporting herds. The possible expansion of import volumes if protocols were to change should also be given some thought.

*Response: More information is provided on the volume of product currently being imported. Information was not required on number of processing plants per country nor average number of farms supplying plants for this simulation model. The between herd prevalence and with herd prevalence of a disease agent were required to determine the likelihood that imported pig meat that has been derived from a single carcass will be infected.*

#### **4) HAZARD IDENTIFICATION**

The identification process consisted of 2 stages. Firstly a wide list of possible pathogens or diseases were compiled, and then refined by a process of elimination. Hazards were eliminated from the list unless there was evidence that they were:

- a. infectious, and
- b. exotic, or subject to official control, and
- c. OIE listed, or would be expected to cause significant disease in Australia.

Diseases caused by environmental, genetic or nutritional factors were excluded. I have classified the identified hazards by 5 categories.

#### **5) HAZARD LIST**

##### **a) Hazards for which pigmeat has been identified as a significant source of disease outbreaks**

These diseases deserve the highest priority. Risk management measures need to be stringent and conservative.

##### **Zoonoses**

##### **Cysticercosis & Trichinellosis**

There is a known risk of transmission of these parasites to humans who consume infected pigmeat.

##### **African Swine Fever (ASF)**

The report of an outbreak in 1999 in Portugal indicates that this disease remains a significant hazard in relation to imports from Europe. The epidemiology is well understood, and it is well recognised that contaminated pigmeat has caused outbreaks of the disease. Major risk management issues therefore include pig movements and swill feeding in the EU, as well as the knowledge that the virus is relatively resistant to temperature and pH.

It is claimed in the Issues Paper that movement of ticks rather than pigs is the predominant method of transmission. If this is so, then the survival of ticks on inanimate objects (eg containers) moving between Africa and elsewhere, should be considered in risk management. This is not addressed in the Issues Paper.

**Response:** *AQIS routinely inspects cargo for invertebrates.*

### **Classical Swine Fever (CSF)**

In as much as endemic CSF is persistent in some European countries, particularly Eastern Europe, and there have been outbreaks in “free” countries (Netherlands and the UK) in the past 5 years, this disease would constitute a major hazard if there were to be pigmeat imports from Europe. CSF has been known for a long time, and so the epidemiology is well understood. The fact that outbreaks are occurring in European countries with well developed animal health systems suggests that current patterns of agricultural commerce, specifically swill feeding and livestock movement, within the EU are at odds with optimum management of this disease, and this should be considered during risk management. Blaha is quoted in the Issues Paper as stating that 2/3 of all CSF outbreaks originate in swill feeding. Given this, then there should be a higher level of risk management for imports from countries which allow swill feeding, or in which it is established that there is illegal swill feeding.

### **Foot & Mouth Disease (FMD) & Vesicular Disease**

The economic impact of FMD means that these diseases are major hazards for consideration, and infected pigmeat has been recorded as sources of outbreaks for all except VS. The current problems in Britain and Europe with FMD highlight the issue raised in the comment on CSF, that current commercial systems of pig feeding and animal movement in the EU are not altogether compatible with effective disease management. This line of argument has a 25 year history within Europe itself.

### **Teschen Disease**

This disease does not have the same potential for damage as the others so far addressed, but is nevertheless a moderately serious pathogen for pigs. There are limited reports that the feeding of pigmeat to pigs has been responsible for transmission, though the usual route is by direct contact. Despite this, there appears to be no information available about the pathogen’s survival in pigmeat. Given that the virus can survive in the environment for a considerable time, it should be assumed that it likewise survives well in meat.

### **b) Hazards for which oral transmission has been demonstrated, but pigmeat is not a major source of disease outbreaks**

Generally, consumption of pigmeat is not a major contributor to outbreaks of these diseases in the field. However it has been demonstrated that in unusual conditions, such as laboratory experimental studies, the diseases can be transmitted through pigmeat. Accordingly risk management of these diseases is less demanding, although the need to make assumptions made should be conservative. Significant contamination of meat would be quite likely in viraemic or bacteraemic animals, but unlikely in chronic carrier animals.

**Response:** *It should be noted that of the diseases listed below, in some instances pig meat has not been implicated in transmission. Further information is provided in the individual risk assessments.*

## **Zoonoses**

Only isolated pigmeat carcasses should be contaminated by these pathogens. Transmission of pathogens via meat has been achieved in exceptional circumstances. Some thought should be given to risks of transmission to meat handlers.

### **Rabies**

#### **TB, bovine**

### **Aujesky's Disease (AD)**

This is a major disease of pigs, present in many of the applicant countries. The most significant routes of transmission are by direct contact and aerosol. Outbreaks have been attributed to pigs eating rats, which in turn are infected by eating contaminated pigmeat. Rodent and other carnivore transmission therefore seems to be as much a risk management issue as direct pigmeat to pig transmission, particularly as the pathogen seems moderately robust in meat. While the Issues Paper contains references to rodents and other animals being infected by eating pigmeat, and pigs being infected by eating rats, there are no references concerning pigmeat to pig transmission, which seems a distinct possibility.

### **Eperythrozoonosis**

It seems unlikely that this disease could be spread by muscle, but possibly by oral consumption of blood (meat) by pigs, or by flies or mosquitoes contaminated by blood. No information is provided about survival times of the pathogen in blood.

*Response: Eperythrozoon suis has been identified in Australia and is no longer included as a hazard.*

### **Haemorrhagic Septicaemia**

No records are provided of pigs being infected by the consumption of infected ruminant carcasses, though it may be possible.

### **Rinderpest**

Although it is stated that pigs may become infected by eating (ruminant) offal, it is claimed that European pigs are resistant to rinderpest. As a hazard, therefore, rinderpest is more of a concern to the ruminant industries than the pig industry. However if the disease were to become established, non-domestic pigs in zoos might be a risk, and in future given semen imports, the non-European breeds such as the Meishan and its hybrids.

While the virus does appear to be fragile and short lived in carcasses, its affinity for lymphatic tissue means its potential as a hazard in meat cannot be ignored.

### **Transmissible gastroenteritis (TGE) & associated diseases**

TGE is a serious enteric pathogen of pigs. Porcine respiratory coronavirus (PRCV) is a closely related respiratory pathogen causing minimal impact. Porcine Epidemic Diarrhea (PED) is also related to TGE and causes a disease of similar appearance and severity. Because of these connections, all 3 are therefore considered here.

TGE is widespread in Europe, the Americas and Asia. The main route of transmission is direct contact between pigs, and there are no records of natural transmission through consumption of meat. However it has been demonstrated that extremely low doses of virus can be infective under experimental conditions. The first risk management issue then is to ensure that when (not if) a viraemic pig has been slaughtered for export, that sufficient steps have been taken to ensure that no virus is consumed by a pig in Australia. This may not be easy given that tissue populations of the virus in viraemic pigs are very high, and viral stability under low temperatures and low pH is high (though heat stability is low).

The second issue is that outbreaks have been attributed to birds acting as passive carriers of fomites, and the virus can multiply in house flies. There are implications here for uncooked pigmeat arriving in Australia even before consumption by a pig is considered.

There is much less known about the epidemiology of PED & PRCV, though again direct contact is the main route of transmission. Assumptions about other routes of transmission should be conservative.

***Response:** TGE, PED, PRCV are discussed under the individual disease risk assessments. It should be noted that experimentally TGE virus was transmitted to naïve pigs by feeding large quantities of tissues obtained from pigs acutely infected with TGE virus.*

### **C) Hazards for which there is no evidence of oral transmission**

A distinction to be made when considering these hazards is whether there have been efforts to demonstrate oral transmission. If experimental work has failed to demonstrate it, then there is a much higher level of confidence than if it is assumed that there is no oral transmission because no-one has taken the trouble to look.

### **Zoonoses**

#### **Eastern, Western & Venezuelan encephalomyelitis (EWVE)**

It has been assumed there is no oral transmission. Insect vectors are the main agent of infection, and again the issue of uncooked meat exposed to flies and mosquitos needs to be addressed. However as pigs are probably dead end hosts, like humans and horses, an infected carcass probably would not contain sufficient organisms to reinfect any vector.

#### **Japanese encephalitis**

The epidemiology is similar to EWVE, except that pigs are known to be important amplifiers of the disease. It is therefore feasible that mosquito vectors could be infected by exposure to contaminated carcasses, especially in northern areas of Australia, and then transmit the disease further. The risk of transmission to meat handlers from blood contaminating scratches is not addressed.

#### **Surra**

The principal route of transmission of this protozoal disease is by biting flies. Pigs are only occasionally infected, so only isolated carcasses would be potentially infective. Again, the most important risk management issue would seem to be biting flies in contact with exposed meat, and any possibility of transfer to other hosts, generally species other than pigs.

***Response:** Noted.*

#### **Swine influenza**

This is a major respiratory disease of pigs, alone or in combination with others, in most countries of the world. It is also believed to be the virus responsible for the 1918 influenza pandemic in humans. It is clear that the major route of transmission is respiratory; the fact that there is no viraemia in an infected pig suggests that transmission by consumption of muscle is unlikely. However as virus particles are concentrated in the respiratory tract, lungs (in lungworm) and associated lymph tissue, some thought should be given to the implications of these tissues contained in imported meat.

***Response:** The definition of pig meat in this IRA excludes respiratory tract tissues.*

### **d) New or emerging diseases**

These are diseases so recently recognised that there has been insufficient time to develop an adequate understanding of the epidemiology. Sometimes they are not so new, but some aspects of the epidemiology and management of the disease remain elusive.

The SPS Agreement dictates that scientific evidence alone should be the basis for making risk based decisions, and this is usually reasonable for “older” better known diseases. However as the “mad cow disease” experience indicates, this precept may not be so appropriate for recently recognised hazards. What is required with such hazards is scientific imagination as well as scientific evidence, a scientifically directed awareness of what could be happening, as well as what is known to be happening, and care that absence of evidence does not become evidence of absence. When assumptions have to be made, they should be conservative and worst case.

## **Zoonoses**

### **Nipah virus**

Nipah virus contaminated meat is a source of risk to meat handlers. The possibility also exists that contaminated meat, if fed to pigs, could produce sufficient rates of infection in pigs to be a hazard to people handling them. Whatever the provisional opinion of the authority quoted in the Issues Paper, the possibility cannot be excluded until experimental work, or sufficient time for adequate empirical observation, has demonstrated the contrary. There is no mention in the paper of the possibility of insect vectors in transmission.

***Response:** It is considered that those abattoir workers infected with Nipah virus resulted from exposure to excretions from infected pigs not from handling meat per se.*

### **Salmonella DT 104**

This is a newly recognised strain of S typhimurium, but there should be sufficient knowledge of the epidemiology of Salmonella species generally to develop sound risk management procedures.

### **PRRS**

While this disease is no longer new, in some respects it is still emerging. An example has been the conventional wisdom that the probability of viral transmission, through feeding infected meat to pigs, is low. This opinion has been based on some experimental work, and a good deal of provisional assumption. Fortunately AQIS’ commissioned studies have now demonstrated the contrary, and AQIS is to be commended for this.

Obviously some further work to demonstrate the effect of heat treatment on virus transmission, preferably under commercial conditions, is essential, given sufficient availability of funds. Risk management should be consistent with the research findings, and consistent with the draft AUSVETPLAN for PRRS.

***Response:** Biosecurity Australia has commissioned further research into the thermostability of PRRS virus.*

### **PMWS**

While it appears that porcine circovirus type 2 is present in Australia, it is not clear that the disease occurs naturally in this country. Therefore while there is evidence that PCV2 might be a necessary pathogen, there is insufficient evidence to indicate that it is a sufficient pathogen.

With our present limited knowledge of the disease, the appropriate conservative view to take would be that PMWS is either caused by an unknown pathogen, or PCV2 in conjunction with an unknown pathogen. Until demonstrated to the contrary, it should be taken that such an

unknown agent(s) can be transmitted in pigmeat. Assumptions about treatment necessary to manage the risk of transmission should be conservative.

**Response:** *Noted. Further information is available on PMWS since the issues paper was written, demonstrating that the disease can be caused by PCV2 alone.*

### **Rubula**

It is assumed that natural infection is only by inhalation. Otherwise very little is described of the epidemiology of this disease. Fortunately the disease has not been a major economic problem, and occurs only in Mexico (though Mexico is one of the applicant countries for pigmeat exports).

### **e) Hazards which have not been addressed**

#### **Transmissible spongiform encephalopathies (TSE)**

This group of diseases is recognised as primarily of ruminants, but humans and cats (experimentally) are also known to be affected. The possibility of TSE in pigs should be considered in the IRA, and acknowledged if rejected.

**Response:** *BSE was included in the hazard identification table but has not been considered further as experimentally pigs were unable to be infected orally with high doses nor is there epidemiological evidence of infection in the field.*

#### **Bat lyssavirus**

Not considered in the preliminary list of hazards.

**Response:** *Bat lyssaviruses have been included with rabies virus. It should be noted that the OIE code exempts European bat lyssaviruses type 1 and 2 when setting the requirements for countries to declare themselves free from rabies.*

#### **Transferable antibiotic resistance patterns**

Contaminant organisms (eg E coli) will enter Australia associated with pigmeat, and it is conceivable that some of these may carry genes for antibiotic resistance which are not present in Australia. It is anomalous that, following JETACAR, Australia should be endeavouring to prevent the development of antibiotic resistance within the country, while at the same time face the risk of importing resistance from countries with different standards.

**Response:** *Strains of organisms that can be clearly identified and that are genuinely different to Australian strains can be considered hazards if they comply to the usual OIE hazard criteria. An example of this is Salmonella typhimurium DT104, which is not present in Australia, and which has been considered in this IRA as a hazard. Imported food must also comply with the Imported Food Control Act 1992 and the Food Standards Code.*

### **f) An expanded classification of hazards based on methods of transmission**

The following classification, based on methods of transmission rather than other biological characters, helps to focus on the major risk management issues.

#### **Diseases known to be transmitted in nature by consumption of pigmeat**

<b><u>Affecting humans</u></b>	<b><u>Affecting animals</u></b>
Brucellosis	Classical swine fever, African swine fever
Cysticercosis & Trichinellosis	FMD & Vesicular diseases
Salmonella DT 104	Teschen disease

Highest priority required.

**Diseases which are known to be transmitted by consumption of pigmeat in exceptional circumstances, but are uncommonly transmitted in this way in nature**

<u>Affecting humans</u>	<u>Affecting animals</u>
	Aujesky's Disease
	PRRS
	TGE; ? PED, PRCV
Rabies	?PMWS
Bovine TB	Rinderpest
	?Swine Influenza

Priority diseases.

**Diseases possibly transmitted from pigmeat by vectors (rodents, birds, insects)**

<u>Affecting humans</u>	<u>Affecting animals</u>
Japanese encephalitis	Aujesky's Disease
	African swine fever
	<b>TGE</b>
	Eperythrozoonosis
	Surra

As well as these specific diseases, many of the major hazards discussed in the paper are subject to passive transmission by flies, rodents or birds. While other methods of transmission contribute more to the epidemiology of pig disease, vector transmission should not be overlooked.

**Diseases in which there is possible transmission from pigmeat to meat handlers**

<u>Affecting humans</u>
Brucellosis
Nipah virus
?Japanese encephalitis
Rabies
TB

**Diseases in which there is little risk of transmission by pigmeat**

<b>Affecting humans</b>	<b>Affecting animals</b>
EWV encephalitis	Haemorrhagic septicaemia
	Rubula
	Surra
	Swine influenza

**6) OTHER RISK MANAGEMENT ISSUES NOT ADDRESSED IN THE ISSUES PAPER**

**a) Heat treatment of imported pigmeat**

When considering heat treatment of imported meat as a risk management tool, there are pros and cons as to whether it should be located offshore or onshore. Theoretically risk is lowered most by offshore treatment.

Proponents of onshore treatment have argued that exporting plants or countries do not have the integrity or resources to ensure that offshore treatment is effective, whereas treatment in Australia might reduce risk more because it can be scrutinised better. However the recent case of imported pigmeat being accidentally deposited into an Australian river, before it could be treated, casts doubt on the presumption that treatment can be better scrutinised locally.

Wherever imported pigmeat is to be heat treated, a comprehensive auditing system is obviously desirable. Protocols for independent random and scheduled auditing should be developed and approved by AQIS. These protocols should be part of an overall QA system and have tough sanctions policies for non-compliance.

*Response: AQIS currently has in place an auditing system to ensure compliance for those processors using imported product.*

**b) Management of thaw water and wrappings from untreated imported meat**

This is an issue related not so much to the meat itself, but to agents external to meat: containers, wrapping and thaw water, rodents, birds and insects. Risk from these agents is most easily addressed through offshore management. Once onshore management is considered, a whole cluster of risk management problems have to be addressed.

*Response: This issue is addressed through the compliance agreement.*

**c) Swill feeding, pet pigs**

Obviously these are issues requiring close scrutiny, and abandonment of assumptions. It appears that states' prohibitions of swill feeding are not as absolute as thought. There is a case for review of existing permits for swill feeding in Australia, and tighter conditions or even cancellation attached to them, if there is to be a greater level of imports from additional countries. It is logical that a higher level of risk management should be applied to imports from countries which allow swill feeding, or in which illegal swill feeding is identified.

*Response: Noted. The issue of swill feeding and licences has recently been examined by States.*

**d) Traceability**

Risk management should incorporate a system of traceability for imported pigmeat, to quickly identify suspect batches should there be any failure in risk management.

**Response:** Under the Food Standards, for traceability purposes, it is a requirement that imported food has to be labelled either with the vendor or the Australian importer's details. AQIS has also to be advised of the manufacturer or packer in Australia.

**e) Zoning**

While the distribution of major diseases remains stable, zoning is subject to little objection. When distribution becomes unstable, however (eg FMD in Europe), then clearly effective risk management demands greater scrutiny of the biosecurity of disease free zones.

**Response:** Noted.

**f) Diagnostics**

Before any shipments of product commence under a generic IRA, the pig industry would be seeking an update report from AQIS on the current status of diagnostic capability within Australia, particularly at AAHL, to identify the diseases of potential risk listed in the Issues Paper and in the IRA. There would be particular interest as to whether AAHL had supplemented its IDDEX ELISA with a PCR to diagnose PRRS.

**Response:** Noted.

**7) CONCLUSION**

There is little to disagree with in the content of the Issues Paper. There are some matters which could have been addressed more fully, but as they relate to risk management, they should be addressed in the IRA document itself: appropriate level of protection, current quarantine procedures for pigmeat entering Australia and their adequacy, and the volume of pigmeat currently entering Australia (or might enter Australia if import protocols were to change).

Again, the discussion of specific diseases is comprehensive and uncontroversial, though inevitably there are some knowledge gaps. Three hazards were not entered in the preliminary list. The diseases transmissible by consumption of pigmeat are of the highest priority for risk management, specifically FMD and the vesicular diseases, classical and African swine fever, PRRS, Aujeszky's disease and TGE. The roles of swill feeding and livestock movement in the epidemiology of recent outbreaks of FMD and CSF deserve particular attention. Transmission by vectors, and to meat handlers, should not be overlooked.

**Response:** Noted.

**8) ACKNOWLEDGEMENTS**

Dr John Allen of PRDC, and Kathleen Plowman of PCA, were of considerable assistance in developing and editing this paper.

### **Australia New Zealand Food Authority**

The Australia New Zealand Food Authority (ANZFA) would like to make the following comments regarding the above Import Risk Analysis (IRA) Issues Paper.

All food imported into Australia must meet the requirements of the *Imported Food Control Act 1992* which requires food to comply with the *Australia New Zealand Food Standards Code* (FSC).

Biosecurity Australia has stated in its Issues Paper that irradiation has been recognised by ANZFA as an acceptable method to increase the shelf-life of products. Currently irradiation of pig meat is not permitted in Australia. Standard A17 – Irradiation of Food, of the FSC, prohibits the irradiation of food, or food ingredients unless specific permission is provided in the standard. Currently, no specific permission for the use of food irradiation has been included for extended shelf-life of any food product. The standard for food irradiation also imposes a labelling requirement for any food that has been irradiated and any food containing irradiated ingredients.

Before an application to irradiate food can be approved, there must be a technological justification for the irradiation of the foods in question. Technological justifications may include extension of shelf-life. The safety of the irradiated food must be assessed and an approval for use of the treatment made through ANZFA's statutory decision making process.

It is also noted in the issues paper that chemicals such as sodium chloride, sodium nitrate and nitrate are often used as curing agents used in the preservation of meat. The use of such curing agents must also meet the requirements of the FSC.

We emphasize the need to address the risk posed by the pathogens *Trichinella spiralis* and *Salmonella typhimurium* DT 104 from a public health perspective and request that an expert with relevant public health expertise be on the Risk Analysis Panel.

I trust that you will give these matters consideration in the draft IRA and that any quarantine measures will be compatible with the FSC. Please do not hesitate to contact Narelle Marro on ph 02 6271 2257 if you require further information.

**Response:** *Noted. With regard to the request that an expert with relevant public health expertise be on the risk analysis panel, the Panel was formed quite some time ago in January 1999 following consultation on the membership (Animal Quarantine Policy Memorandum 1998/99). The IRA of pig meat will not directly examine the public health issues i.e. the risks associated with the consumption of imported pig meat by humans. Biosecurity Australia has consulted with Department of Health and Ageing and FSANZ on 'zoonotic' diseases that may establish in Australia's animal population through the importation of pig meat. Any imports that might result from the findings of the report would remain subject to imported food controls determined by FSANZ and administered by AQIS.*

**Dr Frank Doughty, AQIL**

**Import Risk Analysis: Importation of Pig Meat Issues Paper  
ABPM 2001/02**

The Issues Paper as part of the IRA for importation of pigmeat appears to cover all relevant matters under the technical information on pig diseases and the preliminary results of research.

I would appreciate your advice of any significant outcomes of the public meeting scheduled for Thursday March 1<sup>st</sup>.

I look forward to receiving the draft report of the import risk analysis in due course.

*Response: Noted.*

**COMMENTS OF THE HEALTH AND CONSUMER PROTECTION DIRECTORATE  
GENERAL OF THE EUROPEAN COMMISSION ON THE AUSTRALIAN  
DOCUMENT: GENERIC IMPORT RISK ANALYSIS (IRA) FOR UNCOOKED PIG  
MEAT**

**General comments**

The Australian document is of a high quality and it provides for comprehensive and updated information on the potential risk of transmission of diseases via feeding of pigs with infected pork.

However, the Commission remarks that this document, which is preliminary to a proper risk assessment, has been awaited for a long time. The very long lasting procedures applied by Australia in relation to import of animal and animal products represent in itself an obstacle to trade.

**Comments on Chapter 2 – Policy environment**

In this chapter, the document correctly re-calls the right of each WTO Member Country to establish its appropriate level of protection, as provided for in the SPS agreement.

However, in the same chapter reference should also be made to the obligation of the Member Countries, established in the said agreement, that, when determining the appropriate level of protection, the objective of minimizing negative trade effects must be taken into account.

The Australian document does not deal with the probability that infected pork, if introduced in Australia, is used to feed pigs and then, in this way, the disease in question is transmitted to those pigs. The Commission recommends that this probability is estimated during the completion of the risk analysis, in accordance with the guidelines of the OIE on exposure assessment and consequence assessment.

More in general, the European Commission wishes to underline that it would consider an approach to this issue not excluding a “zero-risk policy” as unacceptable.

***Response:** The methods section of the draft IRA report explains the approach to determining the likelihood of entry and exposure and the likely consequences, in line with the OIE guidelines.*

**Comments on paragraph 5.6 – Classical swine fever**

Some of the epidemiological features of CSF have not been properly described in the Australian document and the current distribution of disease in the EU is not detailed and updated as necessary.

In particular, the document has not taken into consideration the major scientific advance on the epidemiology of CSF in the last decade, which concerns the role of the wild pigs as a potential virus reservoir. Indeed, discrimination between the occurrence of disease in the wild and in domestic pigs is essential to ensure that appropriate disease control measures are taken. A large amount of knowledge has become available in Europe in the last years on this topic!

CSF eradication plans, which include additional surveillance and control measures in domestic pig farms, are implemented in the Member States of the European Union where this disease

occurs in the wild pigs. Thanks to these measures, the risk that CSF spreads via pig meat from domestic pigs is largely mitigated.

The trade restrictions, which may be necessary to prevent the spread of CSF in such situations, must be based on a risk analysis that takes into account the different epidemiological features between CSF in the wild fauna and in domestic animals and the measures which are applied to control the disease, in accordance with the epidemiological situation.

Due to the generic character of the Australian document, at this stage the Commission does not deem it necessary to produce detailed information on the classical swine fever situation in the EU and on the measures which are adopted to control this disease, in particular in those few areas where the disease is persisting in the wild pigs. However, it is ready to forward this information to the Australian Authorities whenever necessary, during the next risk assessment procedures.

*Response: Noted. Biosecurity Australia looks forward to receiving a submission on the CSF situation in the EU.*

#### **Comments on paragraph 5.16 – Porcine reproductive and respiratory syndrome**

From the data included in this paragraph it results that:

- the viability of PRRS virus under a number of physical and chemical factors to which many other pig viruses are resistant is rather poor;
- PRRS virus may rarely be isolated from pork obtained from infected pigs and when it occurs its titres are quite low ( $-10^3-10^4$  TCID<sub>50</sub>/g);
- The viability of PRRS virus in meat is probably rather limited and most or all of the treatments used for preservation of meat seem to be able to lead to a reduction in virus titre or total inactivation;
- A recent experiment seems to have shown that, under certain experimental conditions, disease transmission may occur via feeding of pigs with pork from experimentally infected pigs. However, detailed data on this experiment have not been provided and it is not possible to proper comment on this topic.

As a matter of fact, to date there is no evidence that PRRS virus may be spread via trade in pig meat<sup>2</sup>.

The European Commission requests that the data on the recent experiment carried out on PRRS virus transmission via infected pork are made publicly available as quickly as possible. The Commission also requests that in order that the probability of introduction of PRRS virus in a disease free country via import of infected pork may be properly estimated, the low probability that pork from infected pigs contains the PRRS virus and the limited viability of this virus are taken into account.

*Response. Noted. The factors mentioned above have been considered in the PRRS risk assessment. Full details of the PRRS research undertaken at Lelystad have been provided to all stakeholders.*

## Canadian Food and Inspection Agency (CFIA)

### **SUBJECT: Australia's Import Risk Analysis: Importation of Pig Meat Issues Paper**

We are in receipt of the Australian document "Generic Import Risk Analysis (IRA) for Uncooked Pig Meat – *Issues Paper*" dated January 2001 and the accompanying explanatory material from your office. We very much appreciate receiving the information with an opportunity to provide comment at this stage.

The Issues Paper document is very inclusive. However, the list of diseases/disease agents identified as a hazard associated with importation would appear to be excessive for the commodity in question, given the epidemiology of diseases such as rabies, pseudorabies and WEE/EEE which are not transmitted in meat.

**Response:** *Noted. These agents have been transmitted experimentally and/or in natural circumstances through the ingestion of carcass material (may include offal) or meat and, as such, warrant further consideration in the IRA.*

The findings of the research with PRRS viruses, which was recently commissioned by AFFA at Lelystad in the Netherlands, is not unexpected, given the level of exposure of naïve piglets to the virus and sampling times in this research. I suggest that AFFA should take into account relative practical factors including the nature of the virus, the epidemiology of the disease and husbandry practices in the rearing of commercial hogs in Canada. Importantly, the low prevalence of viraemia in commercial, slaughter-weight hogs in Canada would greatly mitigate any risk of PRRS that might be associated with the importation of fresh or frozen pig meat. Canada would expect to see a realistic evaluation of the probability of the presence of the virus in uncooked pig meat and transmission of the disease to Australian swine, as opposed to a theoretical discussion of potential risks.

**Response:** *Noted. These factors have been taken into account as part of the risk assessment for PRRS virus. Biosecurity Australia understands that Canada has been undertaking research into PRRS and transmission via meat and would appreciate any information that could be supplied on this matter.*

The identification of post-weaning multi-systemic wasting syndrome with its apparent association with porcine circovirus type 2 (PCV2) as an animal health hazard would appear to be unwarranted given the presence of PCV2 in Australia and the absence of any control program.

**Response:** *PMWS has not been observed in Australia, despite the identification of PCV2.*

Canada will await with interest the findings of your risk determinations for the various diseases identified. It is expected that any sanitary measures that will be put into place following completion of this exercise will be based on scientific principles and not maintained without adequate scientific evidence.

**Response:** *Noted.*

It is currently almost three (3) years since the AQIS Policy Memorandum on the import risk analysis for pig meat was published. In the review of the document, I find no time frame for the next steps and completion of the project. In the interests of transparency, I suggest that the relative time lines should be published.

I appreciate being kept informed on this issue and having the opportunity to provide comment.

## **Animal and Plant Health Inspection Service (APHIS), United States of America**

I am writing with regard to Australia's development of an import risk assessment (IRA) for pork meat. Recently, the Animal and Plant Health Inspection Service (APHIS) forwarded comments to New Zealand in response to that country's draft risk assessment for imported pork, which was based largely on the Lelystad study. As Australia's Technical Working Group will address the same issues, including the Lelystad study, we would like to offer similar comments for the consideration of your Technical Working Group and Risk Assessment Panel.

APHIS also is drafting specific comments on the Generic Import Risk Analysis for Uncooked Pork Meat Issues Paper, dated January 2001, which was published as a foundation document for the IRA. This letter will contain a few relevant comments on the section of the Issues Paper dealing with Porcine Reproductive and Respiratory Syndrome (PRRS), along with supporting research references. Additional comments on the Issues Paper will be forwarded to you under separate cover.

The letter will also comment generally on the practical considerations of importing U.S. pork.

### **Lelystad Study**

By overemphasizing a single research effort such as the Lelystad study, APHIS is concerned that erroneous conclusions may have been reached by Biosecurity Australia which could negatively and unnecessarily impact upon the export market for U.S. pork. APHIS is unconvinced that the science supports the contention that pork meat constitutes a serious threat for PRRS virus transmission. Indeed, APHIS believes that U.S. pork is safe as U.S. butcher hogs must pass through inspected slaughtering channels and are subjected to antemortem inspection. These provisions preclude the slaughter of sick and febrile pigs. Furthermore, such butcher hogs are less likely to be infected with PRRS virus than younger pigs, as the disease is more closely associated with the farrowing house and nursery-age animals. Similarly, APHIS does not consider persistent viremia due to PRRS virus infection to be a concern. Below, we have cited specific supporting research for your reference.

***Response:** In the draft IRA report ante-mortem and post-mortem inspection are considered as part of the release scenario. It is recognised that persistent viraemia may not be a commonly reported finding, however, persistent infection of pigs with PRRS virus is reported.*

The Lelystad study created a highly artificial situation for transmission of the virus. That is, piglets were starved, fed relatively large quantities of meat from acutely infected pigs, and not offered food more representative of swill feeding. The likelihood of a similar situation happening outside of the research laboratory is remote. As the risk analysis itself says, "It is important to consider that this experiment was designed to maximize the potential for transmission of PRRS virus through pig meat."

In addition, although the Lelystad study did not utilize four control pigs that were not challenged with PRRS virus-contaminated muscle tissue, we did not find evidence in the study that sham-inoculated pigs (that is, pigs fed muscle tissue collected from PRRS virus-free pigs) were used to control for any laboratory contamination or pre-existing infection with PRRS virus.

***Response:** All animals were tested negative prior to the experiment. Control pigs were housed separately to demonstrate that laboratory/worker contamination did not occur.*

Clearly, further analysis is necessary to determine the likelihood of virus transmission under more realistic conditions. Interestingly, Canada is currently undertaking research to investigate the potential for infecting susceptible pigs, using pork obtained from commercial slaughter

channels. Also, in her recent visit to the United States, Dr. Robyn Martin, Biosecurity Australia, noted that a new study is currently underway at Lelystad investigating transmission of the PRRS virus from market-aged hogs, and that the results from this study will be incorporated into the draft IRA. APHIS looks forward to reviewing the results of these works, as they should more closely reflect conditions as they occur outside of the laboratory.

**Response:** *Biosecurity Australia would welcome any information on the Canadian study. Dr Robyn Martin stated on her visit to the United States of America that Australia was not conducting research into PRRS virus transmission with market-age pigs but would welcome information on this matter from other countries such as the USA.*

APHIS found the Lelystad study to have proven only that under controlled laboratory conditions which amplify exposure levels, pigs could be infected from large doses of meat from acutely infected pigs. Specifically, the researchers captured peak viremia at the time of slaughter and immediately fed large quantities of infected meat to feed-deprived susceptible pigs. We cannot correlate the results of this artificial situation with any substantial levels of risk during normal slaughter and trade activities.

### **New Zealand's Draft Risk Assessment**

I also would like to share APHIS' concerns regarding New Zealand's incomplete draft risk assessment. As stated in the draft risk analysis, a risk assessment consists of four interrelated steps: release assessment; exposure assessment; consequence assessment; and risk estimation. To date, New Zealand has completed only the release assessment.

The conclusion of the release assessment was that "there is a non-negligible likelihood that chilled or frozen pig meat from a country with endemic PRRS will harbor infectious PRRS virus when imported into New Zealand." The other three steps are not completed yet. Thus, the magnitude of the risk and potential for adverse consequences has not been established yet.

APHIS has other specific concerns about the release assessment. For example, New Zealand concluded that "there is a moderate to high likelihood of a pig being infected with either a field or vaccine strain of PRRS virus at the time of slaughter." APHIS rejects this conclusion for the following reasons:

- 1 Research documents that infection of weaned pigs with PRRS virus is much more likely to occur in the nursery than during the latter 2-4 weeks of the finishing period. Consequently, exposure of finished market pigs is less likely. (Dee SA and Deen J, *Vet Rec*, 2001,149:678-680; Dee SA and Philips RE, *Swine Health and Production*, 1999, 7:237-239; Dee SA et al, *Vet Rec*, 1997, 140:247-248; Dee SA and Joo HS, *Vet Rec*, 1994, 135:6-9; Dee SA et al, *Swine Health and Production*, 1993, 1:20-23).
- 2 Viremia in older pigs tends to be quite short (viremia tends to disappear rapidly in those pigs that might have been exposed). The tabulated data below demonstrate typical results of persistence of viremia when comparing pigs of different ages when exposed. The data indicate that as the number of weeks post exposure increases, the number of viremic gilts or pigs decreases.

**Response:** *Noted. One recent study detected viral RNA up to 251 days post-infection in one of 28 pigs. Viraemia is not the only indication that meat will contain PRRS virus. Persistent infection is a feature of PRRS. Virus has been detected in tonsils for prolonged periods.*

Weeks post exposure						
1	2	3	4	5	6	Gilts
3/6	0/6	0/6	**	**	**	Lager et al, 1997, Vet Micro 58:113-125
7/9	**	0/9	**	**	**	Lager et al, 1997, Vet Micro 58:127-133
7/16	0/16	0/16	0/16	**	**	Lager, et al, 1996, Vet Record, 138:227-228
8/11	2/10	0/10	**	**	**	Mengeling, et al, 1994, AJVR 55:1391-1398
16/16	8/16	3/16	1/16	1/16	0/16	Mengeling et al, 1996, AJVR 57: 834-839
14/16	2/16	0/16	**	**	**	Mengeling, et al, 1998, AJVR 59:1540-1544

						Pigs
10/10	9/10	**	**	**	**	Mengeling, et al, 1999, AJVR 60:334-340
3/3	2/3	1/3	1/3	0/3	0/3	Mengeling, et al 1996, Vet Micro 49:105-115
18/18	18/18	16/16	15/16	**	**	Wesley, et al 1998, J Vet Diagn Invest 10:221-228

\*Numerator = number of gilts or pigs viremic; Denominator = number of gilts or pigs tested. Pigs are exposed to virus at about 3-4 weeks of age. \*\*=samples not collected because study was finished.

- Persistent infections, if present, seldom result in prolonged viremia, and the virus is concentrated in tonsil or lymph nodes, not in musculature.

**Response:** *In this draft IRA report tissues such as lymph nodes which are associated with muscle are considered as pig meat.*

- Pigs of market age and weight would not be vaccinated for this disease under normal husbandry practices, nor would such vaccination be allowed because the vaccinated pigs would be subjected to a withdrawal time prior to slaughter.
- A viremic pig that displays clinical signs would not pass the antemortem examination required at slaughter plants.

**Response:** *This is taken into account in the draft IRA report.*

- Experience (both in research environments and in ongoing trade practices) demonstrates that it is relatively difficult to find viable PRRS virus in muscle tissue of market weight hogs.

As you know, the general consensus of all previous studies has been that there is a minimal risk of virus transmission through meat. The Lelystad study is not so compelling as to supersede all previous research. Since PRRS viremia appears to be an age-related phenomenon, and in general is fairly short in market weight pigs, the presumption that a significant number of market weight pigs would maintain viremia is erroneous. Indeed, research done at APHIS' National Veterinary Services Laboratories (NVSL) can give a more realistic estimate of the likelihood of finding PRRS virus in meat.

The NVSL studies, which have been presented at meetings but are not published, were conducted on sample pools taken from lots of fresh pork that were intended for export sale from 12 commercial packing plants. A total of 1,049 sample pools were taken from 178 lots of pork.

All except six of the sample pools were negative for virus isolation. Presence of virus was determined only in the second cell culture passage in some of these samples, indicating that virus was present in marginally detectable amounts. In two of these six pools, virus levels were so low that confirmation was not possible by reisolation in cell culture. In these two samples, a polymerase chain reaction (PCR) was used to demonstrate the presence of PRRS viral RNA. This research gives a more realistic estimate of the low possibility of finding virus in meat derived under standard commercial conditions.

**Response:** *Noted. This information is considered in the draft IRA report.*

APHIS is aware there are concerns that the PRRS virus might survive chilling and/or freezing. Indeed, APHIS agrees that the PRRS virus generally survives chilling and freezing temperatures. However, most research demonstrates a reduction in viral levels after freezing.

In conclusion, APHIS informed New Zealand that it disagrees with the validity of their assumptions. While APHIS acknowledges the possibility that the PRRS virus may persist in chilled meat, the conclusion that the likelihood is moderate to high is insupportable. Further studies are needed regarding the magnitude of such risk. APHIS believes that when the risk is accurately quantified, it will be insignificant.

### **Generic Issues Paper**

APHIS notes that the Generic Import Risk Analysis for Uncooked Pig Meat Issues Paper concurs with the APHIS' position that further research needs to be undertaken. APHIS further notes that the Issues Paper addresses persistence of infection as a concern, and cited the Horter study (Horter et al, 2000, Amer Assoc Swine Pract, 31<sup>st</sup> Annual Meeting, p.401) to support concerns of long-term viremia in pigs. However, in the Horter study, market-sized pigs were not used. Instead, the study used two to four-week-old pigs. The likelihood that 90 percent of older pigs would be virus carriers 105 days post infection is small. Consider the following research evidence wherein older pigs were studied:

- In a study on PRRS virus infection in boars (Swenson, S., JAVMA, 1994, Vol.204, no.12, pp 1943-1948), viremia was only detectable 7-14 days post-infection. In this study, four boars (1 to 1.5years of age) were infected with PRRS virus and bled on days 0,7,10,14,21,28,35,42, 49 and 56 following infection. Viremia based on virus isolation was only detectable between days 7-14. No virus was isolated at day 21.
- Another boar study indicated that 8 of 8 adult boars were negative for virus isolation and PCR testing 39 days post infection, and that 6 of 7 boars (one boar could not be collected) no longer had PRRS virus in the semen at 63 days post infection (JVDI 13:133-142;2001, Christopher-Hennings et al).
- Dr. Laura Batista (proceedings AASV, Kansas City, 2002, PP;357-360, manuscript accepted for publication CJVR) reported inability to detect virus at 120 to 180 days post infection using gilts infected at four months of age and slaughtered at 240-300 days of age.
- Bierk et al (2001 CJVR 65:261-266) reported inability to detect viremia in adult pigs at 14 days post infection.

These research efforts support APHIS' contention that the risk of importing PRRS virus into the Australian swine population through pork meat is inconsequential.

### **The Importation of U.S. Pork**

APHIS understands that New Zealand recently has eliminated its domestic requirement to cook garbage fed to domestic swine. Cooking this material effectively mitigates the risk of

transmitting a number of swine diseases. Nevertheless, mitigation is a moot point if no significant risk is present.

As noted above, clinical PRRS is less likely to appear in slaughter weight pigs. The U.S. Department of Agriculture's antemortem inspection procedures significantly reduce the risk of acutely infected pigs entering slaughter channels. Moreover, the time expended from slaughter to consumer is also a factor which helps to minimize any potential for risk.

The Lelystad study remarked that pigs find raw pork unpalatable, and that even following feed deprivation for two days, in many cases it was not consumed enthusiastically. From a practical standpoint, should raw pork be both available and contaminated with PRRS virus, it appears pigs will only consume it if they have been previously deprived of feed for an extended period.

Furthermore, there is a history of uneventful importation of pork from countries affected with PRRS. From 1993 through 2000, approximately 50,341,796 metric tons of frozen pork was imported into New Zealand from countries affected with PRRS. Despite this, New Zealand pigs were never infected, the country reports being free of the virus to date. Over that eight year period, the chance of importing and disseminating infection from a kilogram of infected pork, during any given year, was less than one in 6 million.

The same point is illustrated by Australia's previous PRRS survey. In 1995, surveillance was conducted using the IDEXX ELISA test, a method proven to detect antibodies to both European and North American PRRS virus isolates. The results of that study were completely negative for PRRS virus antibodies. Apparently, pork import requirements in place before the time of the survey were adequate to prevent the introduction of PRRS virus. Although a current survey in conjunction with the IRA might be instructive, it is difficult to see a need for further risk mitigation when the current system is working well.

***Response:*** *Australia has required that pig meat be cooked to address the risk of PRRS virus in meat since 1992.*

The U.S. Department of Agriculture considers Australia to be a valuable trading partner and a peer in the area of animal health and science. I trust that our comments, based on both empirical and scientific sources, will be relevant and useful to completing your IRA. We are confident that a balanced risk assessment will demonstrate that market access for U.S. pork can be established which is safe and achievable from an animal health standpoint. Please do not hesitate to contact me if you have questions or require additional information on any of these issues.

## **Animal and Plant Health Inspection Service (APHIS), United States of America**

This letter is intended to provide comments on Australia's Issues Paper on the Generic Import Risk Analysis (IRA) for Uncooked Pork Meat, dated January 2001, which was published as a foundation document for the development of an IRA for pork meat. In a letter of July 8, 2002, to Dr. J. Gardner Murray, the Animal and Plant Health Inspection Service (APHIS) commented on the section of the Issues Paper.

### **Aujeszky's Disease Virus (ADV)**

Section 5.7 of the Issues Paper addresses the disease characteristics of ADV, also known as pseudorabies virus (PRV). The paper states that "pigs and possibly rodents appear to be the only primary host". APHIS questions the statement that rodents may act as possible primary hosts for ADV. The chapter on pseudorabies (Aujeszky's disease) in "Diseases of Swine" (Kluge, et al, 8<sup>th</sup> edition, 1999, pp.233) states that the "pig is the only natural host of PR virus". Some studies not cited in the Issues Paper provide additional information about the role of rats in the transmission of ADV. An earlier chapter on pseudorabies in "Diseases of Swine" (Gustafson, 6<sup>th</sup> edition, 1986, pp.277-278) states that "if species other than swine are potential or actual reservoirs for the virus, they remain unidentified", and that "the weight of evidence suggests that wild rats do not have any specific significance either as a reservoir or disseminator of [ADV]" (Maes et al 1979) [Am J Vet Res, 1979, 40:393-396].

Furthermore, McFerran, et al (Brit Vet J., 1970, 126(4):173-8) state that "it was concluded that rats are not likely to be the reservoir for Aujeszky's disease or to play an important role in its spread." They go on to note that, "if it was infected it would die and if the pig ate the carcass [sic], it could certainly become infected. Likewise, if a pig died from Aujeszky's disease and the carcass [sic] was allowed to remain and was eaten by rats, they could become infected. However, with a required oral infective dose of about 1,000,000 virus particles, it would appear that the rat is often infected...Once infected...there appears little tendency for spread to occur".

McFerran, et al (JAVMA, 1972, 160(4):629-630), also state that "it is unlikely that a wildlife reservoir [for ADV] exists". This study further asserts that the "rat is about 1,000 [times] as resistant to infection as a sheep, and in view of this resistance to infection, our failure to obtain rat-to-rat transmission of virus, and the virulence of the virus for the rat, we feel that although the rat could play a minor role, it is unlikely to be a major factor in the epizootiology of pseudorabies disease".

Other researchers also have come to these conclusions. For example, Pensaert, et al ("Virus Infections of Porcines", 1989, p.41) state that "The pig is the only known reservoir for AD virus", and that "animal species other than swine do not seem to play a role in the dissemination of ADV either among themselves or to swine" (Ulbrich, 1970; Vandeputte and Pensaert, 1979).

It should be noted that with regard to the role of rodents in the transmission of ADV between herds, mice normally travel an area averaging 10 to 30 feet in diameter, while rats seldom travel farther than 300 feet from their burrows (Timm, "House Mice and Norway Rats, Prevention and Control of Wildlife Damage," 1994). These distances limit the ability of rodents to be of practical relevance to transmission between herds. Also, Kluge et al (Diseases of Swine, 8<sup>th</sup> edition, 1999, p.235) explain that the "incubation periods in [rats and mice] are commonly short, within 3 days; the clinical periods are characterized by rapidly progressing encephalitis with variable pruritis; and death is certain, usually within 2-3 days. The short incubation and clinical periods usually restrict transmission to a single farm."

The Issues Paper also states that a report of epidemiological evidence suggests that "farm cats may in some situations act as a reservoir for possible reintroduction of AD virus to pigs" (Weigel et al, Proceedings of the 3<sup>rd</sup> International Symposium on PRRS and Aujeszky's

Disease, 1999). According to Dr. Weigel (personal communication), further sampling of cats and rodents in 2000 on five of the six farms tested in the initial report showed no positive serology results for ADV. These farms also were no longer vaccinating for AD. According to Dr. Weigel, the final results of the study provide information that on farms that vaccinate for AD, cats and rodents may become exposed to, and immunized with, the vaccine strain of ADV. Additional laboratory evidence indicates that if these animals are then exposed to a wild type virus strain, they are able to survive. The study suggests that ADV is not maintained in the rodent, cat, and other mammalian wildlife population subsequent to removal of the farm from quarantine and cessation of vaccination.

It is also important to note that while the ADV eradication program in the United States relied on vaccination, depopulation, test and removal, and segregated weaning, the eradication program has been successful and is nearly completed without incorporating specific cat and rodent control procedures.

The Issues Paper refers to a study by Thawley et al (JAVMA 176:1001-1006, 1980) that addresses the role of rats, dogs and barn-housed ruminants in the transmission of AD infection in Norway. APHIS believes that the reference listed in the Issues Paper may be in error as the cited Thawley paper discusses PRV transmission between swine, sheep, and cattle. APHIS would appreciate clarification of the references on this issue.

***Response:*** *Noted. The draft IRA report has been amended as appropriate.*

#### *Hazard Identification*

At the recent Bilateral Sanitary Phytosanitary (SPS) meeting with Biosecurity Australia in Washington, DC, APHIS was advised that Australia's IRA process includes publication of an Issues Paper in order to identify the pest and diseases of concern and to determine whether each disease agent would be given detailed consideration in the IRA. Stakeholders are invited to comment on the technical aspects of the Issues Paper including the risk categorizations for each agent. While APHIS acknowledges the broad scope of this Issues Paper and appreciates the extensive efforts that went into development of the document, we do have some comments on the hazard identification process and categorization of disease agents.

#### *Menangle virus*

Section 4.2 of the Issues Paper addresses the process whereby causative agents associated with a variety of porcine diseases are categorized. The Paper states that a disease agent will be given detailed consideration in the IRA if it is infectious and either exotic to Australia or present in Australia but subject to official control, and either Office International des Epizooties listed and/or would cause significant disease in Australia.

Based on this categorization system, it is unclear why porcine paramyxovirus (Australia), also known as Menangle virus, is not identified as a disease of concern to be considered in the IRA. Table 1 (Preliminary index – diseases/agents of possible concern) states that porcine paramyxovirus (Australia) is not included because the disease was eradicated in pigs in Australia. As such, APHIS would classify this disease as exotic in pigs in Australia.

As noted by Kirkland et al (Aust Vet J. Vol 79, No 3, March 2001), "Although Menangle virus has been eradicated from the pig population, it remains endemic in the fruit bat colony that roosts in close proximity to the affected piggery and there is a continuing risk of reintroduction of infection. As the immune breeding herd is replaced with susceptible gilts, reintroduction of the virus could result in a reproductive problem of similar magnitude to that which occurred in 1997". APHIS questions the exclusion of Menangle virus as an identified hazard in the Issues Paper, as it appears to fulfil the requirements described in section 4.2, Hazard Refinement (page

29). The disease is undoubtedly infectious and it appears to be exotic in pigs in Australia. Menangle virus has caused significant animal disease in Australia, and the virus has demonstrated a zoonotic potential that is not yet fully defined. Moreover, the natural host (fruit bats) is present in the area, and the disease is endemic in these hosts (Halpin et al, Vet Micro, Vol 68, 83-87, 1999).

As a point of reference, in accordance with the Agricultural Bioterrorism Protection Act of 2002, APHIS has established, by regulation, a list of biological agents determined to have the potential to pose a severe threat to animals or animal products. The Act requires that all persons in possession of any listed biological agent must notify the Secretary of Agriculture of such possession. An interim rule was published in our *Federal Register* (Vol. 67, No.155, August 12, 2002, page 52, 386) which states that “two emerging paramyxoviruses (Menangle virus and Nipah virus) were included on the list...based on our determination that they potentially pose a severe threat to animal health or animal products.”

**Response:** *Noted. Australian bat paramyxovirus (Menangle virus) has not been included as a hazard for further assessment, as Biosecurity Australia is unaware that this disease is present elsewhere.*

#### *Nipah virus*

Section 5.21 (page 75) of the Issues Paper states that “as yet there does not appear to be any information available regarding virus titres in the muscle tissue of infected animals, nor the ability of the virus to withstand post mortem changes in muscle PH”. The Issues Paper further quotes the editor of Pro-MED as saying “Bear in mind that it has not been proved that Nipah virus can be transmitted by eating muscle”. APHIS is unsure whether this quotation from a Pro-MED editor as a primary source of information in the Issues Paper is relevant to the potential transmissibility of this zoonotic disease in meat to humans.

While APHIS agrees that the research has not yet been conducted to determine whether Nipah virus can indeed be orally transmitted through consumption of infected meat (although studies in Australia have demonstrated infection in pigs following oral exposure), it is important to note that, until recently, similar research was not available concerning oral transmission of the PRRS virus. Research on that issue was commissioned by Australia which demonstrated that, under extreme laboratory conditions, the virus could be transmitted in pig meat. APHIS notes that it may be possible to design a research protocol which could result in the successful oral transmission of many diseases, although oral transmission may not be a significant route of transmission.

APHIS would be interested in knowing if any research is currently being conducted or is being planned by Biosecurity Australia to investigate the transmissibility of the Menangle or Nipah viruses to pigs from consumption of infected pig tissue.

To help us better understand the current status of porcine diseases in Australia, we would also appreciate receiving the most recent survey information for Menangle virus, Nipah virus, and PRRS virus in Australian pig herds.

Thank you for providing APHIS with the opportunity to comment on the Generic Import Risk Analysis for Uncooked Pig Meat Issues Paper. We look forward to reviewing the draft IRA on pig meat when it is available.

If you require additional information regarding this issue, please contact Dr. Sara Kaman, Sanitary Trade Issues Team, National Center for Import and Export, Veterinary Services, APHIS, USDA, 4700 River Road, Unit 38, Riverdale, MD 20737. Her telephone number is

301-734-4356; her fax number is 301-734-3222; and her e-mail address is sara.Kaman@aphis.usda.gov

***Response:*** *Noted. Biosecurity Australia is not currently conducting research on Nipah virus or Menangle virus. Biosecurity Australia will forward survey information to APHIS on Menangle virus, Nipah virus and PRRS virus in Australia pig herds. None of these disease is present in the Australian domestic pig population.*



**Comments on the *Draft Methods Paper* (ABPM 2002/45)**

**Dr Frank Doughty, AQIL**

Many thanks for the recent papers providing information on the proposed approach to be used for undertaking the risk analysis.

It was very comprehensive and should result in a well-researched draft IRA report.

***Response: Noted.***

**Centres for Epidemiology and Animal Health, Animal Plant Health Inspection Service (APHIS), United States of America**

Thank you for allowing us to review and comment on the document “Generic Import Risk Analysis (IRA) for Uncooked Pig Meat: Draft Method for Import Risk Analysis,” October 2002. It is a substantial document dealing with an extremely complex topic. We very much appreciate the opportunity to provide comments while the document is still in draft form.

**Decrease dependence on assumptions:** In our review, we’ve identified some areas where the method described needs to be improved and strengthened. Specifically, we believe the document should more correctly represent qualitative and quantitative risk analysis approaches. Scientific evidence should be used whenever possible to support actual input value estimates. Instead, the proposed approach seems to promote the use of conservative assumptions. This use will lead to an overestimation of the probabilities of release and exposure. We believe that by addressing these concerns the proposed method will constitute a more accurate tool for decision-making and facilitate trade while, at the same time, achieving Australia’s appropriate level of protection.

***Response:** Where precise information is available this was utilised in the draft IRA. However, frequently this information was not available and, accordingly simple Uniform probability distributions were used. It is relatively unusual to obtain either: (a) quantitative data or a quantitative distribution that can be used directly in an import risk analysis model; or (b) quantitative data that can be used to estimate the parameters of theoretic probability distributions (e.g. the exponential distribution for bacterial decay). More commonly reported studies are examined, and the similarities and differences in design and outcome analysed.*

*This approach is a practical and transparent way of obtaining a realistic representation of the uncertainty inherent in each model input. This uncertainty can then be propagated through the model by the use of simulation. The system is not biased inherently toward conservative estimates.*

**Promote incorporation of actual data:** There are many model input values discussed in the document for which data are collected routinely and are available for many countries, including the United States. An example is the model value R1 which represents the prevalence of infected herds. On page 21, the document states “Given its dynamic nature, the herd prevalence of each identified disease will be modelled conservatively by adopting a value considered sustainable in an endemically infected country, zone, or region. It is recognized that serological evidence of infection often forms the basis of determining herd prevalence, and although this indicates exposure to the pathogenic agent it may not reflect active infection at the time of testing.”

The approach described for R1 appears to advocate the use of estimates versus actual information generated by the surveillance systems of many countries. There are well-established, scientifically-valid methods of estimating actual prevalence levels from the apparent prevalence levels obtained from serologic testing. Disregarding these methods and the data presented by potential trading partners in favor of conservative values assumed by experts in the potential importing country is not likely to be viewed as consistent with the requirements of the World Trade Organization’s Sanitary and Phytosanitary (SPS) Agreement. The SPS Agreement requires that Members take into account “available scientific evidence” (Article 5.2).

There are other examples throughout the document where conservative expert judgments are represented as being quantitatively estimated using a Pert distribution, when it would appear that available scientific evidence should be used instead. For these instances, it would seem to

be more appropriate to present the available evidence, develop a probability distribution that represents the evidence as best possible, and describe the rationale for using this distribution.

**Response:** *The pig meat IRA is generic in that it is not restricted to specific exporting countries. With regard to R1 the approach to this has been to seek to identify the sustainable herd-level prevalence, where this differentiates between the very high prevalence states observed in epidemic situations and the lower and generally more stable level of disease in animal populations in which a disease is endemic. This approach does not use directly the prevalence data from any particular exporting country but considers data from all countries where the disease is endemic.*

*Particular exporting countries may wish to submit information on their animal health situation such as, between and within herd prevalence for those diseases that require risk management, for further evaluation.*

**Appropriate use of distributions:** When the draft document discusses the incorporation of quantitative data, it encourages the use of the Pert distribution for modelling the data, pg. 15-16. The Pert distribution is used most appropriately used when modelling expert opinion, not quantitative data. The manual for @Risk (the risk analysis software discussed on page 16 of the draft document) describes the Pert distribution as being for “Rough modelling when actual data are absent” (“@Risk: Advanced Risk Analysis for Spreadsheets,” Windows version, Palisade Corporation, July 1997, page 247).

Certainly there will be model input values for which data are not available and a Pert distribution based on expert judgment would be needed and appropriate. However, rather than using the Pert distribution as a principal tool for quantitative modelling, as described in the draft document, it would best be used as a supplement to other probability distributions that are consistent with the data and evidence available for specific input values.

**Response:** *Biosecurity Australia supports the intent of the comment, in that either theoretic or precise probability distributions have been used where it is practicable to do so, but recognises the limitations of data commonly available for this import risk analysis, and hence, the need for more general distributions to represent expert opinion. The Pert is one of these, with other common examples, the Triangular and Uniform distributions. The special case of the Uniform distribution that Biosecurity Australia has used for its qualitative likelihood descriptors is a transparent way in which large numbers of analysts and readers can move toward consistent terminology for the application and interpretation of simple likelihoods.*

**Address use of expert panels in more detail:** In the case of input values for which data for quantitative modelling are not available and expert judgment must be used as a final recourse, the use of an expert panel as described in the report is reasonable. The description of the expert panel approach in the document could be enhanced by including some detailed discussion of how the makeup of the expert panel would be determined, and the method by which the panel would arrive at estimates for the parameters of the probability distributions. For example, would joint parameter estimates be determined by the panel or would the probability distributions represent the distribution of individual estimates by each panel member?

Regarding the qualitative analysis approach described on pages 15 and 16, we have suggestions on the *a priori* definition of likelihood values and their descriptors. The likelihood boundaries described on page 16 are categorised from high to negligible. The expert panel is asked to describe the likelihood of an event in words using these value-laden descriptors. These words are then translated into numerical likelihood estimates using the category boundaries described in Table 1. These numerical estimates could be viewed as purely arbitrary assignments. Instead, why not use the Pert distribution approach described in the quantitative analysis section of the document. In this way the panel could provide their opinion regarding the most accurate

numerical estimates for an input value rather than forcing numerical assignments arbitrarily. As discussed above, the Pert distribution is intended for modelling expert judgment.

**Response:** *These comments make a very useful distinction between the use of panels to obtain parameters for distributions (e.g. the minimum, most likely and maximum values of a Pert distribution), and the use of distributions to map the collective opinion of the panel. Biosecurity Australia has followed the former route, with detailed and specific panel discussion.*

*The Uniform probability distributions are simple, although frequently likelihood estimates for many variables in this import risk analysis rest on data or scientific evidence that is no more precise than this. The counter-argument for more complex distributions is that the added complexity may not be present in the underlying science.*

**Technical discussions:** We hope that you find our comments on the draft document useful and again we appreciate the opportunity to review it. Given the detailed, complex and highly technical nature of the document. We would welcome an opportunity for a technical level dialogue on its content. Perhaps an opportunity can be developed for risk analysts from both countries to review the approach together and discuss further ideas for overcoming some of the limitations we've identified above. We believe this would be beneficial for our analysts as well.

**Response:** *Noted.*

## **Department of Health and Ageing**

The methods paper refers to the Department of Health and Aged Care. The name has changed to the Department of Health and Ageing (DoHA).

*Response: Draft IRA report amended.*

**Department of Primary Industries, Victoria**

In response to ABPM 2002/45 and ABPM 2003/01, I wish to advise that Victoria has no comments to make at this time.

I look forward to the opportunity to consider further outputs from these IRAs as they become available

***Response: Noted.***

**Northern Territory Government Department of Business, Industry & Resource Development**

I refer to your letter of 12<sup>th</sup> March 2003 considering ABPM 2002/45 (pig meat) and ABPM 2003/01 (uncooked chicken meat).

I must admit that I did not allocate a lot of resources for consideration as we have one piggery and one chicken farm. I provided a copy to the pig farmer and Inghams would have been consulted at head office level.

I realise that both will be topical. I found both documents to be sound technically and did not have any constructive comments.

There will be much more interest at the next steps when the likely consequences of a hazard release are considered or change to quarantine restrictions are realised.

*Response: Noted.*

## **Australian Pork Limited (APL)**

### **Pig Meat Import Risk Analysis Draft Methods Paper**

Australian Pork Limited (APL) welcomes the opportunity to comment, on behalf of the Australian pig producers, on the Pig Meat Import Risk Analysis (IRA) Draft Methods Paper.

APL's review and comments of the IRA Draft Methods Paper is attached. APL's key concerns on the methodology are:

1. While the principles of release and exposure methodology are fundamentally sound, concerns arise on specific assumptions made including:

- Volume of trade
- Volume and distribution of waste
- Number of infective units
- Exclusion of large piggeries as an exposure group, and the classification of small pig producers
- Proportion of illegal feeders
- Unidentified disease pathways
- Proportion of pig meat purchased by the food service sector.

2. The methodology of the consequence assessment and risk estimation is unsatisfactory, as certain sections of the methodology are considered unsound and unscientific including:

- The opportunity to make estimations of risk over a period longer than a year is frustrated by the structure of the methodology.
- The complex and contrived nature of the rules and matrices obscures comprehension and transparency.
- There is a failure to provide a 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 even more abstract, is intuitively, logically and scientifically suspect.
- There is a consequent compromise of the absolute accuracy of the estimates, and a failure to match the objectivity of the earlier quantitative assessment.
- There is a particular failure of the methodology to allow objective check or challenge to 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 challenge them except by reference to one's own subjective opinions. This further renders the process unscientific.
- There is no provision for uncertainty estimates to be included in the estimation of consequences.

APL seeks to have all of the concerns raised in our review addressed and strongly encourages Biosecurity Australia to revisit these areas. It is vitally important that the questionable assumptions made in the release and exposure assessment and the flaws in the consequent and risk methodology are addressed if APL (and the exporting country applicants) are to have confidence that Biosecurity Australia's estimates and calculations do indeed provide an appropriate level of protection to the Australian pork industry, the environment and economic activity and human life.

I look forward to further advice from Biosecurity Australia on the progress of the issues raised concerning the Method Paper for the IRA of Pig Meat.

***Response:*** *Noted. These comments are addressed in the following submission from APL.*

**Review of the Biosecurity Australia (BA) Method Paper for  
the Import Risk Analysis of Pigmeat**

**7 January 2003**

**Australian Pork Limited**

**Eric Thornton<sup>1</sup>, David Pullar<sup>2</sup> and Ray Correll<sup>3</sup>, Warren Muller<sup>3</sup> and Mary  
Barnes<sup>3</sup>**

<sup>1</sup> Amulet Veterinary Consultancy, PO Box 518, Beechworth Vic. 3747

<sup>2</sup> David Pullar & Associates, 219 Argyle Street, Fitzroy Vic. 3065

<sup>3</sup> CSIRO Mathematical and Information Sciences, PMG 2, Glen Osmond SA 5064

## **SUMMARY**

The Biosecurity Australia paper is principally concerned with risk assessment. The release and exposure assessments use a quantitative methodology that is sound in principle, with some room for dispute over some of the assumptions to be entered into it.

A qualitative methodology is applied to the consequence assessment and risk estimation, using the outcomes of the quantitative methodology by converting them to quantitative terms. Generally the method is unsound, the final estimate being derived from the use of contrived and arbitrary rules, excessively subjective categorisations, and pseudo-mathematic constructs which are compounded upon each other to a high level of abstraction. The structure of the method frustrates any attempt to estimate risk over a number of years of imports, rather than just one year. The method is also unscientific, in that assessment of most of the parameters cannot be judged by reference to any external objective standard.

While Australian Pork Limited (APL) accepts that the principles of the release and exposure methodology are fundamentally sound, APL has significant concerns on some (questionable) assumptions made. Further, APL rejects the methodology of the consequence assessment and risk estimation as unsatisfactory since certain sections of the methodology are considered unsound and unscientific.

It is imperative that all of the concerns raised by APL in our review are addressed, if the industry (and the exporting country applicants) is to have confidence that Biosecurity Australia's estimates and calculations do indeed provide an appropriate level of protection to the Australian pork industry, the environment and economic activity and human life.

### **1) INTRODUCTION**

This paper presents the views on the Draft Method for Import Risk Analysis as part of the Generic Import Risk Analysis for Uncooked Pigmeat, released by Biosecurity Australia (BA) on October 1, 2002.

In the interest of brevity, this paper does not summarise and recapitulate the BA paper except where necessary to enhance explanation. This review should therefore be read in conjunction with the BA paper itself.

### **3) METHOD FOR HAZARD IDENTIFICATION (P11)**

This topic has been addressed in the Technical Issues paper and subsequent discussion. The methodology described is quite acceptable for well-understood diseases. Concerns that less well understood diseases like PMWS are addressed appropriately are met in the 2<sup>nd</sup> criterion by reference to Evans' postulates, and in the 3<sup>rd</sup> criterion: "a pathogenic agent is considered exotic if there is no report of the disease in Australia; and where strains in other countries are thought to be more virulent, then they will be considered to be exotic".

### **4) METHOD FOR RISK ASSESSMENT (p12)**

#### **a) Risk assessment (p12)**

The risk assessment begins with release and exposure assessments. These formulations yield quantitative estimations, and are generally sound in principle, though with the occasional questionable assumption. There are real challenges in obtaining quantitative estimates of the

components used in the formulations, and in fact often semi-quantitative estimates are inserted into the estimation process. Uncertainty in the estimates is acknowledged and provision is made through the use of simulations to accommodate this uncertainty.

Following the release and exposure assessments are the consequence assessment and the risk estimation. Here the methodology used is qualitative, not quantitative. In contrast to the release and exposure assessment, there is no provision for the inclusion of uncertainty into the modelling of consequence assessment.

**Response:** *Noted. The release of the Draft Methods Paper provided stakeholders with an opportunity to provide data on the assumptions.*

*It is Biosecurity Australia's opinion that the qualitative approach to consequence assessment and risk estimation is designed to accommodate uncertainty, due to the very broad and general categories used to rank consequences.*

## **b) Principles of generic risk assessment (p13)**

It is not made clear what is meant by “sustainable” prevalence.

**Response:** *Prevalence is sustainable if the remaining proportion of susceptible at-risk animals is sufficient to maintain ongoing infection and disease. This concept is central to the Reed-Frost model for disease in populations,<sup>1</sup> and is the reason why epidemics of disease die-down to a stable endemic state. The Panel has been careful not to base this or any other generic analysis on the high prevalence of disease that might be observed during an ‘epidemic’ of disease, because, under these circumstances, it is very unlikely that affected pigs would be eligible for slaughter and export.*

The assumption, that the relevant Australian standards cited are applied in the exporting country, is valid in the absence of any evidence to the contrary. This assumption might need further scrutiny if sensitivity analysis were to indicate that slaughter inspection was a critical factor in the pathway of a particular disease.

Preliminary simulations indicate that indeed slaughter inspection (L3) may be a critical factor. An output from @risk is given in Figure 1 in the Appendix (page 18). Note that the R3.1 refers to the sensitivity of the inspection process.

**Response:** *Exporting countries must meet, as a minimum, the Australian Standard for the Hygienic Production and Transportation of Meat and Meat Products for Human Consumption as is the case for domestic meat production. Some countries may employ standards of meat hygiene higher than that prescribed in the Australian Standard. Evaluation of a country's veterinary services and plant inspections may be required in some instances.*

*The sensitivity analysis supplied by APL needs to be carried out in the context of a particular disease-specific assessment. At the time of the release of the Draft Methods Paper no disease specific assessments had been released.*

Sensitivity analysis is an important aspect of risk modelling. Some facility is available for doing this in the Excel add-on @risk. The manner in which the sensitivity analysis is handled in @risk needs careful interpretation as it includes both the effects on the estimation of the risk estimate as well as the uncertainty of the risk estimate. APL is willing (through its consultants) to assist Biosecurity Australia with this aspect of the risk modelling.

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<sup>1</sup> Martin, Meek and Willeberg (1987). Veterinary Epidemiology: Principles and Practice. Iowa State University Press, Ames, Iowa, USA

**Response:** *Biosecurity Australia has used the non-parametric rank correlation as the basis for sensitivity analysis. This approach is available in @Risk, and is used routinely.*

**c) Likelihood (p13)**

**Quantitative model**

Sound justification is presented.

The use of the Pert distribution for simulations is noted. In general this distribution offers realistic shaped distributions for probabilities near 0.5. Skewed distributions can simply be achieved by modifying the most likely value in the distribution. However, a more skewed distribution may be more appropriate when there are low probabilities being modelled. In that case, a distribution whose logarithm (or perhaps inverse logit) has a Pert distribution may be more realistic.

**Response:** *The Pert distribution can be shaped simply and intuitively by specifying its maximum, most likely and minimum values. These can take whatever values the analyst feels most closely align to the variable in question – that is, there are no restrictions as regards modelling skewed variables.*

The likelihood categories, as given on page 16 of the ‘Draft Method for Import Risk Analysis’ paper, have a single category above the median, one including the median and four below the median. This is summarized in Table 1.

The final column of Table 1 is the ratio of the class limits, and is a measure of the granularity of the classes. There is a consistent trend of increasing relative class width with the decreasing likelihoods.

**Table 1 Nomenclature for likelihood categories**

Likelihood	Minimum	Maximum	Ratio Maximum/ Minimum
High	0.7	1	1.42
Moderate	0.3	0.7	2.33
Low	0.05	0.3	6
Very low	0.001	0.05	50
Extremely low	0.000001	0.001	1000
Negligible	0	0.000001	Infinite

Many of the likelihood components used in the risk modelling are in fact complements (e.g. 1 – low). Ideally therefore the likelihood categories should be symmetric about the median. This is not possible with the current categories as listed in Table 1.

**Response:** *Biosecurity Australia has chosen the particular categories because likelihoods to be estimated often lie closer to 0 than to 1. Because Biosecurity Australia has sought to minimise the number of likelihood categories, it has deliberately chosen to concentrate classification at the lower end of the 0-1 interval.*

*Whilst APL maintains that the lower likelihood categories are of increasing ‘relative width’, it should also be note that they are of rapidly decreasing ‘absolute width’. For example, the width of the negligible category is approximately  $10^{-6}$ , whilst the width of the low category is 0.25.*

*Thus, lower likelihoods have not been attributed higher 'value' by the method. The system is aligned in the manner chosen so as to allow analysts greater freedom when attributing likelihoods at the low end of the 0-1 interval.*

*All likelihoods can be viewed as complements by simply reversing the intent of the question to which each applies. This is recognised and the wording of questions has been chosen carefully.*

### **Expert judgements and quantitative data**

Often likelihoods will need to be derived qualitatively by categorisation through expert judgement. However categorisation should be used sparingly, and not substituted for quantitative information when it is available. An additional advantage of quantitative analysis is that it does not have to be constrained to the bounds of the categories, with any end points and 'most likely' points being able to be specified by experts. An extra category, "almost certain" or "approaching certainty" (P = 0.9 to 1) would allow more precision. In a sense it would approximately correspond to '(1 – Very Low)' and is a step toward obtaining symmetric likelihood categories.

*Response. If quantitative data is available this is used in the IRA. The Draft Methods Paper stated that "events considered almost certain to occur will be assigned a likelihood of 1". This has been retained in the Draft IRA Report.*

### **Evaluation (p18)**

The last sentence, "where the distribution spans more than a single range..." needs to be further explained. The import risk assessment (IRA), where there is uncertainty, will take a cautious approach. Generally this will mean using the upper 95% percentile. The estimate of the uncertainty should include all the components of the risk assessment, both the likelihood estimation and the consequence assessment.

*Response: Biosecurity Australia has determined that the median value should be reported. The reason is that the output distribution from an import risk analysis model tends to be strongly right-skewed – i.e. it has a long 'tail' which, if a probability, tends toward 1. Relatively few iterated values contribute to this tail which, as a result is quite 'imprecise'. Thus, it is believed that a more robust estimate of likelihood can be obtained from a measure of central tendency – the most appropriate in this case being the median value, or 50<sup>th</sup> percentile.*

### **(d) Release assessment (p18)**

#### **Release scenario**

The conceptual representation in Figure 3 seems sound, except that if contamination of muscle tissue by enteric organisms is to be considered, there is no apparent reason why it has not been incorporated into the model (or is this to be addressed in R4?).

*Response: Generally the issue of contamination has been considered at R4 but in the case of Salmonella DT104 the issue of contamination was examined separately.*

### **R1 & R2**

The possibility that an abattoir, whose product is destined for Australia, is drawing animals from a region with higher than country prevalence, is not specifically addressed. Is this to be addressed in the maximum value for the distribution?

**Response:** *The methods section of the Draft IRA Report states that the prevalence was modelled by adopting a value considered sustainable in an endemically infected country or zone. The values used incorporate the reported prevalence in endemic countries or zones.*

### **R3**

Assessment of efficacy of ante mortem and post mortem inspection should be conservative. This likelihood should not merely address the likelihood that efficient inspection would detect or eliminate a pathogen, but also the likelihood that inspection would be efficient, eg to account for the prevalence of inspector inattention.

**Response:** *The 'prevalence of inspector inattention' cannot be considered explicitly in an import risk analysis, however, AQIS has the ability to audit inspection and other quality assurance or biosecurity procedures. The effectiveness of inspection (in particular, its sensitivity as a diagnostic procedure) was considered in the analysis.*

### **Calculation of likelihood of entry (p24)**

This generally seems sound, but further consideration may be required for the derivation of R3.3. In particular, the consistency of R3.1 may need to be evaluated.

**Response:** *Biosecurity Australia is unclear as to the meaning of this statement, and would welcome further explanation.*

### **(e) Exposure assessment (p25)**

#### **Volume of trade**

The volume of trade is difficult to assess. Figure 4 indicates an increasing volume of imported pig meat. If this trend is repeated for uncooked pig meat, a large volume of trade should be contemplated - perhaps 200 000 t / year. This in turn will affect the potential number of infective units, and hence the likelihood of importation, spread and establishment.

The maximum value is far too low. The *worst case* scenario for the Australian industry is that all processed pig meat sold domestically becomes derived from foreign product, as in New Zealand. This means that the maximum value should be 60-65% of the domestic market. This is a possible outcome being addressed seriously by industry leaders, and there is some speculation that foreign product could even impinge on the domestic fresh pork market.

Obviously the most likely value should increase once the maximum value is raised.

**Response:** *The maximum volume of trade has been increased to 151,160 tonnes shipped weight. The most likely value has remained the same at 75,580 tonnes.*

#### **Distribution pathways (p26)**

The distribution pathways for fresh or frozen pig meat imported directly to smallgoods manufacturers have not been fully considered.

Frozen pig meat received by smallgoods manufacturers would need to be thawed before further processing. No provision has been made to consider the inactivation of pathogenic agents in meltwater.

Fresh or frozen pig meat is also further prepared for retail sale by wholesale and retail butchers. No provision has been made in the distribution pathways for waste units to include washdown water or meltwater from unfrozen imported product.

**Response:** *Biosecurity Australia maintains that the distribution pathway of pig meat to smallgoods manufacturers' has been fully considered as evident by the discussion in the methods section. Because the waste generated by smallgoods manufacturers' was considered to be very small, the quantitative analysis examined the major pathways for waste generation i.e. households and food service establishments.*

*The draft methods paper stated that if imported pig meat poses a quarantine risk to Australia, this would be apparent through the major distribution pathways. Any potential risk through minor pathways such as wash down water or melt water was examined in the context of risk management.*

### **Proportion of pig meat purchased by food service establishments (p27)**

The assumptions for the food service sector cannot be proven. The publications from the USDA (2000), Cashel (2001) and BIS Shrapnel (2002) do not provide any support for the information cited in the methodology as they do not refer specifically to pork but to the food service sector and do not accurately represent the level of pork consumed in that sector. A maximum value of 30% of pig meat production purchased by the food service sector is too high. Due to the uncertainty surrounding the levels of pig meat purchased by the food service sector and to provide sector to provide informed risk determination, specific research needs to be conducted by BA to show the proportions of pig meat purchased by the food service.

**Response:** *Further information was obtained from APL on the proportion of fresh meat purchased by food service establishments. This information, together with that presented in the Draft Methods Paper support the figures used.*

### **Waste (p29)**

Much of the material in this section is based on supposition; waste proportions, pet food, waste unit size, food service multiple. At some point evidence for these estimates is required, particularly after the results of sensitivity analysis.

**Response:** *Conservative assumptions have been made where information is lacking.*

### **Waste units**

There is a problem here that is recognised by BA. A suggestion of 250 g (with the possibility of as low as 10g) as an infective unit is suggested. These numbers appear arbitrary and should be justified.

An alternative approach is to consider the number of infective organisms required to initiate an infection – for instance in the case of the PRRS virus a value as low as 10 infective particles has been suggested (Cited in Diseases of Swine 8<sup>th</sup> Edition 1999 page 207 Pub. Blackwell Science). In that case, a 10 g waste unit would be appropriate if there was 1 unit (say virus particle) per gram. If there were 100 infective units per gram, only 0.1 g would be required to initiate a new infection. Typical densities of infective particles in infected meat need to be obtained so that a realistic and transparent method for obtaining the distribution of the weight of a waste unit can be obtained.

No reason is given why a 'Custom' distribution is chosen here (p31). Further, the 'Custom' distribution is not defined, and is not specified elsewhere in the document. It is not a standard distribution in @Risk.

**Response:** *Biosecurity Australia considers that the size of a waste unit is realistic, in that it encompasses the minimum, most likely and maximum amount of pig meat that might be discarded as trimming or spoiled meat and which a pig may consume in a day.*

*APL suggested that an alternative approach be used based on the number of organisms required to initiate infection. Generally there is limited information to model adequately oral transmission of infectious disease (notably, oral infectious dose and the precise 'load' of infectious agent present in a unit of imported pig meat – variably, frozen, thawed and cooked). It should be noted that the example given for PRRS virus of an infectious dose of 10 virions is not an oral infectious dose.*

*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)).*

### **Exposure groups (p32)**

There are a number of viable pathways which have not been considered under Exposure Groups or which may not be given sufficient weight in a risk analysis.

It is inappropriate that large piggeries should be ignored as an exposure group. While not disagreeing with the reasons given, it does seem anomalous that the IRA is failing to assess risk pertaining to the largest group of domestic pigs in the country. While the risk of exposure might be slight, the consequences of infection, eg with FMD virus, are so potentially serious epidemiologically that one would have thought large piggeries could not be ignored. For diseases specific to pigs, movement of breeding stock and semen has the most potential to transmit exotic pathogens around the country, and most of this movement originates in "large" piggeries.

**Response:** *Large commercial piggeries are included in the outbreak scenarios and accordingly the consequences of infection of this group are considered. Each of the four exposure groups has a set of outbreak scenarios, and, in each set, one scenario at least relates to the involvement of large piggeries. There is no evidence to suggest that illegal swill feeding occurs in large commercial piggeries and thus, they are not included as a primary exposure group.*

Has the Panel considered that water supply, unlike feed supply, is often beyond the control of large piggeries? There has already been one case in Australia in recent years of foreign pigmeat contaminating a river. Has the Panel considered the possibility that even in large piggeries with biosecurity rules, workers or contractors may still feed an unwanted ham sandwich to a (favourite) sow?

**Response:** *The issue of contaminated water i.e. from melt down water has been addressed above. The Panel is unaware of any evidence to suggest that illegal swill feeding occurs in large commercial piggeries, including the feeding of ham sandwiches. If APL has evidence of illegal swill feeding this should be brought to the attention of the relevant authorities.*

Also there is a concern whether the cut-off point of 99 sows for a small commercial piggery is appropriate. In this context a piggery should be considered small until it is of sufficient size that the nuisance of illegal feeding considerably outweighs its economic attractiveness in adverse conditions, eg drought. It is appropriate for this level to be closer to 500 than 100 sows.

**Response:** *There have been no prosecutions for illegal swill feeding of piggeries containing more than 100 sows. If APL has supporting evidence that piggeries with more than 100 sows have fed swill illegally this can be taken into account.*

A further pathway for exposure is that provided by animal rights activists. A small but persistent problem for the pig industry (along with poultry and other intensive livestock) is that of animal rights actions. These tend to increase with publicity for the industry such as that provided in association with changes to quarantine measures or suspected disease outbreaks.

**Response:** *The Panel were unsure of the relevance of the above comment.*

It is most important that the import risk analysis consider all possible pathways by which imported infected pig meat may present a potential risk of exposure to susceptible animals however unlikely. The further step of determining the overall importance of all pathways can then be calculated using a quantitative model and consequence assessment. In all such risk assessments, omission of a pathway will lead to an under-estimation of the risk. Unfortunately it is impractical to enumerate all the pathways, but a very serious attempt must be made. Furthermore, some pathways that may not at first be obvious may in fact be very important.

**Response:** *Biosecurity contends that all major pathways have been considered. It should be noted that at any branch in a likelihood model, the sum of likelihoods for alternative pathways must be 1. Thus, adding a pathway will lead to a reduction in the likelihood of existing pathways, rather than an automatic increase in overall “risk”. Furthermore if risk management measures are deemed necessary, the potential risk of exposure of susceptible animals to infected pig meat via minor pathways was examined in the context of risk management.*

An example of a new pathway that has recently been brought to the consultants’ attention is hand feeding of feral pigs. There is a ‘wild pork’ industry that is supported by this practice. There is no effective control on the feeding of feral pigs, and this may present an important pathway for the risk assessment, albeit one that is difficult to quantify. There may be other such pathways that hopefully will be found in the risk assessment process.

**Response:** *Feral pigs raised in this way are considered in the Draft IRA Report under the category of ‘backyard pig’. Further supporting information (numbers, location, size of operation) on this practise would be appreciated.*

### **Exposure assessment for feral pigs (p35)**

Definitions are not given for ‘Remote regions’, ‘Rural regions’ and ‘Large towns’.

**Response:** *Reference is made to the source of these categories in the Draft IRA Report.*

The binomial formula  $1-(1-P)^N$  to produce an annual likelihood for a sector is introduced without explanation. It would be good to include some words explaining the derivation of this formula.

**Response:** *The formula appears in most quantitative import risk analyses because, by and large, analyses of this type are based on the assumptions of the binomial process.*

The Panel should be cautious about making inferences about pathogens by reference to “similar or related pathogenic agents” (p36). This approach was taken when PRRS was first recognised as a pathogen, and was later demonstrated to be spurious. It might be reasonable to provisionally treat such inferences as “most likely” values. However this should be qualified

by selecting conservative minimum or maximum likelihoods as appropriate, and not be a reason to relax in the pursuit of scientific evidence to confirm inferences.

**Response:** *The Panel has taken a cautious approach with reference to relating a pathogen to similar or related pathogenic agents.*

While not disagreeing with the Panel's conclusions about the likelihoods of feral pig exposure (p39), it wonders why they departed from their own qualitative nomenclature (p 15).

**Response:** *The Draft Methods Paper did not depart from the qualitative likelihoods (see Table 1). However, to avoid confusion for readers of the Draft IRA Report likelihoods are reported. On further consideration the Panel has amended the likelihoods assigned to a feral pig locating and scavenging a waste unit in a remote and rural region in the Draft IRA Report. Given that, this likelihood examines the likelihood of a feral pig locating and scavenging an **individual** waste unit not waste units over a year. For a remote and rural region a 'very low' and 'extremely low' likelihood has been assigned respectively.*

#### **Exposure assessment for backyard pigs (p42)**

The case that "wastes fed to backyard pigs are derived from the household associated with those pigs" is not convincing. Many of the people involved in such activity are members of extended families, who would also supply their own contribution of waste.

There is a concern whether the estimate of "very low" for the proportion of illegal feeders is appropriate. "Low" would be the more conservative and appropriate estimate unless there is clear objective information to the contrary.

**Response:** *The proportion of illegal feeders was based on the number of prosecutions for people keeping backyard pigs and assumed that not all those practicing it would have been prosecuted (hence the distribution). Any data that APL has on this would be appreciated.*

#### **Exposure assessment for small commercial piggeries (p45)**

Evidence from the number of convictions suggests that the estimate of "very low" for the proportion of illegal feeders may be inappropriate. "Low" would be the more conservative and appropriate estimate unless there is clear objective information to the contrary. Reference to the recent UK FMD outbreak and its source might provide more information.

**Response:** *As above, the proportion of illegal feeders was based on the number of prosecutions for people keeping pigs (10 to 99 sows) and assumed that not all those practicing it would have been prosecuted. Any data that APL has on this would be appreciated.*

#### **Exposure assessment for 'other susceptible species' (p50)**

The susceptibility of many of the Australian species to the exotic diseases has not been evaluated thoroughly. Gaps in this knowledge provide potential pathways that are difficult to quantify. The list of potential hosts/carriers could include insects.

The uncontrolled spread of the calicivirus from Wardang Island, perhaps by a fly that was not previously considered a vector, and offers this as an illustration of how infections can move in quite unpredictable manners.

**Response:** *Noted.*

#### **Summary : Exposure assessments (p50)**

As explained, the assessments so far provide an annual likelihood of exposure for each of the exposure groups. These are later combined with consequence assessments to produce an estimate of “unrestricted annual risk”.

There is an issue here, that there is a failure to take the next logical step forward from an estimate of annual risk. If the annual risk of exposure is multiplied by the estimated likelihood of an uncontained outbreak (p55), then the outcome is a figure for the annual likelihood of an uncontained outbreak. If  $P$  = annual likelihood of an uncontained outbreak, and  $N$  = number of years then the expected number of outbreaks is  $NP$ . For example, over a 10 year period where the annual likelihood of 0.027, the expected number of outbreaks is  $0.27^2$ . The likelihood of an uncontained outbreak over a period of years can then be obtained using the binomial formula  $1-(1-P)^N$ , where  $P$  = annual likelihood of an uncontained outbreak and  $N$  = number of years.

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. After 10 years the likelihood of at least one incursion is 0.24 (*low*), after 15 years the likelihood is 0.31 (*moderate*) and after 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 19<sup>th</sup> century and classical swine fever for some 50 years or so, without reinfection. It would therefore compromise historical norms of ALOP if pigmeat 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 should fall into the “extremely low” or “negligible categories”.

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 on long periods of imports. Instead, the approach is to immediately combine annual exposures with a qualitative methodology of consequence assessment. Once this is done, it becomes impossible to consider risk implications of decisions beyond a time frame of one year.

**Response:** *Noted. The basic tenet of the comment is that, all things being equal, risk increases with the volume of product imported. As the volume imported increases, the likelihood of pest or disease introduction gets closer to one. Australia has a managed risk policy for biosecurity risks, it is not a zero risk based policy. The ALOP is based on annual risk, thus it is appropriate to compare the calculated annual risk to the ALOP.*

#### **(f) Consequence assessment (p51)**

While the methodology for the release and exposure assessments is quantitative, the methodology for consequence assessment and risk estimation is qualitative. A justification of mixing quantitative and qualitative methods of risk assessment in this way is required, especially as the qualitative methodology compromises, rather than complements, the accuracy of the quantitative estimates.

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<sup>2</sup> The formula  $1-(1-P)^N$  needs to be used to calculate the probability of at least one outbreak. Where the expected number of outbreaks is low, the expected number of outbreaks and the probability of at least one outbreak are similar. In the above example, the expected number of outbreaks is 0.27 but the probability of at least one outbreak is 0.24.

**Response:** Biosecurity Australia has chosen to model likelihood in a more quantitative way to incorporate some of the benefits of quantitative modelling – most notably, to allow a transparent analysis of the effect of trade volume on the likelihood of entry and exposure. Whilst some aspects of the consequence assessment can be considered in quantitative (monetary) terms, many are either very difficult to quantify or considered ‘intangible’. For this reason, the overall consequence assessment is qualitative. Likewise, because risk is the combination of likelihood (a probability) and consequences (a qualitative ranking) then risk will also be expressed in qualitative terms. This is desirable, because risk is evaluated against Australia’s (similarly qualitative) statement of ALOP.

### **Direct and indirect consequences**

It is claimed that indirect consequences are all costs, but it is unclear whether this means strictly \$ costs, or something more (bullet point # 4). By implication, direct consequences may be \$ costs, or other factors more difficult to cost, eg human life, environmental damage.

The estimation of consequence is difficult, as it must take into account the economic, environmental and social impacts. Furthermore, these impacts may be ongoing, so some form of discounting or compounding should be included in the modelling.

**Response:** It is recognised that some consequences were difficult to estimate in monetary terms, and for this reason (see above), a qualitative framework for consequence assessment has been adopted.

### **Describing direct and indirect disease effects (p52)**

The first step in the process is to give each consequence a qualitative impact score for each area of impact.

There is a problem here in that the classifications of district and region are not so much wrong but confusing, in as much as they are at variance with common usage. What is described as a ‘district’ (eg North West Slopes and Plains) is normally described as a ‘region’. It is claimed that a region is expected to be generally a state, but in commonplace usage all the states, even Tasmania, are referred to as a composite of a number of regions

*Response.* Classifications have been amended in the Draft IRA Report to now include, National, State or Territory, District or Region and Local.

A further weakness is that some of the terms used to classify impact into one of four categories are imprecise. Relative to each other, what is meant by ‘Unlikely to be discernible’, ‘minor’, ‘significant’ and ‘highly significant’? Without some sort of quantitative definition of these terms, it is difficult to see how the impact of a particular disease can be *objectively* categorised.

*Response.* These terms have been clarified in the Draft IRA Report.

Table 7 is set out in an unusual fashion in that the Impact score is on a margin, whereas it would normally be obtained from the body of the table. The units in that table presumably are on a logarithmic scale, with multiplicative intervals going both across and up the table. The outbreak scenarios are for local, district, regional and national importance. Presumably only the columns associated with that scenario in Table 7 (at least for direct effects) should be used – this places a large constraint on the allocation of the impact scores.

*Response.* The units of the table are not on a logarithmic scale. There are no mathematical rules as such underlying this table – it is a representation of a method for obtaining an estimate of impact measured on a national scale.

The translation of consequences to an impact score is thus not well explained. It is unclear whether the impact scores in Table 7 are meant to be consistent across levels/areas, but it does not seem that they are. For example, recent outbreaks of Newcastle Disease in poultry do not seem to fit well in any of the impact scores C to F.

*Response. The table has been amended in the Draft IRA Report.*

#### **Estimating the likelihood of outbreak scenarios (p54)**

For each of the four exposure groups, possible outcomes are categorised into four outbreak scenarios. It is stated (p55) that “an approximation (to one decimal place) is provided for the likelihood that each identified outbreak scenario would occur...” Furthermore, these four likelihoods must total 1. No data are available (nor are likely to be available) for the allocation of these likelihoods, so best guesses will be required. Presumably it is because of the lack of data that the approximations are to be to one decimal point. It will be important to determine the sensitivity of the risk assessment to these chosen likelihoods.

The application of likelihoods estimated to one decimal point presents a problem in the application of Table 8. For example 0.0 covers negligible, extremely low and very low (to one decimal place), thus making some rows of Table 8 unattainable (although in fact they do differ).<sup>3</sup>

*Response. APL has identified a typographical error in the Draft Methods Paper. This should have read one significant figure. The Draft IRA report has been amended and qualitative likelihoods are used to describe the likelihood of an outbreak scenario.*

#### **Estimating the consequences associated with each outbreak scenario (p56)**

The method of estimating consequences for each outbreak scenario is to apply a complex, rather contrived and arbitrary set of rules to the impact scores previously described. The consequences of each outbreak scenario are described in qualitative terms, ranging from “extreme” to “negligible”. While these terms have some meaning in a relative sense, ultimately they are artificial constructs one step away from the real world in an absolute sense; and from this point onwards each stage of the process in a similar way moves the assessment further into abstraction.

The above begs the question as to why the sophisticated stochastic methodology used in the release and exposure assessments has been abandoned in favour of crude deterministic point estimates. It is arguable whether the use of point estimates for the likelihood of outcomes is sufficient to meet the OIE requirement to describe the uncertainty of consequences (BA Guidelines for Import Risk Analysis p42, “Principles of Risk Assessment”, #5).

*Response. Biosecurity Australia has chosen to carry out a qualitative assessment of consequences (see above for reasons), and having made this choice, the combination of consequences and the estimation of risks must depend on decision rules rather than mathematics.*

#### **Evaluating the ‘likely consequences’ for each outbreak scenario (p56)**

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<sup>3</sup> Note that a likelihood of 0.01 (which would be considered in the very low category) is accurate to two decimals and would then require at least one other likelihood to have two significant figures to ensure the four likelihoods total to 1.00.

The likely consequences are the product of outbreak likelihood and its consequences. This is achieved by creating a qualitative matrix of consequences against estimated (p55) likelihood.

The familiar mysteries of ‘multiplication’ in BA tables are found here. It is quite unclear why moderate\* moderate = moderate, but low\*low = very low, or extremely low\*high = very low. Not only do these outcomes appear illogical, they cannot be challenged other than to offer one’s own arbitrary opinions on what the product should be. Accordingly there is a sense in which use of a table *to make estimates* is unscientific; there is no external objective standard by which the validity of these multiplications, or the accuracy of the accompanying rules, can be assessed. If there were some matrix arithmetic or other objective method behind the multiplications that would add some scientific rigour to the use of matrices in this way, then it would be advantageous to all concerned to have it explained.<sup>4</sup>

It is essential that BA explains the rules/methods used to come up with its tables.

Programming the rules and table look-ups has been undertaken in Excel so that these rules can be used in @risk simulations. The process could not be simply formulated because of the problems outlined in the previous paragraph. Accordingly that code is heavily dependent on Excel’s look-up functions.

*Response. The matrix that is used by Biosecurity Australia to combine likelihood and consequences is unique in its specifics, although not dissimilar to that which is described in an appendix to the Australian and New Zealand Standard for Risk Management (AS/NZS 4360). Similar matrices are used in most areas of risk management. Given this, the principle behind Biosecurity Australia’s matrix is that likelihoods close to 1 will not greatly alter ‘expected consequences’ or ‘risk’, whereas very small likelihoods will. Thus, the rows associated with high and moderate likelihoods are similar, whilst the rows associated with the likelihoods closer to 0 contain systematically decreasing fractions of the consequence score in the corresponding column.*

*The model need not be implemented using lookup tables.*

### **Evaluating the ‘likely consequences’ of exposing each group of susceptible animals (p57)**

The likely consequences for each outbreak scenario in the face of exposure are then combined, a process engineered by another set of unsupported rules. Once again it is essential that BA explains the rules/methods used to come up with its tables.

### **(g) Risk estimation (p58)**

This is the integration of likelihood evaluation and consequence assessment, producing another matrix and more rules follow.

Partial annual risk, the annual risk associated with each exposure group, is obtained by multiplying annual likelihood of exposure (expressed qualitatively, after conversion of the quantitative estimates) by the likely consequences on a matrix (Table 9) subject to more rules (p58).

Overall annual risk is then estimated by combining the partial annual risks, using more rules, into one of 6 risks ranging from extreme to negligible.

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<sup>4</sup> At first glance it would appear that Table 8 could be validated by using the definitions of likelihood on page 15. This is not so because although one dimension relates to likelihoods, the other dimension relates to unquantified consequences. An attempt to derive Tables 8 and 9 is given in the Appendix.

## **Comment on consequence assessment & risk estimation**

From the impact scores onwards, qualitative abstract constructs are built upon to develop constructs even more abstract, using rules and matrices which tend to be arbitrary and contrived, and require a good deal of subjective input. It is therefore inevitable that the final construct, the overall annual risk, must be divorced from reality, to an imprecise extent. Accordingly the process is far from being objective or scientific, and the outcome may be inaccurate. While it may be considered that the use of a table to rank and value estimates is valid, it is concerned that the method used here, of qualitative tables to *make* estimates, lacks scientific and logical legitimacy.

Efforts to quantify the method used for consequence analysis and risk assessment have reinforced the need for an explanation of the rules/methods used.

*Response. Biosecurity Australia has discussed above the reasons for undertaking the consequences assessment qualitatively. It is recognised that this will have flow-on effects regarding the collection of qualitative scores in a single assessment of consequences, and the combination of qualitative consequences and (generally) quantitative likelihoods.*

*Australia's statement of ALOP is qualitative, and thus, it is desirable that unrestricted risk be evaluated against this benchmark.*

## **5) METHOD FOR RISK MANAGEMENT**

This section shows how the overall annual risk is to be assessed in terms of ALOP, using firstly the unrestricted and then restricted risk. It is explained that only risk considered “very low” or “negligible” meets Australia’s ALOP. However as explained in the discussion of exposure assessment, the term “very low”, used in an annual sense, may convey a false sense of long term security.

## **6) GENERAL COMMENTS ON ESTIMATION OF RISK**

The use of @risk provides a convenient manner of undertaking a Monte Carlo simulation of the model. APL has commissioned modelling the risk analysis following the methodology outlined by BA. Such modelling enables not only the median risk to be assessed, but also various quantiles. It is suggested that the 95<sup>th</sup> percentile is used so that a conservative (precautionary) estimate of the risk can be considered by BA.

The definition of risk used takes into account not only the likelihood of entry, spread and establishment but also the consequence. The modelling effectively requires a product of the likelihood of entry and the expected consequences. It is therefore equally important to quantify both the likelihood and the consequences. Not only should distributions be applied to the likelihood estimation, but also to the consequence estimation. It must be stressed that while this paper considers that the uncertainty of the estimate of consequences should be considered, this should not be taken as an endorsement by this paper of the methodology proposed by BA for the estimation of consequences.

*Response. The Draft IRA Report uses the median value. As discussed previously, the reason is that the output distribution from an import risk analysis model tends to be strongly right-skewed – i.e. it has a long ‘tail’ which, if a probability, tends toward 1. Relatively few iterated values contribute to this tail which, as a result is quite ‘imprecise’. Thus, it is believed that a more robust estimate of likelihood can be obtained from a measure of central tendency – the most appropriate in this case being the median value, or 50<sup>th</sup> percentile.*

## **7) CONCLUSION**

The usual approach by BA, for papers issued prior to the IRA, is that no further criticism of their content is allowed after the initial release and discussion, unless new information comes to light. This approach is too stringent for the Draft Method for Import Risk Assessment, as in this case there are flaws in the methodology that may only be exposed by application of the method to particular diseases.

*Response. Comments are sought on all draft papers released, including the Technical Issues Paper, The Draft Methods Paper and now the Draft IRA Report. The Draft IRA Report incorporates the method for the IRA and stakeholders can include comments on this aspect.*

### **Release & exposure**

The release and exposure assessments are sound logically, and the quantitative methodology can be used to provide a range of possible outcomes that can be useful to the risk assessment process. With a little mathematics and the use of its own or BA estimates of the likelihood of uncontrolled outbreaks, a stakeholder can use the exposure assessments to arrive at estimates of risk over long periods of imports which it can use to mount arguments about ALOP, or alternatively reassure itself that risks are acceptable.

Accordingly the principles of the methodology are not challenged, only the specific assumptions that have been mentioned, in particular:

- Volume of trade
- Volume and distribution of waste
- Number of infective units
- Large piggeries as an exposure group, and the classification of small pig producers
- Proportion of illegal feeders.

The IRA Panel has dismissed as insignificant a number of minor components of disease pathways, eg smallgoods waste and pet food manufacture. These areas must be revisited if it is shown by sensitivity analysis to be a significant component of a biological pathway.

### **Consequence and risk estimation**

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

- The opportunity to make estimations of risk over a period longer than a year is frustrated by the structure of the methodology
- The complex and contrived nature of the rules and matrices obscures comprehension and transparency
- There is a failure to provide a 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 even more abstract, is intuitively, logically and scientifically suspect
- There is a consequent compromise of the absolute accuracy of the estimates, and a failure to match the objectivity of the earlier quantitative assessment
- There is a particular failure of the methodology to allow objective check or challenge to 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 challenge them except by reference to one's own subjective opinions. This further renders the process unscientific

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

Accordingly these sections of the methodology are considered unsatisfactory. If it were to accept them, then APL's capacity to challenge the outcome will be constrained; it will be unable to put to BA any estimate of risk over years of imports rather than just one year; and in the absence of confidence in BA's estimates, it will be unable to apply any objective standard to challenge BA's abstract calculations.

***Response:*** *These specific comments have been addressed above.*

APPENDIX

***What is the source for Tables 8 & 9?***

**(1) Table 8 & 9 Risk estimation matrix** page 57 & 59

	IMPACT					
	Negligible	Very low	Low	Moderate	High	Extreme
High	Negligible	Very low	Low	Moderate	High	Extreme
Moderate	Negligible	Very low	Low	Moderate	High	Extreme
Low	Negligible	Negligible	Very low	Low	Moderate	High
Very low	Negligible	Negligible	Negligible	Very low	Low	Moderate
E. low	Negligible	Negligible	Negligible	Negligible	Very low	Low
Negligible	Negligible	Negligible	Negligible	Negligible	Negligible	Very low

**(2) Likelihoods & Consequences** page 15 & 16

	Lower	Upper	
Extreme	0.9	1	<b>I Gussed at the Extreme Category</b>
High	0.7	0.9	
Moderate	0.3	0.7	
Low	0.05	0.3	
Very low	0.001	0.05	
E. low	0.000001	0.001	
Negligible	0	0.000001	



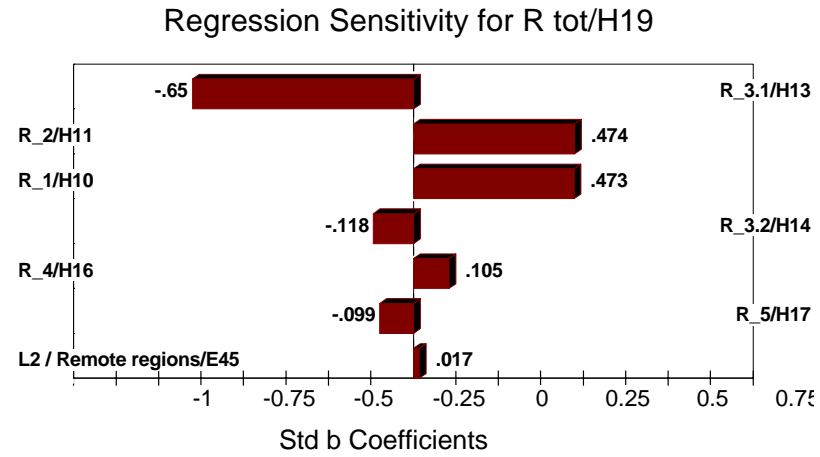


Figure 1. Sensitivity of risk estimate to input variables.  
Tornado Graph

## **Primary Industries and Resources, South Australia**

Have you included hospitals and entertainment venues in your figures for the number of food service establishments on page 48. If not, would their inclusion make any significant difference.

I have no other comments to make, but I have passed the document on to others in PIRSA who may wish to comment.

***Response:** Hospitals and institutions were not directly included in the figures, but by using a distribution of up to 105% the Panel considers that these will have been incorporated. Moreover, the number of food service establishments used included bars (which may not serve meals), and all take-away premises (such as fish and chip and chicken establishments).*



**COMMENTS ON THE *DRAFT IRA REPORT* (ABPM 2003/19)**

Stakeholder submissions on the *Draft IRA Report* have been reproduced verbatim. Responses by the Panel have been made to relevant issues as they appear in the original submission.

Some issues raised by stakeholders are outside the scope of the IRA terms of reference. Biosecurity (quarantine) policy is developed within the framework set by:

- Australia's international rights and obligations, especially as set out in the WTO's SPS Agreement;
- the Quarantine Act, and other relevant legislation, which specify the considerations that may be taken into account by AQIS decision-makers; and
- the policies of the Australian Government, especially with regard to the ALOP.

These matters have been outlined in the Biosecurity Framework section of the *Final IRA Report*.

**Department of Business, Industry and Resource Development, Northern Territory**

The NT supports the generic IRA for pig meat, and we have no particular comments.

***Response: Noted.***

## **W. Evans**

It is with great concern that I write to you about the pig meat imports.

It is just stupid to put our industry at such a grave risk by bringing in such serious diseases that are so prevalent in some of those country's that want to import pig meat into Australia.

Australia has the potential to develop a great pig meat industry. There are enormous amount of markets just north of Australia for export purposes we also have a chance of increasing the domestic markets considerably with the influx of Asian immigrants.

Australia has large open areas that are very suitable for this benefit from farms of this nature, Australia is also able to produce large quantity's of raw materials that are needed to service this meat industry.

It is ridiculous to put it all at such a great risk by allowing a few large foreign company's to import large amounts of pig meat into Australia.

These large foreign company's that are importing this meat are only interested in making a quick buck at Australia expence.

When they have stripped the country of all they can they will just pack up and leave and our grandchildren will have to try and patch up the mess they leave behind.

It seems as through the powers to be want our industry to fail, by all accounts they are recommending to the government that we need imported pig meat to supplement the export market which is just ridiculous.

The Australian farmer only needs a level playing field and, fair go, and they will produce it.

Anybody that has followed the pig markets closely over the last 5 to 8 years would know that these large company's that have been importing the pig meat have been deliberately using it to suppress the local domestic market which enables them to buy cheaper off the local farmer in a lot cases forcing them into bankruptcy. Their aim seems to be to gain full monopoly of the industry.

I beg with somebody to do something to try and save our industry as it is being forced down the gurgler at a very fast rate. We do not need imported pig meat.

***Response:*** *The Panel considers that the biosecurity policy developed protects the Australian pig industry from serious diseases of concern that could be transmitted via imported pig meat.*

*Under the SPS Agreement Australia has the right to take measures to protect human, animal or plant life or health. Such measures cannot be applied as a disguised restriction on international trade to prohibit the importation of pig meat. Similar concepts apply under Australian quarantine legislation and Government quarantine policies which have as their object the prevention or control of the introduction, establishment or spread of diseases that could cause significant damage.*

## **National Pork Board**

The National Pork Board (NPB) appreciates the opportunity to provide comments on the recently released draft Generic Import Risk Analysis (IRA) for Pig Meat, dated August 2003. The National Pork Board was established by an act of Congress in 1985 and is responsible for the collection, distribution, and program accountability for the money generated by the pork checkoff. A Board led by 15 pork producers creates programs in the areas of promotion, research, and consumer information. The export of pig meat is important to our industry and we look forward to processes such as these that allow us the opportunity to gain access to new and expanded markets.

Biosecurity Australia (BA) is to be commended on the work put into the draft IRA to this point. It provides a review of much of the swine disease literature. We do, however, wish to bring several of our concerns to your attention as you move forward with future revisions of the document:

### Risk Analysis Methodology:

NPB has consistently reviewed requests by numerous other countries to permit or alter the pig meat exporting status of their countries which includes risk assessments. The methods utilized in the Australian IRA have opted for a unique approach to the actual risk calculation. We are concerned that the statistical methods used consistently rely on data that presents a “worst-case” situation (for in-country disease prevalence as an example) rather than a “most-likely” situation that more accurately represents the risks that may be encountered. This biases each step of the risk model and results in a cumulative effect that considerably overestimates the final reported risk for each disease. We would encourage Australia to reevaluate its risk analysis methodology with particular attention to the choice of disease prevalence estimates and use of qualitative rather than quantitative outputs. We would also be interested in further understanding any potential appeal process that may be available to specific countries that are able to provide data that contradicts the data used in the current risk models.

***Response:** The likelihoods assigned to the steps in the pathway are based on the available scientific information and not worst-case scenarios. The likelihoods are distributions with upper and lower limits, they are not based on single worst-case values. These distributions take into account natural variation and uncertainty. The Panel notes that in some instances a specific exporting country may have a different between and within herd disease prevalence, to that modelled, particularly in the case where control programs are in place. The Panel also notes that disease prevalence is not static, nor constant across a country or within different herds. As this IRA determined the unrestricted risk such things as control programs to reduce prevalence of disease were not considered. Nonetheless if an exporting country provides specific relevant data for a disease, then Australia will re-evaluate the risk for that specific disease. Provision is made in the disease specific measures for recognition of country and zone freedom.*

### Porcine Reproductive and Respiratory Syndrome:

While the Lelystad study commissioned by BA, does confirm the possibility of transmission via raw meat, it does not provide a good basis for estimating the risk of this happening. Simple issues such as group-housing of the experimental animals prohibit an analysis of the results that allow one to quantify, with statistical relevance, the likelihood of this kind of transmission happening outside of the laboratory. Additionally, mitigation measures such as commercial slaughtering processes were not assessed. It is likely that meat moving from the pig-dense areas of the Midwestern U.S. will require significant travel time to be transported to distribution facilities in Australia and would be expected to further reduce risk. We would also suggest that market age swine (as opposed to the 8-week old pigs in the study) are much less likely to be in the acute stages of infection and present a much-shortened duration of viremia.

**Response:** *The pigs used in the Lelystad study were slaughtered under conditions mimicking commercial slaughter i.e. the pigs were bled out, the meat was hung for 24 hours and then frozen. The release assessment considered the effect of cold storage and transport (R6) on the survivability of PRRS virus. The virus is stable when frozen, although, as demonstrated in the Lelystad study there was a reduction in titre following freezing and thawing. Nonetheless meat was still infectious when fed orally to naïve pigs. The likelihood that a slaughter-age pig is infected was considered at step R2 of the release assessment. The Panel noted that typically pigs are infected soon after weaning, however, some pigs may become persistently infected. In light of the research conducted by Canada, which demonstrated that 4.3% of serum samples from slaughter-age pigs were positive for PRRS virus by PCR and that 1.9% of meat samples were positive the Panel has amended R2 (the likelihood that a slaughter-age pig from an infected herd is infected) from 'moderate' to 'low'. When the simulation was rerun with the new value the overall annual unrestricted risk is 'low' and risk management is still required for PRRS virus.*

**Postweaning Multi-systemic Wasting Syndrome (PMWS):**

PMWS has been diagnosed in the U.S. based on a widely accepted case definition describing clinical signs and unique histological lesions. Circovirus type 2 (PCV2) is consistently demonstrated in PMWS lesions around the world and experiments performed by several groups have established PCV2 to be the cause of these unique lesions.

To better understand PMWS and the role of PCV2 in U.S. swine herds, pork producers and USDA are collaborating on an observational field study which was initiated in February 2003. Major swine veterinary practices have been recruited to participate in the study. Practitioners were provided a defined clinical case criteria to enroll qualified farms into the study. Once enrolled, samples are submitted to state diagnostic labs and the practitioner and producer complete a detailed questionnaire to identify possible risk factors.

A number of interesting observations have been made to date. First, the clinical signs of PMWS are so non-specific that certain practitioners find themselves enrolling multiple farms each week. "Wasting" is a common event on farms for multiple reasons. This syndrome cannot be diagnosed grossly. Secondly, it was soon discovered that a percentage of pork producers would not participate in a study based on an offer to simply assist them with the cost of an investigation. To ensure that a field study is not biased, all producer expenses associated with an investigation of a defined case criteria have to be paid. Thirdly, the difference in farm factors between PMWS positive cases and negative cases is not evident. The producer management surveys are necessary. Finally, PMWS does not seem to be a yes or no syndrome. The diagnostic results obtained to date clearly demonstrate a gradient of lesions and viral load. Currently, histologically positive cases are being graded and range from mild to severe in both lymphoid depletion and the level of PCV2 antigen in the lesion. We have included with these comments the Case Herd Questionnaire and the Sample Submission Form. Further results of the study will be made available as the study progresses.

**Response:** *Australia is interested in being kept up to date on the results of the study.*

Based on our project, we would ask how Australia has determined that the disease is not present. What are the criteria for declaring PMWS to not be present in Australia? It was interesting to note that Australian producers themselves noted in previously submitted comments (page 22, Annexes) that "it is not clear that the disease occurs naturally in this country."

**Response:** *Laboratories investigating cases of wasting of pigs in Australia, use the criteria of Sorden (2000) (clinical signs, histopathological lesions and PCV2 antigen associated with these lesions) to determine if a case is PMWS. There is a high level of veterinarian and*

*producer awareness of this disease. There is a continuing awareness program on PMWS and its clinical signs for veterinarians working in the pig industry. Industry has also funded a PMWS surveillance project. Despite the high awareness of veterinarians in the field, there would appear to be few cases with clinical signs suggestive of PMWS. These cases have been investigated and did not meet the above criteria for PMWS.*

Aujeszky's Disease (Pseudorabies, PRV):

The U.S. currently has no herds infected with PRV. This is a result of a concerted effort by pork producers and the government starting about 15 years ago. Through this period of time, we have learned how to successfully eradicate the virus, contain outbreaks, implement surveillance testing in both breeding and market animals, and successfully manage the feral:domestic swine interface. A plan for official declaration of freedom from PRV has been created and we are working to define the steps necessary to be recognized PRV-free. We have maintained a continuous trade in pig meat with Canada throughout the 15 years of our PRV eradication program during which Canada has remained free of the disease. We would ask Australia to consider this situation in its assessment.

***Response:*** *Provision is made in the quarantine requirements for sourcing pig meat from an Aujeszky's free country or zone.*

Swine Brucellosis:

The Brucellosis control program in the U.S. has evolved along side the PRV eradication program. Will BA accept regional disease free status (i.e. State) for Swine Brucellosis?

***Response:*** *The Department of Health and Ageing require that in countries where Brucella suis is endemic and uncooked pig meat is imported for retail sale, the meat is derived from herds that have tested negative or are accredited free from B. suis. Australia would consider a submission for regionalisation. It should be noted that there are no requirements with regard to B. suis for cooked or cured imported pig meat or uncooked imported pig meat required to undergo further processing in Australia prior to release from official control.*

Coronaviruses:

The U.S. swine industry has two Coronaviruses that may be present in herds. The Porcine Respiratory Coronavirus (PRCV) is endemic in most production regions and is generally thought to be non- or lowly pathogenic. Rarely is clinical disease associated with this organism. The enteric Coronavirus found in the U.S. is Transmissible Gastroenteritis virus (TGEV). Porcine Epidemic Disease Virus (PEDV) has not been detected in this country. TGEV presents most often in an epidemic form and used to be considered a significant pathogen in the industry. Over the last 10 to 15 years, however, the incidence of clinical outbreaks has dramatically decreased. This is thought largely to be a result of cross-protection afforded by an inapparent infection by PRCV. Other factors may be involved but have not as yet been identified. We agree with BA's conclusions in this area.

***Response:*** *Noted.*

In addition to our comments, we support the more detailed technical comments submitted by USDA on this IRA. We appreciate this opportunity to review and comment on the draft IRA. We look forward to future discussions and would welcome any questions you may have.

**Ministry of Agriculture and Fisheries, New Zealand**

**NEW ZEALAND'S SUBMISSION ON THE AFFA DRAFT IMPORT RISK ANALYSIS  
REPORT ON PIG MEAT, RELEASED FOR PUBLIC COMMENT 12 AUGUST 2003**

Thank you for the opportunity to comment on draft pig meat risk analysis.

I have discussed the texts with my technical advisers and offer the following comments.

## **COMMENTS ON THE GOVERNMENT, DEPARTMENT OF AGRICULTURE, FISHERIES AND FORESTRY'S PAPER: GENERIC IMPORT RISK ANALYSIS (IRA) FOR PIG MEAT.**

The New Zealand Ministry of Agriculture and Forestry thanks the Australian Government, Department of Agriculture, Fisheries and Food, for the opportunity to comment on the document: Generic Import Risk Meat Analysis (IRA) for Pig Meat. MAF believes the document is technically sound and congratulates the authors on the standard and comprehensive nature of the document. MAF wishes to make the following comments:

### **CONSTANTS IN THE CALCULATIONS**

Estimates for the following criteria are constant for all diseases:

L4 - the likelihood that the waste unit would be accessible to a feral pig.

L5 - the likelihood that a waste unit would be located by a feral pig

N - the number of waste units discarded each year

R3.2 - the specificity of ante-mortem, slaughter and processing requirements described in the Australian Standard (this is always 99.9- 100% and could be assumed to be 100% and left out of the calculations).

It seems unnecessary to repeat these for each disease as they could be given as a single constant to be used in the calculations this would shorten the length of the document.

***Response:** The Panel considered that some stakeholders may not read the full document, preferring to read one or two diseases of interest. Accordingly for completeness all data were included for each disease.*

### **COMMENTS ON SPECIFIC DISEASE ISSUES**

#### **Aujeszky's disease (pages 243-68)**

MAF is concerned that Australia does not recognise the whole of New Zealand as being free from Aujeszky's disease and only allows importation of uncooked meat from the South Island of New Zealand (Australia's quarantine policy, page 19). A successful eradication campaign resulted in the eradication of the virus from North Island pigs by 1997 (Motha et al. Vet. Rec. 144, 365-9) and New Zealand has been maintained free from Aujeszky's disease since that time. There are only about 40,000 breeding sows in New Zealand (North and South Islands) and there has been no importation of live pigs from any country other than Australia since 1989.

Moreover, MAF considers that since countries have achieved freedom from this disease without imposing measures more restrictive than those listed in the OIE code, the justification for the measures recommended in this risk analysis is not clear. MAF also considers that there are definitional issues surrounding 'head and neck' that would require clarification.

***Response:** MAF has previously provided information to Australia on its Aujeszky's disease eradication program. Australia would require an update on current surveillance in New Zealand in consideration of recognition of freedom with regard to the importation of pig meat.*

*The unrestricted risk of the introduction, establishment or spread of Aujeszky's disease through imported pig meat did not meet Australia's ALOP. Risk management was required i.e. removal of the head and neck. This has now been defined in the IRA. Meat must not be derived cranial to the fourth cervical vertebrae.*

### **Porcine reproductive and respiratory syndrome (PRRS)**

New Zealand strongly supports the Australian view on PRRS (pages 269-99 and 753g). After its emergence the disease spread rapidly through Europe and the USA and has caused unspecified economic losses in their pig industries. The virus has been demonstrated to be present in muscle and has been transmitted by the feeding of meat. A requirement for cooking of imported meat is fully justified (pages 274-5).

**Response:** *Noted.*

### ***Cysticercus cellulosae***

The logic for not doing a risk analysis on this parasite is not apparent (page 357). Although pig meat will not generally infect pigs, introduction of *Cysticercus cellulosae* cysts into Australia could infect humans and establish a human/pig cycle of infection.

**Response:** *This IRA did not directly examine the public health risks to humans associated with the direct consumption of imported pig meat. Products intended for human consumption may undergo a separate risk assessment by FSANZ to determine the public health risks. It should be noted that due to methods of disposal of human sewage in Australia it is considered unlikely that a human/pig cycle of infection would establish.*

### ***Salmonella typhimurium* DT104**

New Zealand acknowledges the problems involved with trying to devise restrictions that will reduce the risk of introducing this organism. However, it seems paradoxical that the risk assessment should conclude that the overall annual risk is very low, therefore meeting ALOP requirements, when it is reported in the **Background** section (page 411) that infection with the organism has been seen in people who became infected after eating infected imported foods.

**Response:** *In this IRA the overall annual risk does not take into account human health. This is considered separately by the Department of Health and Ageing, who advised that biosecurity measures would be required to address the risk to human health.*

On page 433 it is stated that: *"The Department of Health and Ageing has advised Biosecurity Australia that biosecurity measures would be required for S. typhimurium DT104 to manage the risk to human health associated with the importation of pig meat should the disease enter and establish in the Australian animal population. An appropriate measure would include imported processed (cooked, cured) pig meat classified as 'Risk must comply with the Food Standards Code including testing for Salmonella. No additional measures are required for imported uncooked pig meat which is processed in Australia prior to retail sale'".* It seems that measures to control the infection will only be taken after it has become established in Australia and that those measures are likely to force importers to import uncooked meat and cook it in Australia. Nothing is mentioned about the sale of fresh (uncooked) Australian pig meat after the establishment of the infection in Australia. Since there appears to be no technically sound way of addressing this problem it is questionable whether the half-measures proposed by the Department of Health and Ageing will achieve anything other than an increase in costs.

**Response:** *The measures required by the Department of Health and Ageing are designed to protect human health. Currently products classified under the Food Standards Code as 'Risk',*

*which would include processed pig meat must comply with the Code. Imported uncooked pig meat, not subject to further processing prior to release from quarantine control will be cooked prior to consumption and accordingly is not classified as 'Risk'. Public health issues associated with the direct consumption of pig meat are considered by the Department of Health and Ageing and FSANZ.*

### **Post-weaning Multisystemic Wasting Syndrome (PMWS)**

It is suggested in the IRA that porcine circovirus 2 (PCV2) plays a pivotal role in the etiology of PMWS. PMWS can be reproduced by infection with PCV 2 and either PRRS virus or porcine parvovirus. The authors of the IRA also quote four recent articles that describe the induction of PMWS by PCV 2 alone (page 384). Given this situation, it is illogical to require a heat treatment of meat that does not inactivate PCV2. The argument that this is because all countries that are infected with PMWS are also infected with PRRS and that cooking will therefore be imposed in any case is not credible. Heat treatment will be specified for PRRS and there is no need to repeat it under the requirements for PMWS. If the further argument that it will result in the production of fewer waste units of imported meat (page 743) is correct, it should apply equally to all pig meat and not be related to restrictions for a single disease.

**Response:** *The risk management measure for PMWS is to reduce the volume of waste discarded and remove tissues most likely to be a risk such as bone and major peripheral lymph nodes. The Panel concluded that cooked and cured deboned pig meat would result in a reduction in the volume of waste. Hence no specific cooking temperatures are stated. Nonetheless as most countries with PMWS also have PRRS, the cooking or curing specifications for PRRS will apply. The reduction in waste units associated with cooked deboned product can be applied to all diseases requiring risk management. However, this measure did not meet Australia's ALOP for other diseases of concern with the exception of Aujeszky's disease. This risk management measure has been included for Aujeszky's disease in the Final IRA Report.*

A major etiological role is suggested for PCV 2, either on its own or in conjunction with parvovirus or PRRS (page 384). Since PVC 2 and porcine parvovirus are already present in Australia, the implementation of restrictions that are based on the occurrence of PMWS, require justification.

**Response:** *The IRA states that PCV2 has been detected in Australia, however, the disease PMWS has not. A surveillance program for this disease is in place, veterinarians are aware of the disease and Australia has diagnostic capability.*

### **The Department of Health and Ageing**

MAF is interested to see how the Department of Agriculture addresses the requirements of the Department of Health and Ageing with respect to zoonotic diseases (see Assessment and management of risk page 6). Hazards attributed to *S typhimurium* could equally be attributed to other *Salmonella* spp, and other enteric organisms such as *Yersinia* spp, and *Campylobacter* spp. While it is important that the Departments of Agriculture support Health Departments in controlling zoonotic diseases it is also important that Departments of Agriculture are not forced into positions of trying to achieve what is not possible.

**Response:** *As discussed above cooked or cured imported pig meat must meet the Food Standards Code. This includes testing for various organisms of human health significance.*

## **Additional comment from Ministry of Agriculture and Fisheries, New Zealand**

In Derek's 9 October letter to you in which he made certain comments on the AFFA pig meat risk analysis, he stated the following: "Since PCV 2 and porcine parvovirus are already present in Australia the implementation of restrictions that are based on the occurrence of PMWS, require justification."

Derek has asked me to send you MAF's additional comments on this point.

The focus of the AFFA risk assessment for PMWS is PCV2, which your risk analysis acknowledges is endemic in Australia. Therefore, although it is not openly stated as such in the AFFA risk analysis, the hazard that is the focus of the PMWS chapter is exotic strains of PCV2 of higher virulence than the endemic strains. Thus the AFFA risk analysis is implying that there is significant strain variation in pathogenicity of PCV2 although it is acknowledged on page 384 that it is not known whether this is in fact so.

The structure of your risk analysis does not adequately focus on this key assumption, and MAF considers that this assumption has not been justified in your document.

As you can imagine, since we have made the diagnosis of PMWS on a single farm in this country, a number of questions regarding the aetiology of this complex clinical syndrome have arisen. We are aware of an unrefereed paper by Buddle and others [Buddle J.R., Muhling J., Raye W., Raidal S.R. & Wilcox G.E., (2003), Porcine circovirus in Australia. Australian Association of Pig Veterinarians Cairns Proceedings, pp 67-77] in which there is a certain amount of speculation about the possibility that strain differences may exist, but in our view the majority view is that the opposite situation is the case, and that all strains of PCV2 have the ability to cause PMWS given the correct circumstances.

New Zealand recognises the right of Australia to impose provisional sanitary measures under article 5.7 of the SPS agreement where scientific evidence is insufficient, but we do not believe that the AFFA risk analysis has made it sufficiently clear that this is in fact what has been done. Moreover, we would ask for clarification as to how AFFA intends to obtain the additional information necessary for a more objective assessment of risk and review the sanitary measures accordingly within a reasonable timeframe. Finally, we would ask what timeframe AFFA has in mind for this reassessment.

***Response:*** *It has been hypothesised that differences in virulence may be one of the reasons for clinical expression of the disease PMWS. As indicated above Australia has both PCV2 and porcine parvovirus but does not have PMWS. It is considered that a difference in virulence of strains of PCV2 is one potential explanation. Another potential explanation is the presence of an unknown disease agent which acts as a trigger for PCV2. A preliminary study in which an Australian isolate of PCV2 together with immunoenhancers were inoculated into pigs did not result in PMWS or PMWS type lesions in tissues (Buddle, et al., 2003). Further work is being conducted. Biosecurity Australia will continue to monitor scientific information on this disease and Australia's disease status. Nonetheless, at present, Australia considers that risk management is required for this disease with imported pig meat.*

**Animal Plant Health Inspection Service (APHIS)**

This letter is intended to provide comments on Australia's draft Generic Import Risk Analysis (IRA) for Pig Meat dated August 2003. The United States acknowledges the extensive scope of this draft IRA, and the Animal and Plant Health Inspection Service (APHIS) appreciates the opportunity to provide comments on the findings and conclusions of the document. As you know, the U.S. agricultural industry has identified access for pork to the Australian market as a high priority issue in the ongoing negotiations for a free trade agreement between Australia and the United States.

In providing the enclosed comments to you, APHIS trusts that you will consider our remarks when finalising the IRA. We look forward to the publication of this document.

Should you need additional information or clarification on our comments, please feel free to contact me.

## Animal and Plant Health Inspection Service (APHIS)

### Comments on Australia's Draft Generic Import Risk Analysis (IRA) for Pig Meat, dated August 2003

#### Methodology

APHIS would like to identify a number of concerns we have with the approach used in this Generic Import Risk Analysis.

#### **1. Generic Import Risk Analysis and Compliance with Fundamentals of Epidemiological Science**

The primary assumption upon which the Australian concept of "generic risk analysis" is based is of great concern to APIHIS,

*That if a disease were present in a country, it would be present at a sustainable herd-level and within-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 by a particular country at the time that a particular assessment is carried out. (Generic IRA, page 25, paragraph 2).*

The credibility of the IRA itself is immediately placed in question because this assumption is contrary to the most fundamental of all concepts of epidemiology, namely the concept of "triad of disease determinants" (ie. host-agent-environment). The prevalence premise described in the assumption quoted above indicates that the disease agent is the sole determining factor of disease prevalence and completely ignores the influence of the host-related factors and environmental factors such as disease prevention programs, host immunity, climatic factors, and animal density factors. This assumption is in direct contradiction to fundamentals of epidemiological science.

The magnitude of this false assumption is dramatically exemplified by data presented in the risk assessment for *Trichinella spiralis* (Generic IRA, page 329). These prevalence data from epidemiologic surveys were reported as ranging from 0.001 percent in the European Union (EU) to 12.4 percent in one region of Mexico and as high as 32.4 percent in one Chinese province. The prevalence citations were presented to justify a generic category "low" prevalence for the disease which then represents all of the values between 5 percent and 30 percent with equal probability for all countries where the disease exists.

However, these data exemplify a quite opposite conclusion based on the science of epidemiology. The wide discrepancy of these prevalence values demonstrates the interdependence of disease prevalence on all of the fundamental triad of disease determinants (host-agent-and environment). In the case of the EU surveys, the generic assessment over estimates prevalence by 5,000 to 30,000 times!

**Response:** *The "host-agent-environment" factors influence the prevalence of a disease in a country. Accordingly the disease agent was not the sole determining factor of disease prevalence in the studies quoted or figures used. Importantly in countries in which there is a wide range of climatic and geographical conditions, and possibly management systems, prevalence can vary markedly between regions. It should be noted that the risk is estimated on an unrestricted basis and disease prevention programs were not considered. Nonetheless it is recognised that for certain diseases, such as Trichinella, some countries have disease control programs in place and if data are provided by such a country Australia will re-evaluate the*

*assessment. Nonetheless in the case of Trichinella, risk management will be required to address human health concerns and the measures are in line with the relevant international (OIE) recommendations.*

## **2. Use of Available Relevant Scientific Information**

APHIS believes that the most precise data available must be used in all risk assessments to calculate true risk parameters for disease introduction to a country. The values from the example above are incorporated into the generic analysis for *T. spiralis* in the context of a uniform probability distribution that gives each value in the range an equal probability of occurring and inserts a multiplicative error into the R1 factor of the analysis equations. This introduction of error at such early stages of any model will likely create great distortion of the final conclusions. On the other hand, precise surveillance data with appropriate confidence ranges are readily available from most exporting countries (as cited for *Trichinella* in the Generic IRA) with both current and historical perspective.

**Response:** *The Panel notes that for many diseases prevalence data are not derived from structured surveys and are not precise. Limited data were available on between and within-herd prevalence of disease. Hence distributions were used to represent this data.*

## **3. Inaccurate use of expert opinion and judgment.**

As discussed in paragraph 1 of this section, the Generic IRA methodology uses expert judgment to translate available scientific data into a qualitative system of categories and then re-quantifies the categories with numerical risk values with a goal of "ensur(ing) consistency in usage and interpretation" (Generic IRA, pages 27-28). However, this attempt at translating data from quantitative-to-qualitative-back-to-quantitative not only loses precision and accuracy, but obscures the actual input data. While expert opinions and judgments are worthwhile to estimate data values when true data is not available, they are improperly used in lieu of, and opposed to, the actual numbers they estimate.

In the *Trichinella* example, prevalence data describing two of the world's most highly infected countries as well as data from countries with near freedom of the disease were considered by the expert panel for the Generic IRA. They defined the generic prevalence for the disease to be a categorical "low" risk that, based on the assumption quoted in paragraph 1 of this section, was generically applied to all countries in which the disease exists. It was then re-quantified in a Uniform Distribution using all values in the "low risk" category (ie., 5 percent up to 30 percent) each having equal probability of occurrence. Finally, results of the quantitative equations were re-categorised into the qualitative groups for the final release risk estimate to be "very low" which equals 0.1 percent to 5 percent probability. This conclusion was described from the quantitative product of \* R1("low" herd prevalence) \* R2("low" = in-herd prevalence) \* R3(no chance of detection) \* R4(certain risk of being present in meat) \* R5(certain risk of survival after carcass maturation) \* R6("high risk" of remaining infectious). Thus, accuracy of the prevalence estimate was doubly distorted, once by each "translation."

**Response:** *The annual likelihood of entry and exposure was calculated using the numerical estimates for each risk factor. A qualitative descriptor was only used in the document to describe the outcome of the release assessment in an effort to enhance readability for stakeholders.*

Alternatively, if the original EU prevalence data (0.001 percent) had been entered into the @risk spread sheet model with no other parameter changes, the mean probability for release risk would equal 0.0000015 which would be translated into "negligible risk." Although the final risk for *Trichinella* is presented with an undefined categorical "A," "B," "C" system, it would appear that the use of real data for this single parameter could dramatically change the

release assessment from unacceptable to acceptable for Australia's appropriate level of protection described on page 14 of the Generic IRA.

**Response:** *The EU prevalence data is country prevalence and therefore represents both between and within-herd prevalence of infection. The Panel notes that prevalence data are never so precise that a single point would be representative, nonetheless if 0.001% prevalence is used the release assessment would be 'extremely low' not 'negligible'. If all other data remains the same the risk of Trichinella is 'low' and risk management is required.*

*The categorical 'A', 'B', 'C' system is defined in the methods section of the IRA and refers to the consequences of introduction, establishment or spread for each direct and indirect consequence. All qualitative terms used in the IRA are described in the methods section.*

#### **4. Consistency with International Standards and WTO Principles**

In addition, APHIS is concerned that the Generic IRA approach is not consistent with the relevant standards of the OIE (OIE International Health Code, chapter 1.3), or with the obligations related to risk assessment in the WTO SPS Agreement,

The WTO SPS Agreement obligates Members to ensure that their measures are based on risk assessments that take "into account the risk assessment techniques developed by the relevant international organisations" (Article 5.1). The International Health Code of the OIE, chapter 1.3, describes risk assessment guidelines in terms of epidemiological concepts (host-agent-environment factors) and the need for best available information that is in accord with current scientific thinking. They further refer to disease factors, country factors, and disease control measures that vary when applied to individual countries. Thus, the concept of generic risk analysis is not compatible with the OIE risk analysis guidelines,

More fundamentally, the generic risk assessment approach is not consistent with the WTO SPS obligation to base SPS measures on a risk assessment that is "appropriate to the circumstances." The Generic IRA for Pig Meat does not in fact evaluate the specific likelihood of entry (i.e., release) of porcine diseases in pig meat imported from the United States (or any other individual country). Failure to evaluate the host and environmental disease determinants associated with an exporting country or region is also directly contrary to obligations of Article 6 of the SPS Agreement, which obligates Members to "take into account, inter alia, the level of prevalence of specific diseases or pests, the existence of eradication or control programs" in assessing the sanitary characteristics of a region.

Furthermore, the process of disregarding actual data in favour of categorical judgment prevents transparent evaluation of the data used in the risk model. In the *Trichinella* example above, the best available knowledge of risk was readily available. The assignment of this data into a category raised the release risk by almost 15,000-fold! This variation is unnecessary in the presence of real data or best expert opinion, and serves the purpose of obscuring the true value of the original input parameters.

This approach, by producing estimates of "generic" risk that far exceed the actual risk posed by pig meat exports from a particular country, is likely to encourage the adoption of sanitary measures that are more trade restrictive than necessary. This will clearly limit Australia's ability to observe the WTO SPS Agreement objective of minimising negative trade impacts.

**Response:** *Biosecurity Australia considers that the approach used is consistent with both OIE and Australia's WTO SPS obligations. As discussed above if an exporting country provides specific prevalence data for that disease, Australia will re-evaluate the risk. It is important to note that risk is a combination of the release and exposure assessment and the consequences of introduction, establishment and/or spread and not just the release "risk".*

### **Porcine reproductive and respiratory syndrome (PRRS)**

In a letter to Dr. Gardner Murray, dated July 8, 2002, APHIS provided comments on the section of the Generic IRA for Pig Meat Issues Paper regarding PRRS, and specifically commented on the research project conducted at Lelystad (“Transmission of Porcine Reproductive and Respiratory Syndrome Virus through Oral Uptake of Infected Porcine Muscular Tissue by Naive Recipients”). In your reply to me, dated August 19, 2002, you stated that the study was commissioned by Biosecurity Australia as a “first step toward addressing the paucity of existing information” concerning the ability of the PRRS virus to be transmitted in fresh pig meat. As stated in our letter, APHIS is unconvinced that the Lelystad study supports the contention that fresh pork meat constitutes a serious threat for PRRS virus transmission. In your letter, you also expressed hope that “in due course, larger studies investigating the titre of PRRS virus in the muscle of naturally infected commercial animals” would be undertaken by other parties. Given these circumstances, APHIS is concerned that the conclusions of the draft IRA regarding the risk of importing fresh pig meat are premature and do not accurately reflect the very minimal risk that fresh pig meat processed in a slaughterhouse is likely to introduce the PRRS virus into Australia. We would be interested in reviewing the results of any new peer reviewed research studies that may clarify the issue.

**Response:** *The Panel understands that Canada has conducted research on PRRS virus in slaughter-age pigs. Information provided by Canada demonstrated that 4.3% of serum samples from slaughter-age pigs were positive for PRRS virus by PCR and that 1.9% of meat samples were positive. As a result of these studies that Panel has amended R2 (the likelihood that a slaughter-age pig from an infected herd is infected) from ‘moderate’ to ‘low’. When the simulation was rerun with the new value it was concluded that there was a ‘very low’ likelihood that imported pig meat derived from an individual carcass will be infected (release assessment) and that the overall annual unrestricted risk is ‘low’. Risk management is still required for PRRS virus. The outcome of the release assessment concurs with the results obtained by Canada. The United States of America may wish to contact Canada to obtain further details of their experiment.*

The report of the Lelystad study has been available since 2001. A number of questions have been raised about the methodology of the study and some of the conclusions that have been drawn. Publishing the study in a peer-reviewed journal would likely address some of these concerns. Has the report of the study been submitted for publication? If not, when can we expect that the study will be submitted?

**Response:** *The study has been published in a peer reviewed journal – van der Linden, I.F.A., van der Linde-Bril, E.M., Voermans, J.J.M., van Rijin, P.A., Pol, J.M.A., Martin, R., & Steverink, P.J.G.M. (2003). Oral transmission of porcine reproductive and respiratory syndrome virus by muscle of experimentally infected pigs. *Veterinary Microbiology* **97**, 45-54.*

Further, the minimum oral infectious dose of the PRRS virus (PRRSV) in pigs has not been determined in any referred study outside of the Lelystad project. Related work with Lactate Dehydrogenase Evaluating Virus (LDV) in mice required  $10^{3.3}$  ID<sub>50</sub> (50 percent infectious dose) by rectal inoculation and  $10^{5.3}$  ID<sub>50</sub> by either ocular, vaginal, or oral routes.<sup>i</sup> This study suggests that higher doses than what are being reported by the Lelystad study ( $<10^{1.8}$  TCID<sub>50</sub>/gram x 500 grams) may be necessary to predictably infect swine with PRRSV.

- i) Ongoing work in the United States is being conducted to establish an oral ID<sub>50</sub> for PRRSV in swine. To date, this work is suggesting a dose in excess of  $10^5$  TCID<sub>50</sub> is necessary to reach an ID<sub>50</sub>.<sup>ii</sup>
- ii) Additional research has shown that swine exposed to PRRSV in semen required a dose of  $10^{4.5}$  TCID<sub>50</sub> (95% CI= $10^{3.8}$ ,  $10^{5.1}$ ) to become infected.<sup>iii</sup>

**Response:** *The experiment conducted by Canada also demonstrated that meat from slaughter-age pigs that was positive for PRRS virus by PCR but not positive by virus isolation resulted in infection when fed to naïve pigs.*

The prevalence of PRRSV infection in the U.S. swine herds is unknown. Data collected in 2000 suggested that only 21.4 percent of the sites in the United States that had breeding females, 17.5 percent of nursery sites and 16.6 percent of finisher sites reported having PRRS in the previous 12 months.<sup>iv</sup> These numbers are much lower than the 59.4 percent prevalence cited on page 272 of the draft IRA. It should be noted that use of both modified live and killed PRRSV vaccines in the United States complicates the evaluation of serological surveys.

**Response:** *The data referred to above is not a survey of infection but of those farms reporting disease problems due to PRRS. Herds where the disease is endemic may not show clinical signs of infection. There have been several serological surveys which show that PRRS infection is widespread in pig populations. It is noted that the use of vaccines complicates serological surveys. However, pigs vaccinated with modified live vaccines excrete virus. Interestingly the Canadian study demonstrated that meat containing vaccine-like virus fed to naïve pigs resulted in transmission.*

Also, as we stated in our letter to you dated July 8, 2002, New Zealand has imported frozen pig meat from a number of countries known to be endemically infected with PRRSV for more than 10 years. This includes pig meat imported from Denmark during the 1996-1997 period when widespread shedding of modified live PRRSV vaccine virus was documented to be occurring. Despite this importing activity, New Zealand has remained negative for PRRSV. This is the best practical example of the extremely low risk of introducing PRRSV through the importation of pig meat that is available (assuming that New Zealand and Australia have similar patterns of feral/domestic swine exposure, garbage feeding, etc).

**Response:** *New Zealand and Australia are not comparable with regard to feral and domestic pig populations or risk factors.*

We also wanted to bring to your attention an incorrect reference to Yoon, et al., 1998, made on page 277 of the draft IRA. Yoon's study reported their data in Fluorescent Focus Units (FFUs), which provides only a crude estimate of "virions" as stated in the draft IRA.

**Response:** *It is noted that Yoon and co-authors' data were Fluorescent Focus Units, however, these authors concluded that "we found that 10 or fewer virions were easily sufficient to achieve infection with PRRSV by either intramuscular or intranasal routes of exposure" as quoted in the IRA.*

### **Postweaning multisystemic wasting syndrome (PMWS)**

There appears to be considerable discrepancy in defining the actual risk being evaluated in the draft IRA. Several of the sections in the document refer to porcine circovirus type 2 (PCV2) as the causative agent. Other sections refer to PMWS independent of a specific agent, and other sections suggest a yet undefined or identified agent. In the Executive Summary, "Hazard Identification" (page 3), the document refers to PMWS, and PCV2 as one entity. This causes confusion about the position and objectives of the draft IRA. Is the draft IRA attempting to regulate pork originating from countries with clinical signs of PMWS or countries known to have PCV-2 present in their swine populations?

**Response:** *PMWS is identified as the hazard and the risk management measures are aimed at preventing the establishment of PMWS in Australia. Where it was appropriate to discuss agent characteristics, these relate to PCV2, although it has also been postulated that an unknown*

*disease agent may be the trigger for PCV2 and expression of clinical disease. As PCV2 has been shown to result in persistent infections, has been isolated from many tissues, is a hardy virus and is likely to be transmitted orally, the Panel considered that if an unknown disease agent was involved in PMWS, the risk management measures requiring removal of bone, major peripheral lymph nodes, head and neck and cooking or curing would also act to reduce the risks associated with that agent.*

On page 21 of the draft IRA, it states that "the disease post-weaning multisystemic wasting syndrome (PMWS)" is not present in Australia. Also, page 23 of the draft IRA states that an import risk analysis will be done if an agent is exotic to Australia. Exotic is defined as no report of disease or detection of agent., Further clarification of the case definition and the method by which Australia has declared itself free of PMWS would be helpful.

***Response:*** *Laboratories investigating cases of wasting of pigs in Australia, use the criteria of Sorden (2000) (clinical signs, histopathological lesions and PCV2 antigen associated with these lesions) to determine if a case is PMWS. There is a high level of veterinarian and producer awareness of this disease. There is a continuing awareness program on PMWS and its clinical signs for veterinarians working in the pig industry. Industry has also funded a PMWS surveillance project. Despite the high awareness of veterinarians in the field, there would appear to be few cases with clinical signs suggestive of PMWS. These cases have been investigated and did not meet the above criteria for PMWS.*

Segales, et al., clearly states the criteria for diagnosing PMWS<sup>v</sup> "as the existence of compatible clinical sign, the presence of characteristic microscopic lesions, and the detection of PCV2 within these lesions." Additionally, other references have recognized PCV2 as the necessary causative agent of PMWS.<sup>vi,vii</sup> It does appear that clinical expression of disease depends upon the generation and accumulation of a "critical mass" of infectious virus in target tissues,<sup>viii</sup> adding to the challenge of making a clear diagnosis of PMWS even in a laboratory setting. Despite this, experiments showing protection from PMWS through administration of PCV2 ORF2 (open reading frame 2) protein<sup>ix</sup> further supports the notion that PCV2 has a pivotal role in PMWS. Given this information, we are very interested to know when, and with what methods Australia has used to declare itself free of the disease. Given the fact that PCV2 is known to exist in Australia, and most certainly there are pigs that are exhibiting clinical signs of wasting, has work been done to examine whether both conditions (presence of PCV2 and wasting) exist in a pig at the same time? If a single pig is located that meets this criteria, does that mean the pig has PMWS? Does that mean the herd has PMWS? Does that mean Australia's swine industry has PMWS? We would be interested in reviewing any surveillance data, studies, or other supporting evidence concerning this issue.

The existence of potentially non-pathogenic PCV2 strains was cited as a possible explanation for the fact that PCV2 is known to be present in Australia but reports of clinical PMWS are absent. Several reports describing the close homology of isolates, reproduction of disease with isolates recovered from normal animals, and (of special significance for Australia) reproduction of PMWS with an isolate from a country with no previous reports of disease,<sup>x</sup> strongly suggest that strain differences are insignificant.<sup>xi,xii</sup>

***Response:*** *It is considered that a difference in virulence of strains of PCV2 is one potential explanation. Another potential explanation is the presence of an unknown disease agent which acts as a trigger for PCV2. A preliminary study in which an Australian isolate of PCV2 together with immunoenhancers were inoculated into pigs did not result in PMWS or PMWS type lesions in tissues (Buddle, et al., 2003). Further work is being conducted. Several overseas researchers have suggested that strains may differ in virulence (Ladekjaer-Mikkelsen, et al., 2002; Segales & Domingo, 2002).*

In the Annex (pp 22-23), PCV2 is referred to as a necessary cause of PMWS, but questioned as a sufficient cause. This is of concern as the infectious agent that causes the clinical manifestation of PMWS is still unknown. APHIS questions whether the lack of definitive scientific information about PMWS, combined with the fact that PCV2 is known to be present in Australia, provides sufficient justification for mandatory risk mitigation strategies such as further processing of fresh pork products.

**Response:** *The reference to Annex page 22-23 was a view of a stakeholder, submitted in response to the issues paper of 2001. Australia responded that “Further information is available on PMWS, since the issues paper was written, demonstrating that the disease can be caused by PCV2 alone”. Nonetheless it is well recognised that PMWS is a multifactorial disease and that although PCV2 is considered essential for expression of the disease other factors are also required.*

We would also like to bring to your attention an incorrect statement about the host range of PCV2. The draft IRA (page 383) states that PCV2 has been isolated only from pigs, This is incorrect as a bovine isolate of PCV2 was recovered and found to be indistinguishable from porcine PCV2 isolates.<sup>xiii</sup>

**Response:** *Noted. The IRA has been amended to include reference to the bovine isolate. The Draft IRA Report had mentioned serological evidence in bovines. Nonetheless, it would appear to be generally accepted that pigs are the principal host. As mentioned in the IRA several studies have not found PCV2 in any species other than pigs.*

### **Aujeszky’s disease virus**

The draft IRA (page 20) states that Australia has a significant population of feral swine which act as hosts or vectors of several diseases, As most feral pigs in the United States, Europe, and South America are considered to be potentially exposed to or infected with feral Aujeszky's disease virus (ADV), it is reasonable to question whether the feral pig population in Australia is truly free of this disease. As ADV in feral pigs is attenuated and seroconversion is slow, numerous seronegative feral pigs can be PCR positive and still carry the virus.<sup>xiv</sup> We would be interested in knowing more about the extent and range of the targeted surveillance in feral and contact domestic pigs that demonstrates Australia's freedom from feral forms of ADV.

**Response:** *Aujeszky’s disease has never been present in Australia. Australia meets the OIE requirements for historical freedom from this disease. Feral pigs in Australia have been tested for Aujeszky’s disease virus as part of the Northern Australian Quarantine Strategy, all with negative results.*

We concur with the assessment made in the draft IRA (Page 246) that importation of large amounts of carcass meat into Canada from the United States at a time when ADV was endemic in U.S. swine herds resulted in no transmission of infection to Canadian swine. We believe this real-world example illustrates that margins of safety built into release and exposure assumptions in the draft IRA models are excessive.

On page 5 of the Executive Summary, it states that "country or zone freedom<sup>xiv</sup> would also meet Australia's ALOP" (acceptable level of risk) for Aujeszky's disease. Does Australia recognize those States that have been declared free of Aujeszky's disease as part of APHIS' ADV eradication program? We would be interested in knowing what standards Australia will use to determine zone freedom in general, and in particular, for Aujeszky's disease.

**Response:** *Australia would consider a submission from the United States of America on its regionalisation of Aujeszky’s disease. Australia bases its assessment on the OIE guidelines for zoning and regionalisation. Attached are the major points that should be covered in a*

*submission (Attachment 1). The United States of America may wish to note that the risk management measure for Aujeszky's disease, removal of the head and neck, is also required as one of the measures for PMWS.*

Finally, we re-emphasise comments made in our earlier letter to you, dated October 2, 2002, on the Issues Paper on the Generic IRA for Uncooked Pig Meat. In this letter, we addressed the fact that non-porcine species are considered dead-end hosts of ADV. The weight of the research data, as cited earlier, does not support widespread survival of cats or wild rodents infected with ADV.

**Response:** *The Panel agrees and assigned a high likelihood to containment of the disease within the directly exposed group 'other susceptible species' (outbreak scenario 1).*

### **Salmonella typhimurium DT104**

The draft IRA (page 411) suggests that *Salmonella typhimurium* DT104 is an emerging threat, and that the incidence of human illness caused by DT104 is increasing. However, it is generally accepted that the global outbreak of *S. typhimurium* DT104 has peaked and is decreasing. This assumption is supported by the U.S. National Antimicrobial Resistance Monitoring Study (NARMS) data. In 1997, 35 percent of human cases of *S. typhimurium* were ACSSuT resistant phenotypes. By 2001 (the most recent data available to date), only 29 percent were ACSSuT resistant. The draft IRA incorrectly estimated that 83 percent of *S. typhimurium* isolates in the United States with the ACSSuT phenotype were phage type DT104 when tested.

**Response:** *The NARMS data have been included in the IRA. The Panel does not agree that the data provided by the United States of America demonstrates that the global outbreak of *S. typhimurium* DT104 has peaked and is decreasing. The Panel notes that the NARMS 2001 Annual Report stated that there was no significant difference in the proportion of isolates with at least ACSSuT resistance pattern in 1996 and 2001. The Draft IRA Report presented data as referenced, that of those ACSSuT isolates sent to the United Kingdom 83% were DT104. It was then estimated that 2.13% of herds may be infected with *S. typhimurium* DT104. The Panel recognises the possible bias of this sample.*

The draft IRA (page 411) states that Australia has had human cases that were attributed to foreign travel and/or the consumption of infected foreign food items. This suggests that the risk of human-to-human spread, or human-to-animal spread is higher than the risk associated with the importation of meat from a country with DT104 in its herd. We question whether there have been cases of *S. typhimurium* DT104 in animals in Australia, especially if any of the human cases were associated with an animal handler. Is there any surveillance data to show that this possibility has been investigated?

**Response:** *There have been no reported cases of *Salmonella typhimurium* DT104 in animals in Australia. The only cases in humans in Australia have been with associated with travellers returning from overseas or from people who became ill after eating infected imported food. Human antimicrobial resistance surveillance information is collected and a National Enteric Pathogen Surveillance Scheme (NEPSS) is in place.*

The draft IRA concludes that *S. typhimurium* DT104 is more virulent than other *Salmonella* serotypes or phage types (page 413). However, research has shown that the DT104 phage type does not have increased virulence attributes such as adhesion, invasions, etc.<sup>xv</sup> Increased hospitalisations associated with DT104 may be due to treatment failure when physicians empirically prescribe the wrong treatment. With the advent of the widespread infections with ACSSuT-resistant bacteria, empirical treatments of choice have likely been adjusted to account for the resistance.

**Response:** *The Draft IRA Report did not conclude that S. typhimurium DT104 is more virulent. The report quoted a reference from WHO (1997) stating, "this strain was associated with hospitalisation rates twice that of other zoonotic food-borne Salmonella infections and with ten times higher case fatality rates". The Panel recognises this could be due to a number of reasons.*

The draft IRA states (page 415) that Hazard Analysis and Critical Control Point (HACCP) methods within the abattoir or processing plant appear to be only marginally effective in controlling cross-contamination. HACCP is a process for identifying and addressing critical control points for prevention of microbial contamination. The control points and interventions may vary from plant to plant. Thus, it is inaccurate to state that HACCP does not control cross-contamination. HACCP is not a standardised protocol, but plant-dependant; therefore, what was effective in one plant may have a different outcome in another plant.

**Response:** *Noted. The Draft IRA Report was quoting a published study.*

USDA's Food Safety and Inspection Service (FSIS) data indicate that the prevalence of all *Salmonella* serotypes found on pork carcasses is decreasing. The baseline prevalence of *Salmonella* in pork from the mid to late 1990's was 8.7 percent. By 2001, the prevalence had fallen to 1.9 percent in the large meat processing facilities which are the type of establishments likely to be exporting pork. Additionally, recent retail meat case studies indicated that the prevalence of *Salmonella* in fresh, chilled pork was 0 percent in 981 samples tested in a regional survey, and 2 percent in 2,513 samples in a nationwide survey (NAHMS Retail Meat Studies, preliminary data presented at American Veterinary Medical Association meeting, Denver, July 2003).

**Response:** *Noted. The IRA concluded that there was a 'very low' (0.1 to 5%) likelihood that imported pig meat derived from an individual carcass would be infected/contaminated with S. typhimurium DT104.*

The document states (page 417) that "once infected pigs have been slaughtered, a high proportion of these carcasses may become contaminated." We are not aware of published research that confirms this statement. To the contrary, research by McKean and Davies showed a lack of agreement in the rate of *Salmonella* isolation between swine feces and the rate of carcasses contaminated with *Salmonella*.<sup>xvi</sup> As there is no reference for this statement, we question the conclusion that a "high proportion" of carcasses are contaminated with *Salmonella*. U.S. processing plants rarely find a "high proportion" of contaminated carcasses regardless of the clinical disease status of the animals being processed.

**Response:** *The technical information provided references to the data used in the assessments. The Panel draws the attention of APHIS to page 415 of the Draft IRA Report and the reference of Berends et al (1997).*

On page 415, it states that hot water washes were the only intervention that appeared to be effective in minimising carcass contamination. There are numerous critical control points, and they vary from plant to plant. Significant intervention points during processing include scald time, skinning versus dehairing, evisceration procedures, final trimming methods, and chilling methods. No one method is necessarily more critical than others, each being facility-dependent.<sup>xvii</sup>

**Response:** *Noted. The IRA, quoting a scientific study, stated that washing carcasses with heated water reduced contamination.*

### **Trichinella spiralis**

While much of the section on *Trichinella spiralis* is not in dispute, the draft IRA mischaracterizes the level of infection in U.S. pork by selective usage and over generalisation of a limited serologic study conducted in 1999.<sup>xviii</sup> There are also several misstatements in the draft IRA regarding the serologic survey. Specifically, the study was conducted in the northeastern and not the northwestern United States, in an area of very low pig density, with known endemic trichinellosis due to continuing wildlife exposure. The intent of the research was to look for *Trichinella* infection rather than to determine the true prevalence of the organism throughout the United States. Using data from 4,078 pigs from 156 farms in a low hog density endemic area to characterise the within-herd and between-infection rate is not representative of the true prevalence of the organism in the United States.

Three additional studies have been conducted on more representative samples of domestic pork production in the United States. In the survey conducted in 1995 by the USDA National Animal Health Monitoring System (NAHMS), only one serologically positive pig was found among the nearly 8,000 pigs tested. Subsequently, in the development of the U.S. Trichinae Certification Program in 1997 and 1998, both diaphragm digestion and serological testing was performed on 221,123 pigs from the midwestern United States. None of the pigs were found to be positive for *T. spiralis* using either diagnostic test. In a 2000 NAHMS study, only one serologically positive pig was found among the 14,121 pigs tested. Modern production practices and producer awareness programs have essentially eliminated *Trichinella spiralis* from U.S. pork products in the commercial segment of the industry, which supplies the export market.

**Response.** *The Final IRA Report includes the additional information provided by the United States of America. The reference to northwestern has been corrected to northeastern. The Panel acknowledges that improving husbandry has led to a decrease in trichinellosis, but notes that between 1997 and 2001 eight human cases of Trichinella in the United States of America were associated with the consumption of domestic commercial pork products (Morbidity and Mortality Weekly Report, 2003, 52, SS-6).*

As an added assurance to domestic and world consumers, the U.S. pork industry and USDA are in the final stages of a pilot program for trichinae safety certification. The U.S. Trichinae Certification Program, regulated by the USDA, is a collaborative effort between APHIS, FSIS, and the Agricultural Marketing Service. The program's goal is to verify that certified pork production sites manage and produce pigs according to the requirements of the program's *Good Production Practices*, and verify the identity of pork from the certified production unit through slaughter and processing. Uniform program standards stating the requirements of this program have been developed. Additional Federal regulations in support of the program are currently being developed.

APHIS believes that this program is a scientifically sound alternative to digestion testing and will seek equivalency standards for this program versus individual digestion testing. It avoids, testing sensitivity errors and has the added benefit of enforcing good production practices in the pool of animals providing the pork supply. All testing and auditing is done in statistically valid quantities to assure product safety.

**Response:** *Australia would consider the equivalence of this program should the United States of America provide a submission. The submission should cover the points in Attachment 1. The United States of America may wish to note that due to the cooking requirements for PRRS virus, pig meat would not need to be tested for Trichinella.*

OIE standards give specific guidelines for declaration of freedom from *Trichinella* infection of a region or country. We would be interested in obtaining information on the means by which Australia has met OIE standards to be considered free from infection, both from *Trichinella spiralis* and also *Trichinella pseudospiralis*, a related zoonotic pathogen.

**Response:** *Australia meets the OIE requirements for country freedom with extensive surveillance in the feral pig population. T. spiralis and T. pseudospialris have never been found in the domestic or feral pig population.*

### **Transmissible Gastroenteritis (TGE)**

When the research was conducted by Cook (1991) and Forman (1991), the TGE incidence in the United States was much higher. On page 303, seroprevalence rates of 34.8 percent and 30.9 percent for TGE were quoted from U.S. studies. With porcine respiratory coronavirus (PRCV) infection currently endemic in the United States, those seroprevalence rates are exaggerated, and the assessment of the risk of finding TGE virus in meat/lymph tissue is overestimated.

The Forman study (1991) demonstrates experimental transmission through feeding of pig meat, but it is an extreme case. In the study, meat from acutely affected animals was fed to very susceptible young pigs. In general, biological assays with very young piglets are more sensitive than isolation in swine testicular (ST) cell culture for demonstrating the TGE virus.

Viremia and tissue distributions for the TGE virus are well described in the Forman (1991) paper. There are a few reports of TGE virus isolated from the blood and organs of young pigs. In general, in older pigs there is no viremia detectable and virus replication is restricted to the small intestine and to a lesser degree to the respiratory tract. As market swine that are entering export channels are often 5 to 6 months of age, they are unlikely to become viremic, even during the acute stages of a TGE infection.

Feral pigs in the United States have not been reported to be infected with the TGE virus. A serological survey with a large number of pigs from Florida, Georgia and Texas yielded only negative results.<sup>xix</sup> This further minimizes the risk of market weight swine being exposed to the virus.

**Response:** *The risk assessment for TGE concludes that no risk management measures are required.*

### ***Brucella suis***

The United States has made significant progress on eradicating Brucellosis from our domestic swine population. The U.S. program is based on State vs. herd status. Does Australia recognise our national swine Brucellosis eradication program and will it recognise those States that are declared free of the disease as "Brucellosis-free regions"?

**Response:** *Australia would consider a submission from the United States of America on its regionalisation program for this disease. The United States of America may wish to note that due to the presence of PRRS virus and PMWS, pig meat will need to be cooked/cured either prior to export or in Australia, and accordingly no additional measures are required to address the human health concerns of B. suis.*

### **Certification Statements**

On page 11, of the Executive Summary, Part 3, Certifications, it states "the pigs from which the meat was derived have been continuously resident in the source country since birth..." It is not uncommon for newly weaned pigs to be imported to the United States from Canada for finishing. As these pigs originate in a country with a similar health status as the United States, would these pigs be eligible for export to Australia?

**Response:** *In light of the movement of pigs between Canada and the United States of America and the country's respective health status, Australia could develop combined quarantine*

*conditions applicable to both countries. It should be noted that if either country incurred an exotic disease, for example CSF, trade would initially cease in both countries whilst information on the disease outbreak was considered.*

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- <sup>ii</sup> Zimmerman J, personal communication.
- <sup>iii</sup> Benfield D, Nelson C, Steffen M, Rowland R. Transmission of PRRSV by Artificial Insemination Using Semen Seeded with Different Concentrations of PRRSV. *Proceedings of American Association of Swine Practitioners*, 2000, 405-408, Indianapolis.
- <sup>iv</sup> Swine 2000 Part II Reference of Swine Health & Health Management in the United States, 2000. National Animal Health Monitoring System, United States Department of Agriculture, March 2002.
- <sup>v</sup> Segales J, Madec F, Domingo M. Postweaning Multisystemic Wasting Syndrome and Porcine Circovirus type 2 The European perspective. In: *Trends in Emerging Viral Infections of Swine*, Eds Morilla A, Yoon KJ, Zimmerman J, Iowa State press, Ames, Iowa, 2002.
- <sup>vi</sup> Segales j, Domingo M. Postweaning multisystemic syndrome (PMWS) in pigs. A review. *Vet Quarterly*, 24: 109-124, 2002.
- <sup>vii</sup> Elsingerhorst, Th AM. Postweaning multisystemic wasting syndrome (PMWS) in pigs and porcine circovirus (PCV) An index bibliography. *Veterinary Quarterly* 24: 125-180, 2002.
- <sup>viii</sup> Krakowka S, S Ellis JA, McNeilly F, Meehan B, Rings DM, McCulloch K, Botner A, Nauwynck H, Charreyere C, Allan G. The Pathogenesis of PCV-2-Associated Postweaning Multisystemic Wasting Syndrome in Swine. In: *Proceedings of 4<sup>th</sup> International Symposium on Emerging and Re-emerging Pig Diseases*, Rome, 2003.
- <sup>ix</sup> Jestin A, Mahe D, Blanchard P, et al. Protection of swine from porcine multisystemic wasting syndrome (PMWS) conferred by porcine circovirus Type 2 (PCV2) ORF2 protein. In: *Proceedings 11<sup>th</sup> International Conference on Virology*, VP30.08, 1999.
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- <sup>xi</sup> Blanchard P, Mahe D, Cariolet R, Truong C, Le Dimna M, Arnould c, rose N, Eveno E, Albina E, Madec F, Jestin A. An ORF2 protein-based ELISA for porcine circovirus type 2 antibodies in post-weaning multisystemic wasting syndrome. *Vet Microbiol*. 2003 Jul 17; 94(3): 183-94.
- <sup>xii</sup> Larochelle R, Magar R, D'Allaire S. Comparative serologic and virologic study of commercial swine herds with and without postweaning multisystemic syndrome. *Can J Vet Res*. 2003 May; 67(2): 114-20.
- <sup>xiii</sup> Fenaux M, Halbur PG, Gill M, Toth TE, Meng XJ. Genetic characterization of type 2 porcine circovirus (PCV-2) from pigs with postweaning multisystemic wasting syndrome in different geographic regions of North America and development of a differential PCR-restriction fragment length polymorphism assay to detect and differentiate between infections with PCV-1 and PCV-2. *J Clin Microbiol*. 2000 Jul;38(7):2494-503.
- <sup>xiv</sup> Muller T, Conraths FJ, Hahn EC. Pseudorabies virus infection (Aujeszky's disease) in wild swine. *Infect Dis Rev* 2000; 2(1): 27-34.
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## Ministerio De Agricultura, Pesca Alimentacion (Spain)

Having studied the Draft Import Risk Analysis (IRA) Report on Pig Meat, released by your Department last 12 August, which was provided to us by Mr. Javier Mallo after the meeting he held with you last 14 August, we would like to acknowledge the great effort put by your Department into the preparation of this document, and its trade-facilitation spirit.

Bearing in mind the big interest that the possibility to export to Australia has raised among our national producers, we would like to send you our comments about some of the proposed risk management measures.

### **Reduction of the risk of African swine fever (ASF) and classical swine fever (CSF) viruses during the commercial curing process.**

In the study mentioned in the report (Mebus, et al., 1993a), ASF and especially CSF viruses were inactivated after different curing periods in the different Spanish dry-cured products subject to study, i.e. Serrano hams and Iberian hams, loins and shoulders.

According to the panel, no adequate explanation was given as to why different times were required for a negative sample to be obtained from different products. However, there are two important aspects that should be borne in mind by the panel:

- a) The pieces used for the production of the different products have different tissue composition, which is reflected in the kind of samples taken.
  - Hams: muscle, fat, bone marrow and lymph nodes
  - Shoulders: muscle, fat and bone marrow.
  - Loins: muscle (with a small amount of fat, according to the text).

CSF virus inactivation, as shown in the study, occurs after different curing periods in each one of these tissues, but the in vivo assays were carried out with a pool of the different samples taken for each product. This would account for the differences observed between hams, shoulders and loins as regards their virus inactivation periods.

***Response:** The Panel was aware that different pooled samples were tested for the different products. In addition, for each product only a small number of tissue samples (3) were tested in vitro at predetermined intervals, there was a wide variation in virus titre in tissues of individual pigs and only three pooled samples were used for testing in vivo. These factors could have contributed to different curing times being obtained for different products. The Panel considered that further experimental work would need to be undertaken on the curing time for different products from countries with CSF to provide sufficient assurance that CSF was inactivated in products cured for a shorter period than 252 days. The Risk Management section has been amended to provide clarification, as discussed here, as to why the Panel considers Iberian hams, shoulders or loins and Serrano hams should be cured for 252 days.*

- b) The dry-curing process is faster in smaller pieces. Although no mention is done about the weigh of the pieces cured in the experiment, the body weigh of the animals from which they were obtained was different in the case of the white pigs (92-108 kg.) and the black pigs (133-162 kg.), which reflects conditions of the commercial production of these products. As a consequence, the cured pieces are bigger in Iberian hams than in Serrano hams, and the curing of their tissues is slower. This would explain why the observed CSF virus inactivation period was longer in Iberian hams than in Serrano hams.

**Response:** *Noted. Another explanation may be the initial virus titre in individual samples. There was a wide variation in the virus titres of tissues. For example, the CSF virus titre in bone marrow of individual pigs ranged from just detectable to greater than 10<sup>6</sup> pfu/g.*

As a consequence, the results of the study should be considered as solid empirical evidence, and the minimum curing times proposed as risk management measures should be adjusted to match the ones observed by Mebus et al. There would be no reason, for example, for the application of a minimum 252-day period for the Iberian loins, when the CSF virus is inactivated after 126 days in this kind of product.

The minimum curing times should be as shown in the following table:

Product	ASF virus inactivation time (days)	CSF virus inactivation time (days)
Iberian ham	140	252
Iberian shoulder	140	140
Iberian loin	112	126
Serrano ham	140	140

In line with above, the minimum curing times set to manage risks related to porcine reproductive and respiratory syndrome (PRRS), trichinellosis and post-weaning multisystemic wasting syndrome (PMWS) should be adjusted accordingly.

**Response:** *For countries with PRRS or Trichinella spiralis, Iberian hams, loins or shoulders or Serrano hams must be cured for a minimum of 140 days. The curing time is based on inactivation of PRRS virus or Trichinella spiralis not CSF virus or ASF virus. As most countries with PMWS also have PRRS, the curing specifications for PRRS will apply.*

### **Reduction of the risk of PMWS.**

According to the draft IRA report, “Deboning and processing of pig meat by cooking or curing would reduce the risk of entry, establishment and/or spread to very low, which would meet Australia’s ALOP”

The report does not specify whether the two treatments should be applied in the order expressed in the literal text (deboning and then curing) or the opposite (curing and then deboning) would be admitted.

Deboning in itself would meet the objective of reduction in the volume of waste discarded, both when carried out before the curing process or after it. In the case of Serrano ham, Iberian ham and Iberian shoulder the only possible sequence is to carry out the curing process on whole, bone-in, pieces, as established in their quality standards, and then deboning them. Therefore, this possibility should be observed as an approved risk management measure.

**Response:** *The quarantine requirements for PMWS have been amended to clarify that deboning and removal of major peripheral lymph nodes can occur either before or after curing or cooking.*

Besides the above comments, we would like to get more detailed information about the following aspects:

- Procedure for the recognition of our country as free of animal diseases.

- Conditions to obtain the AQIS approval for the slaughterhouses, cutting plants, meat processing establishments and storage facilities.

Should you have any further questions or comments, please do not hesitate to contact us.

***Response:*** *The OIE recognises FMD and rinderpest free countries or zones. Australia would use this as the basis of recognition of disease status for FMD and rinderpest. For other diseases a country would need to provide a submission to Australia for consideration as to the basis for country or zone freedom. This submission should cover the points documented in Attachment 1.*

*Overseas countries must meet Australia's domestic standards for pig meat production as specified in the IRA. Following the receipt of an application for an import permit a veterinary evaluation and inspection of slaughterhouses, processing establishments may be undertaken as described in the Risk Management section of the IRA.*

## **Consorzio del Prosciutto di Parma**

We are very glad to have raised the draft “Import Risk Analysis (IRA) for Pig Meat” from the Italian Embassy in Canberra.

We think that the document could represent a crucial step in negotiations begun many years ago in order to allow the export of Parma Ham into Australia.

As a matter of fact, we attribute great importance to the recognition of the technological treatment (curing of hams) of pork meat as being effective in eliminating risks related to the transmission of certain diseases. We are also very proud that the Parma Ham processing method is explicitly mentioned in the document.

We think that only one aspect needs clarifying as to the part concerning “Post-weaning multisystemic wasting syndrome (PMWS)”.

In this particular paragraph, indeed, “deboning”, together with curing or cooking of pork meat is defined as a fundamental operation to reduce the risk of contamination by PMWS. We are sure that compulsory deboning of the meat is meant to take place at the end of the process – e.g. deboning of dry cured ham – since, as mentioned above, you often refer to the Parma ham processing method.

As you know, in fact, to obtain our product, pork legs have to be processed with the bone in. Deboning is possible only at the end of curing and this operation is performed especially for commercial distribution. Moreover, in Italy and Europe, cured meat deboned before starting the curing process can not be considered “ham” and cannot undergo a long curing period.

Therefore, we allow ourselves to suggest that you might consider introducing a specification as regards deboning of the meat at the end of the curing process in the paragraph concerning “Post-weaning multisystemic wasting syndrome (PMWS).”

We are very grateful for the publication of the mentioned document and also for the possibility, given to interested parties, to comment on it.

We are truly confident that this will be the first concrete step along the path leading to the opening of the Australian market to Parma ham.

Looking forward to receiving your comment, which we would greatly appreciate, we thank you once again and send our kindest regards.

***Response:*** *The quarantine requirements for PMWS have been amended to clarify that deboning and removal of major peripheral lymph nodes can occur either before or after curing or cooking.*

## **Australian Association of Pig Veterinarians**

Attached for your consideration is a submission from the Australian Association of Pig Veterinarians regarding the Pig Meat IRA Draft Report of 12 August 2003.

The Association is a special interest group of the national body representing the veterinary profession in Australia. Members of AAPV include pig specialist and general practitioners serving the pig industry, as well as government and industry veterinarians. AAPV is deeply committed to the protection of the high health status and biosecurity of Australia's pig industry.

AAPV welcomes this opportunity to provide a submission on the Draft IRA Report on behalf of our members.

## SUBMISSION FROM THE AUSTRALIAN ASSOCIATION OF PIG VETERINARIANS

The following issues and comments have been prepared as the official AAPV response to the draft IRA for Pig Meat (August 2003).

1. The background section on page 1 of the Executive Summary in dealing with the definitions of pig meat implies that all neurological tissue can be readily separated from muscle. It is our contention that in respect to neurological material contained within muscle, this is not the case. We request that the definition of pig meat be clarified.

**Response:** *The definition of 'pig meat' is limited to porcine muscle tissue, blood confined to muscle vasculature, bone and bone marrow, and any other tissues (for example lymph nodes) that may be considered inseparable to muscle. This would also include nerves. However, products derived from offal, blood, bone, neurological tissue (such as brain and spinal cord) are not considered. This has been clarified in the Executive Summary.*

2. AAPV questions the technical basis of the exclusion of TGE (Transmissible Gastroenteritis) from the list of diseases covered in the Summary of Risk Management Measures. Our concern rests with the Release Assessment calculating the following:
  - likelihood of source herd infection
  - likelihood of infection of slaughter-age pigs from infected herds, and
  - the likelihood that the agent will be present in meat harvested for export.

Each of these likelihoods was classified as 'low' based on prevalence data available from various countries, and details of the disease's epidemiology. Using these likelihoods, the overall unrestricted annual risk was classified as 'very low', which meets Australia's ALOP. Given that the IRA is 'generic' and prevalence data from endemically infected countries is considered by us to be limited and in some cases dated, we are uncomfortable with the exclusion of TGE from the summary of risk management measures.

In reality, our concern regarding TGE is satisfied by risk management measures imposed for other diseases, ie Aujeszky's disease and PMWS. However, should Australia become infected with one or both of these, we remain concerned that subsequent release from risk management measures for those diseases could leave Australia open to the risk of infection with TGE.

While the IRA classifies the consequences of Outbreak Scenario Four as 'low', we assert that TGE infection in the general population of domestic pigs would be financially devastating to the pig industry. This view is supported by several authors quoted in the Draft document (Baldock and Webster, 1990, and Mullan et al, 1994). We therefore request either:

- reconsideration of inclusion of TGE to the list, or
- provision for reassessment of risk management measures in the event that establishment of Aujeszky's and/or PMWS in Australia nullifies the respective management measure.

**Response:** *The likelihoods assigned to R1, R2 and R4 are based on the available scientific evidence as presented in the IRA. A 'low' likelihood was assigned to each of these steps. This equates to a uniform distribution of 5-30%. If scientific evidence is presented that these likelihoods should be higher the Panel will re-examine this assessment.*

*The Panel recognises the seriousness of TGE to the pig industry, nonetheless when determining the consequences of a disease, it is examined on a national basis i.e. the impact on the community, not just the pig industry. Factors such as the effect on international and domestic trade are also considered.*

3. On page 5 of the Executive Summary, within the Aujeszky's disease virus section, the control measures refer to removing the head and neck from the carcass. It is our understanding that the IRA applies to boned-out pig meat, not entire carcasses. Furthermore, although the virus resides primarily within the CNS, it can be found in peripheral nervous tissue. We request that this be clarified.

**Response:** *The definition of pig meat as described above includes bone, hence a carcass could be imported depending on a country's disease status.*

*The Panel recognised that Aujeszky's disease virus has an affinity for certain tissues in the head region, but can on occasions and often with low virus titres be found in other tissues. Hence, a 'low' likelihood was assigned to the step that virus would be present in meat for export (R4) following the removal of the head and neck. Before this risk measure was applied a 'moderate' likelihood was assigned to this step. Moreover the likelihood that a waste unit would contain a sufficient dose of the pathogenic agent to initiate infection was influenced by removing the head and neck. A 'moderate' likelihood was assigned to a waste unit derived from the head and neck and 'very low' when derived from the rest of the carcass.*

4. The PRRS section details specific processing criteria for ensuring that the PRRS risk is effectively controlled if uncooked pig meat is imported. How will these processing criteria be monitored to ensure compliance? It is our contention that pig meat derived from high risk countries be cooked prior to entry into Australia.

**Response:** *Uncooked pig meat imported into Australia from a country with PRRS will remain under quarantine control until cooked. Processors will be required to enter into a compliance agreement with AQIS and will be audited to ensure compliance. This is currently in place for pig meat imports from Canada and Denmark. A model compliance agreement currently in use is at Attachment 2.*

5. The *Trichinella spiralis* section on page 6 refers to the use of zone freedom as a risk minimization measure. How will such zones be established and monitored?

**Response:** *The OIE Animal Health Code Chapter on trichinellosis provides details as to how a country or zone may be considered free from the disease in domestic swine. These are summarised in the Risk Management section on Trichinella.*

6. What evidence exists that removing the head and major lymph nodes prior to cooking or curing will effectively control the risk of PMWS? Is there a list of PMWS free countries or zones, and how has this been established, proven and how will it be monitored?

**Response:** *Information is provided in the assessment for PMWS. Porcine circovirus type 2 has an affinity for lymphoid tissue as do many other viruses. Hence the risk management measure to remove major peripheral lymph nodes, including those in the head and neck region and bone marrow (bone-out). The product must also be cooked or cured. Should an unknown disease agent be involved in PMWS the risk management measures would also act to reduce the risks associated with that agent.*

*The Veterinary Authority of the exporting country will be required to provide information on their disease status and certify to that status. A country free from PMWS would need to meet an equivalent standard to Australia's claim to freedom which would include a case definition of PMWS, an active surveillance program in place for PMWS, the disease is notifiable and diagnostic capability.*

7. The positioning of the word “only” in the third sentence of the Conclusion on page 7 creates an opportunity for ambiguous interpretation.

**Response:** *This sentence has been removed.*

8. Finally, it is clearly understood that the scope of the IRA for the importation of pig meat does not cover the direct human public health risks. However, if *Salmonella typhimurium* DT104 & *Trichinella spiralis* should become established within Australia, the resulting monitoring & control measures will be expensive and ultimately, borne by the Australian pork industry. In our view, this is not an equitable outcome. Given the resulting financial burden, we request that additional consideration be given to the diseases/parasites that have human health implications.

**Response:** *It should be noted that the consequences assessment in the IRA for both *Trichinella spiralis* and *Salmonella typhimurium* DT104 considered the effect of control programs should the disease enter and establish in the Australian pig herd. In addition, zoonotic diseases were considered by the Department of Health and Ageing.*

## **Brentwood Piggery, TG and FL Reed**

### **Att: The 'Panel' for Risk Analysis for Pig Meat**

Following is our response to the draft IRA for the import of pig meat into Australia.

- Safeguarding the existing health status of the Australian domestic and export pork industry is paramount. As Australian citizens we do not have the right to dilute this standard in any way.

***Response:** The Panel considers that the biosecurity policy developed protects the Australian pig industry from serious diseases of concern that could be transmitted via imported pig meat. The risk management measures have been developed consistent with Australia's ALOP, Australian law and international rights and obligations.*

- Any breakdown in our current health status would have enormous ramifications on an already struggling industry. We continually feel the effects of drought and lack of access to feed grain at world parity prices.

***Response:** The consequences of disease introduction with imported pig meat are an integral part of the IRA and have been assessed for each identified disease agent.*

- Any breakdown in our current health status would cause damage to us as suppliers to the huge food bowl of South East Asia. As proven, this market is now being developed.

***Response:** The effect of a changed Australian disease status on international trade is considered for each disease in the assessment of consequences.*

- PMWS - We have concerns regarding the cooking time and temperatures outlined in the IRA. The time not being sufficient to minimise disease risks.

***Response:** The risk management measure for PMWS is to reduce the volume of waste discarded and remove tissues most likely to be at risk, such as bone and major lymph nodes. Only cooked or cured bone-out product from affected countries will be permitted for retail sale.*

- PRRS - Cooking off shore should be the only acceptable method to minimise risk. This would then ensure that there would be no transmission of this disease within Australia.

***Response:** The risk management measure for PRRS virus in pig meat is cooking either on or off-shore. Cooking on-shore will require additional safeguards including that all processors using imported pig meat enter a compliance agreement made with AQIS under quarantine legislation, auditing of processors to ensure compliance and restrictions on transport arrangements. These measures provide an appropriate level of security.*

- Cooking on our shore provides no buffer zone at all.
- Potential economic impact would be massive.
  - Totally destroy our clean green image
  - Totally destroy our marginal competitive edge
- Already proven and recognised as a disaster is the movement of imported pork within Australian shores. We refer to a trucking accident on the North Coast of NSW some time

ago. Whilst we do not agree with road transport of the pork in Australia, if it has to be, then it should be processed within a very conservative radius of port. Our thought would be 50 klms maximum.

**Response:** *It has been recommended that the existing transport arrangements be amended to address risk, such that transport of imported pig meat to rural areas for further processing must be from the nearest port and under appropriate security arrangements (for example a refrigerated container).*

- This whole IRA if accepted, has the potential to allow larger quantities of pork to be imported and remember, the larger the quantity – the larger the risk.

**Response:** *The IRA considers annual volume of trade.*

- Finally, we don't allow our children to play with loaded guns so why, as adults can we consider the actions discussed. You are playing with a loaded gun!!

**Response:** *The IRA has been conducted consistent with Australian government policies and international obligations.*

**Government of Canada**

This is further to Biosecurity Australia's Animal Biosecurity Policy Memorandum 2003/19, dated August 12, 2003, which indicated that the draft pigmeat import risk analysis (IRA) had been released. The Memorandum also invited technical comments on the draft IRA by close of business October 13, 2003. Please find attached a copy of the Government of Canada's comments.

Thank you for providing this opportunity to comment.

## Government of Canada Comments on a Draft Import Risk Analysis

### Pig meat import risk analysis (The Department of Agriculture, Fisheries and Forestry, Australia)

These comments are confined to PRRS (pages 269-299, pages 728-732) and where appropriate, the “Method for import risk analysis” (pages 23-72). There are a number of significant issues detailed in this report that need to be addressed before a realistic annual risk estimate for PRRS virus can be made. These issues include:

- Unreasonable assumptions, for example:
  - all scraps whether derived from cooked or processed meat are treated, as uncooked waste “because cooking and processing may not have been carried out to a level sufficient to inactivate pathogenic agents”.
  - All households and food service establishments generate waste.
  - All waste units, no matter what their size, contain sufficient PRRS virus to initiate infection.
- Incomplete exposure pathways, for example, the following steps are not included:
  - the generation of waste prior to or after cooking in households or food service establishments.
  - the impact of processing and/or cooking on the survival of PRRS virus.
- A significant lack of transparency, particularly in the consequence assessment, where a rational link between the discussion and the conclusions for each “outbreak” scenario is not provided.
- An inappropriate model for the “outbreak” scenarios in the consequence assessment that results in implausible probability values whereby the sum of the probabilities for each exposure group is greater than one.

**Response:** *The Panel considers that the assumptions made in the IRA are valid and reasonable. Households and food service establishments do generate waste. The waste generated would be derived from a wide range of products and cuts. Trimmings from cuts of meat are often discarded prior to cooking. Cuts of meat may not be cooked sufficiently to inactivate PRRS virus, particularly bone-in products. Bone will be discarded. PRRS virus may not be inactivated in some fermented products.*

*The Panel concluded that there was a ‘high’ likelihood that a waste unit from an infected pig would contain a sufficient dose of PRRS virus to initiate infection.. Research conducted at Lelystad and more recently in Canada demonstrated that meat from which virus could not be isolated by culture but was PCR positive (i.e. a very low virus titre) when fed to naïve pigs resulted in transmission of the virus.*

*The model was constructed so that the sum of the probabilities for each exposure group add up to 1. It would appear that Canada has assumed that the expected value of each range was used to calculate the sum of the probabilities. This was not the case, however, the probabilities did lie within the stated range.*

Once these issues and the others detailed in this report are addressed, the overall annual risk estimates will most likely be revised from low to either very low or negligible, which would meet Australia’s appropriate level of protection. As a result, sanitary measures for PRRS virus could not be justified.

## 1. Release Assessment

The conclusion of the release assessment (page 277) is that “*there was a ‘low’ likelihood that imported pig meat derived from an individual carcass will be infected*”. A ‘low’ likelihood corresponds to a probability category, as described in Biosecurity Australia’s Guidelines for Import Risk Analysis Recently, of between 5 and 30%. In reaching this conclusion Biosecurity Australia did not differentiate between oropharyngeal/tonsillar tissue and meat. A quantitative release assessment undertaken by Ministry of Agriculture and Forestry in New Zealand in 2001 concluded that there was approximately a one in four chance that oropharyngeal/tonsillar tissues derived from slaughter age pigs in an endemically infected country could harbor the virus. In contrast, there was only a one in three hundred chance that meat from the same pigs would harbour virus. These estimates correspond to Biosecurity Australia’s probability categories of ‘low’ and ‘very low’ respectively. Recently, researchers in Canada confirmed that PRRS virus could be isolated from the meat of approximately two percent of commercial slaughter age pigs. This corresponds to a ‘very low’ probability category and supports the findings of New Zealand’s release assessment. As a result, Biosecurity Australia’s release assessment needs to be revised to take account of the differential persistence of PRRS virus in oropharyngeal/tonsillar tissue and meat and to incorporate the latest findings of the Canadian study.

**Response:** *The Panel has revised the likelihood assigned to R2 (the likelihood that a slaughter-age pig from an infected herd is infected) from ‘moderate’ to ‘low’ after consideration of the Canadian research. This study demonstrated that 4.3% of total serum samples were positive for PRRS virus of 1039 slaughter-age pigs. As it is recognised that viraemia is relatively short, but the virus persists in lymphoid tissue, the Panel considered that more than 4.3% of slaughter-age pigs would have virus present, but this would be less than the ‘moderate’ likelihood assigned in the Draft IRA Report. Hence a ‘low’ likelihood was assigned to this step.*

*When the revised likelihood was inserted into the simulation model, it was concluded that there was a ‘very low’ likelihood that imported pig meat derived from an individual carcass will be infected. ‘Very low’ falls in the 0.1 to 5% range, which is in agreement with Canada’s research results (1.9% of meat samples were positive for PRRSV by PCR). When the simulation was rerun with the new value, the overall annual unrestricted risk of PRRS virus is ‘low’ and risk management is still required.*

## 2. Exposure assessment

Several unreasonable assumptions are made that result in a number of important likelihood estimates not being included in the risk assessment. As a result the, there is likely to be a significant overestimate of the likelihood of that pigs will be exposed to PRRS virus.

- a) Cooked and processed pig meat scraps are treated the same as uncooked scraps “*because cooking and processing may not have been carried out to a level sufficient to inactivate pathogenic agents*” (page 39). While this might be true in some circumstances, it is important to note that a risk analysis must examine the likelihood of a particular event, not simply whether it is possible or might occur. In addition, the normal methods of production, processing, manufacturing, handling and preparation of various pig meat products for human consumption need to be discussed. These do not constitute sanitary measures in their own right. They simply reflect normal commercial and/or domestic practices. As a result, each hazard must be examined individually to assess the likely impact of these practices on its survival.

**Response:** *Each hazard has been assessed individually and likelihoods assigned to individual steps in the exposure assessment. The Technical Issues paper discussed methods for the preservation of meat.*

- b) It is assumed that imported pig meat would be distributed as if it were domestically produced so that households and food service establishments could also purchase it. According to the risk analysis (page 37) between 35 and 40% of domestically produced meat is sold directly to households and food service establishments as fresh or frozen meat with the remaining 60 to 65% used in the manufacture of small goods which is in turn sold to households and food service establishments. Despite providing this important piece of information it is not taken into account as small goods are treated as uncooked pig meat on pretext that “*cooking and processing may not have been carried out to a level sufficient to inactivate pathogenic agents*”. As discussed in point a), the impact of the normal methods of production etc. employed by small good manufacturers and their impact on the survival of each hazard should be considered. Small good manufacturers will have stringent measures in place to meet food safety standards. As a result, information will be readily available on standard methods of cooking, curing etc. that can be incorporated into the risk assessment to obtain a more realistic estimate of the impact of these processes on the likely survival of each hazard.

**Response:** *Food safety standards are generally designed to reduce the number of bacterial contaminants such as Listeria, E. coli. These standards are not designed to inactivate PRRS virus.*

*As discussed previously, there are a very wide range of small goods, processed to a wide range of temperatures and including bone-in and fermented products. Data providing sufficient breakdown of the types of products and whether PRRS virus would be inactivated, or virus titre reduced were unavailable. Nonetheless it should be noted that even if the volume of waste discarded was reduced to one tenth of that estimated for the unrestricted risk, the likelihood of entry, establishment and/or spread was not reduced to an acceptable level.*

- c) It is assumed that ALL waste discarded by food service establishments and households is “uncooked”. The risk analysis needs to estimate the likelihood of generating uncooked/uncured or inadequately cooked/cured scraps rather than simply concluding that “*cooking and processing may not have been carried out to a level sufficient to inactivate pathogenic agents*” (page 39).

**Response:** *See comment above.*

- d) It is assumed (implicitly) that ALL food service establishments and ALL households discard some amount of pig meat as waste. This represents a worst case scenario. How realistic is such a scenario? Since it is likely that a reasonable proportion of food service establishments and households do not discard scraps, particularly prior to cooking, a more realistic estimate of the likelihood of discarding scraps need to be obtained.

**Response:** *The Panel considers that households and food service establishments all produce waste of varying quantities. The Panel’s assumptions are supported by a survey conducted in the United Kingdom which assessed the proportion of purchased meat that is discarded uncooked in domestic kitchens (range of 1 to 20%) (referenced in the IRA Report). In addition there will always be waste such as blood and protein on wrapping material.*

- e) It is assumed that ALL waste units, no matter what their size, if contaminated with PRRS virus, contain sufficient virus to initiate infection when discarded. Even if a pig consumes pig meat that is harboring PRRS virus, the virus must be present in a sufficient amount to initiate infection. Although the oral infectious dose is not known, this assumption is based on an observation that as few as 10 virions by the intranasal route can initiate infection and an experimental challenge study in the Netherlands, which was designed to maximise the potential for transmission of PRRS through pig

meat. A large chunk of meat (250 gm per day for two days) was fed to each of the three-month old challenge pigs, which had been deprived of food, other than water, for 2 days. These pigs had to chew the meat before swallowing. This was considered necessary as the researchers were concerned that the low pH of the porcine stomach would rapidly destroy the virus. In addition, it is thought that infection via the oral route occurs as a result of virus contact with the mucosal surface of the oro-pharynx and tonsils. Such contact would be maximised by forcing the pigs to chew the meat. Recently, researchers in Canada replicated the Dutch work and confirmed that PRRS virus could be isolated from the meat of commercial slaughter age pigs and that when fed to naïve pigs under the same artificial conditions, successful transmission of infection occurred. However, these findings are of limited importance as most scraps generated from household, restaurants, processors and manufacturers are likely to be considerably smaller than 500 gm. Pigs would be unlikely to chew small scraps to any extent so the virus would be exposed to the low pH of the porcine stomach where it would be rapidly inactivated. In addition, most scraps are likely to have been derived from cooked or processed meat, in which the viral titre, in the vast majority of cases, is likely to be negligible.

**Response:** *The Panel concluded that there was a 'high' likelihood that a waste unit from an infected pig would contain a sufficient dose of PRRS virus to initiate infection. Research conducted at Lelystad and more recently in Canada demonstrated that meat from which virus could not be isolated by culture but was PCR positive (i.e. a very low virus titre) when fed to naïve pigs resulted in transmission of the virus. Although the Lelystad researchers considered that chewing of meat may be important to allow for enhanced contact between oropharyngeal mucosa and virus, in the field oral transmission is likely to occur via infected secretions with no chewing involved.*

- f) It is assumed, based on the daily intake of a lactating sow, that a pig could consume up to 5 kg of pig meat (page 42). The basis for choosing both the minimum (10 g) and most likely (250 g) values and a truncated log logistic regression to model the size of a waste unit is not discussed, resulting in a considerable lack of transparency. Is there any information available to support these values? Why was the log logistic distribution chosen? There is significant amount of uncertainty in the size of a waste unit as the coefficient of variation of the chosen distribution is 38%.

**Response:** *The information was based on the Panel's observations.*

To assist in identifying and modelling appropriate exposure pathways the following figures (1 to 5) are provided. In addition to the events outlined in the existing exposure assessment, these figures account for a number of important likelihood steps omitted from the analysis including, the distribution of imported pig meat, the generation of waste prior to or after cooking in household or food service establishments and the impact of processing and/or cooking on the survival of PRRS virus.

Figure 1

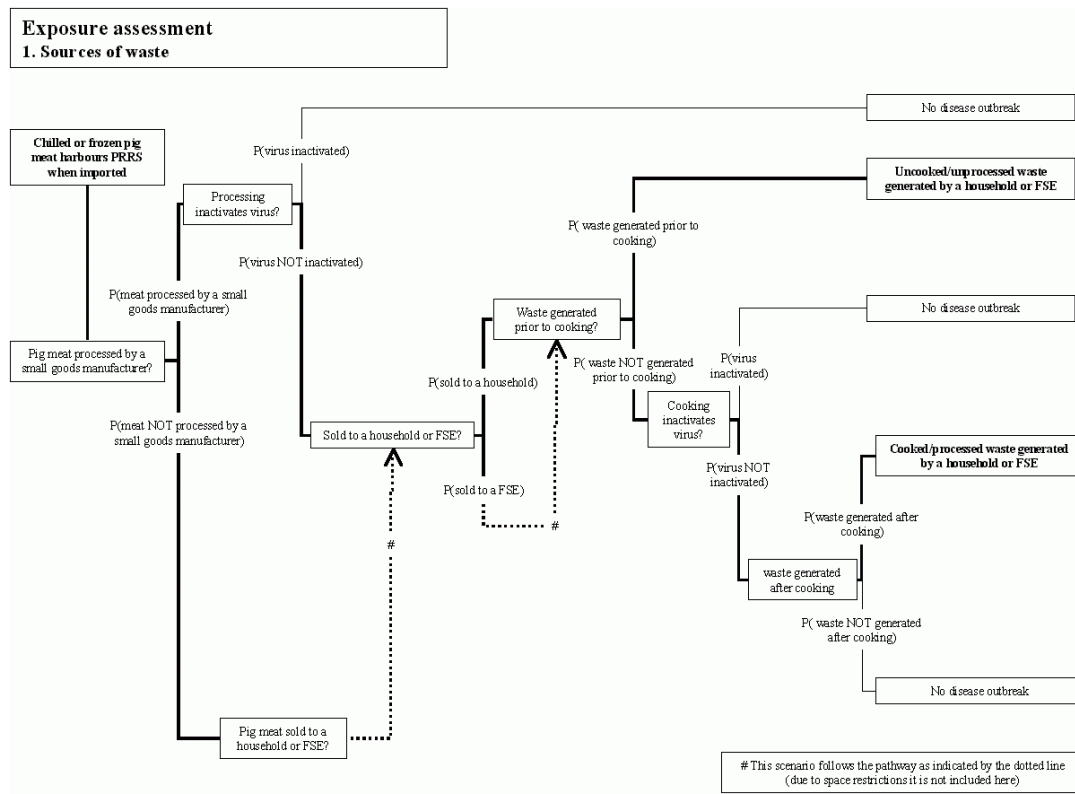
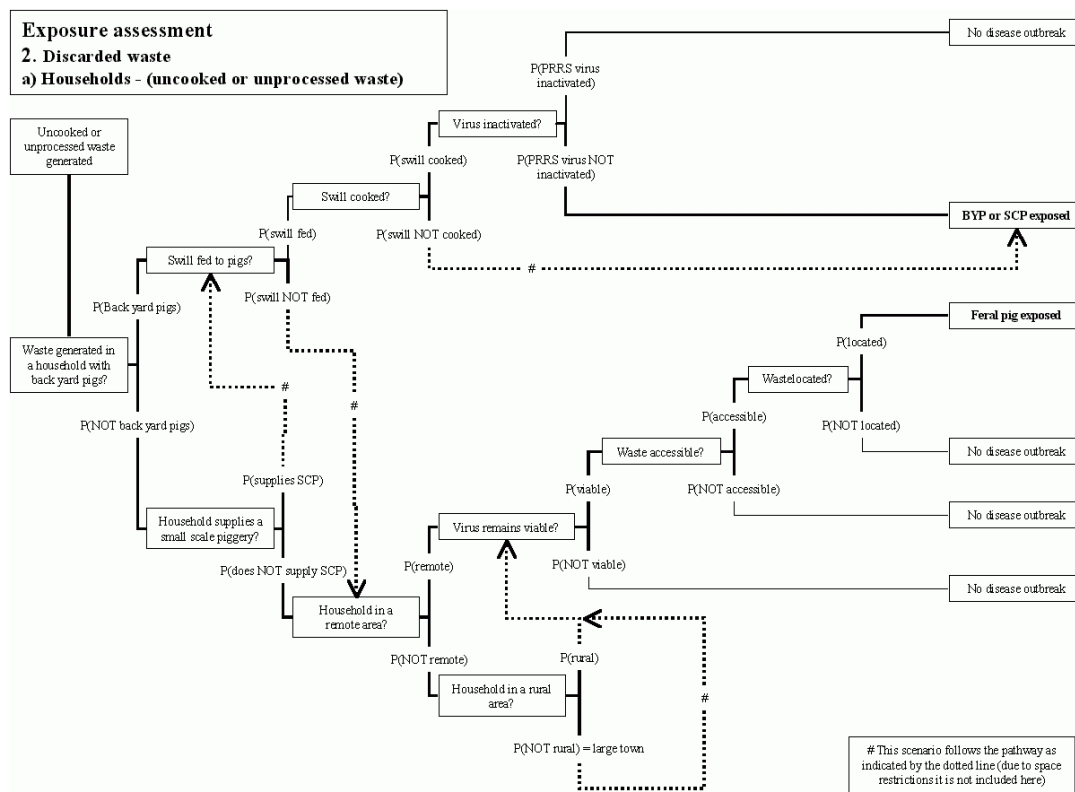
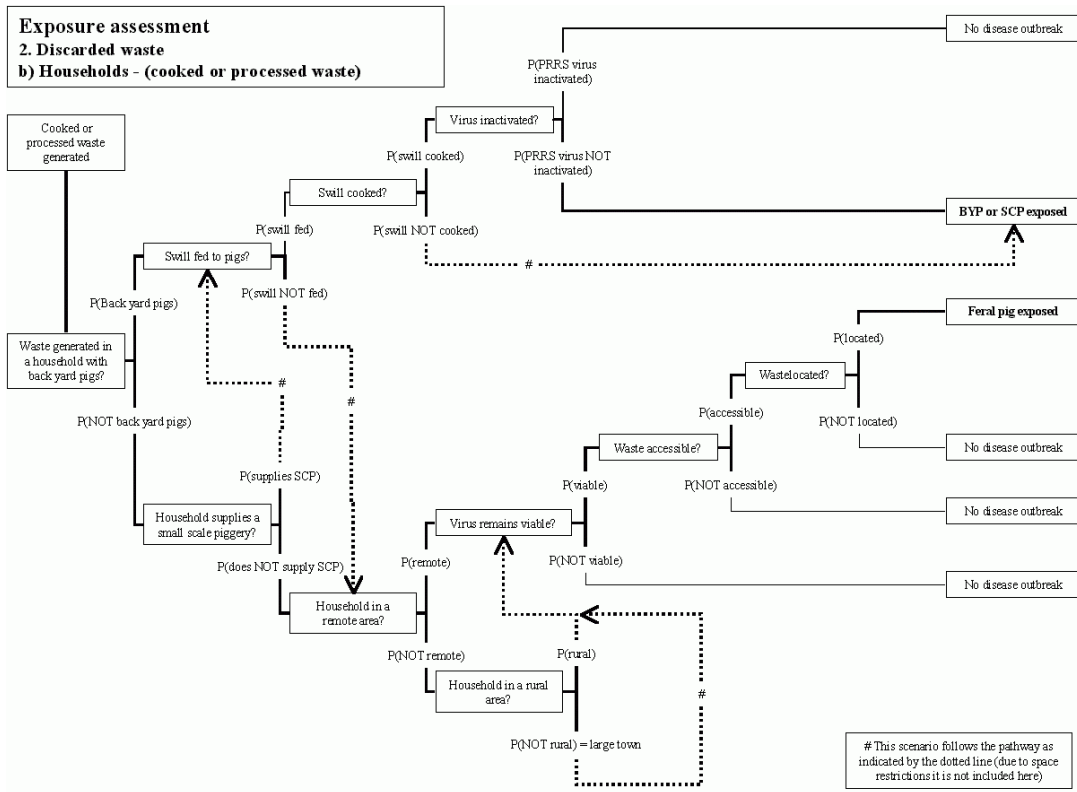


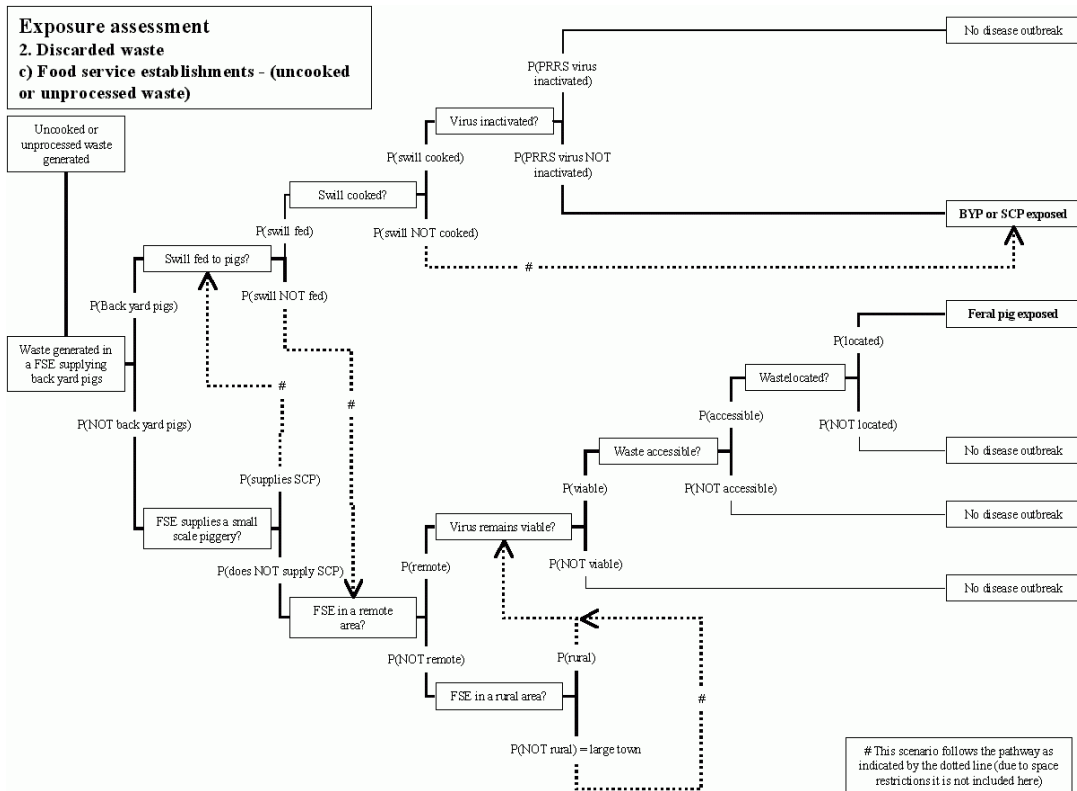
Figure 2



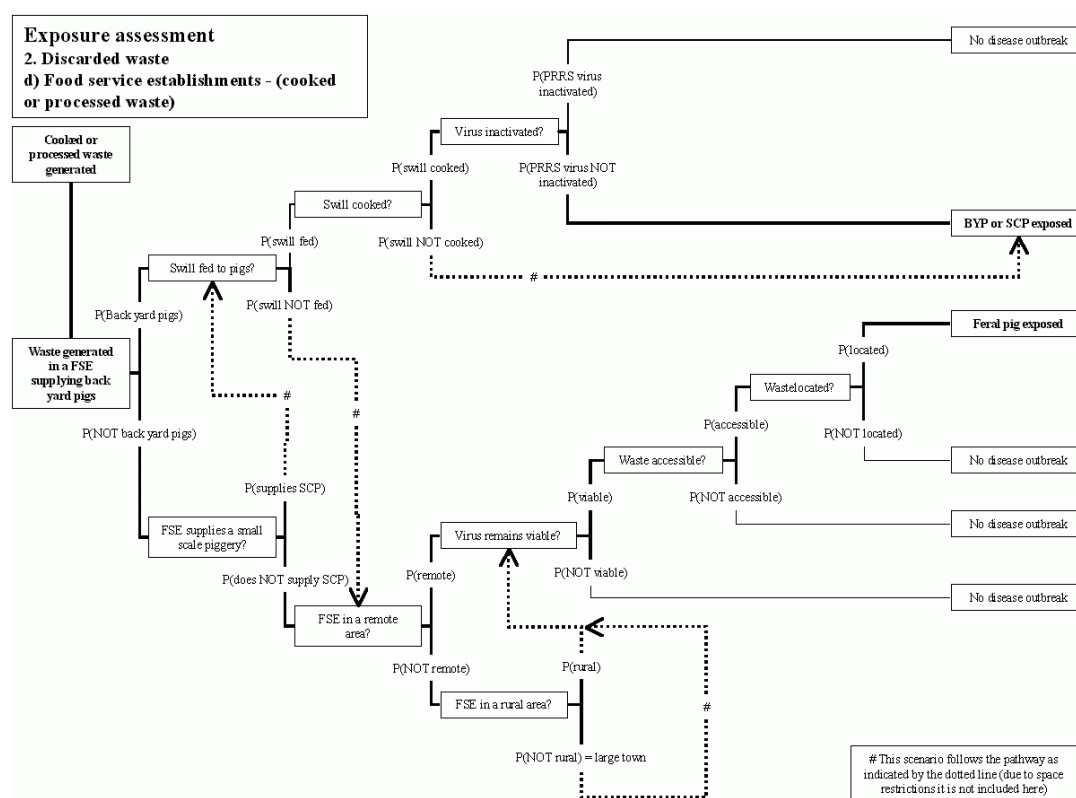
**Figure 3**



**Figure 4**



**Figure 5**



### 3. Annual likelihood of entry and exposure

The annual likelihood of entry and exposure for each exposure group (feral pigs, backyard pigs or pigs in small commercial piggeries) is calculated as the probability that at least one unit of waste will result in exposure (pages 50, 54, 59):

#### *Annual likelihood of entry and exposure*

Where:

P = the probability that each unit of waste will result in exposure

N = the number of waste units in a year that are eaten by or fed to the exposure group

The implicit assumption in this calculation is that exposure results in infection of the “exposure group”. Effectively, each exposure group is a discrete unit to which a waste unit would be discarded:

- i. Feral pigs – each pig is discrete unit
- ii. Backyard pigs – all the pigs in a backyard piggery are treated as a discrete unit that is up to 10 pigs are treated as though they were all just one pig
- iii. Pigs in a small commercial piggery – all the pigs in a small commercial piggery are a discrete unit that is between 10 and 99 pigs are treated as though they were all just one pig

Since all the pigs in either a backyard or small commercial piggery constitute a discrete unit, the distribution of waste units amongst the pigs, the amount likely to be eaten by each pig and the likelihood that a pig will become infected after consuming a partial waste unit is ignored. As a result, these calculations are unrealistic and constitute a simplistic worst case scenario. If a

waste unit harboring PRRS virus end up being fed to backyard pigs or pigs in a small commercial unit, infection is the inevitable outcome.

***Response:** The likelihood of exposure of each group was estimated taking into account the probability that each pig meat waste unit will result in exposure and the number of waste units consumed in a year by the exposure group. In determining the probability that each unit of waste will result in exposure, the likelihood that a waste unit is infected, the likelihood that a waste unit would contain a sufficient dose of PRRS virus to initiate infection and the likelihood that PRRS virus would remain viable during the period prior to ingestion were calculated. These likelihoods were assigned as ‘low’, ‘high’ and ‘moderate’ respectively. Accordingly infection is not the inevitable outcome. Importantly the likelihood of exposure was determined on an annual basis not on a per day basis. Moreover discarded pig meat is more likely to be consumed by one or two pigs in the same pen. The risk assessment concluded that the overall annual likelihood of entry and exposure for backyard pigs and small commercial pigs was ‘low’ and ‘high’ respectively i.e. infection is not the inevitable outcome.*

#### 4. Consequence assessment

##### 4.1. Estimating the likelihood of each outbreak scenario (stated on page 63 to be “the likelihood of establishment and/or spread”)

While some discussion is provided for each exposure group, there is a considerable lack of transparency in estimating the likelihood for each of the outbreak scenarios. There is no rational link between the discussion and the conclusions reached. The only link provided is a statement that “on balance, the following likelihood’s were assigned to each scenario”. In addition, the discussion for each likelihood estimate is, to a large degree, based on un-referenced speculation of possibilities. It is important to note that both the SPS Agreement and the OIE Code stipulate that a risk assessment evaluate the likelihood of an event, not simply focus on possibilities. Phrases such as “it is conceivable”, “if ...” “may/might occur/result”, “it is theoretically possible”, etc., as highlighted in the following extract from the risk assessment (pages 281-283), do not provide sufficient justification for the likelihood estimates given for the various outbreak scenarios.

- i. Feral pigs
  - *“it is conceivable that nocturnally foraging pigs may be attracted to an enclosure housing domestic pigs, and that while mixing per se is unlikely, contact sufficient for the transmission of PRRS virus may occur”*
  - *“if transmission to a backyard or small commercial piggery occurred” and “if large commercial piggeries were also situated in the region, spread to these might occur, and that this may subsequently lead to a more general outbreak”.*
- iii. Backyard pigs
  - *“it is feasible that backyard pigs kept in rural areas may come in close contact with nocturnally foraging pigs, and that transmission of PRRS virus from one group to the other may result”*
  - *“it is feasible that some mixing of pigs between backyard herds may occur”*
  - *“pigs raised for personal consumption may be transferred between backyard holdings”*
  - *“indirect spread by fomites or by mechanical vectors is also feasible although not substantiated”*
  - *“it is theoretically possible that PRRS virus in saliva and/or urine may be transferred from an infected backyard herd to other domestic pigs through inadequately cleaned vehicles, equipment or footwear”*
  - *“it is likely that the disease would be amplified and spread regionally by pigs, semen, fomites, or other means to other piggeries”*

- *“if large commercial piggeries were also situated within the region, spread to these might occur, and this may lead to a more general outbreak.”*
- xi. Small commercial piggeries
  - *“**the potential for** (a) close contact with either feral pigs or other domestic pigs, and, (b) indirect spread to either of these groups by fomites or mechanical vectors”*
  - *“it is **more conceivable** that infection would be amplified within a small commercial herd to the extent necessary for transmission via fomites or mechanical vectors”*

**Response:** *Noted. The Panel considers that Canada’s comments are really a semantic argument arising from the situation which is trying to model potential future situations. Nonetheless likelihoods have been assigned to each outbreak scenario.*

Despite the discussion for backyard pigs on page 282 indicating that “spread by fomites or by mechanical vectors” has not been substantiated, the analysis theorises about the possibility of PRRS virus being transmitted to other domestic pigs “through inadequately cleaned vehicles, equipment or footwear” or, with an absolute lack of transparency, by “other means”. Although PRRS virus, as the analysis indicates in an un-referenced statement, may have been detected in saliva, urine and faeces there is no discussion concerning its stability in the environment. Unless it is a relatively resistant virus transmission by fomites would be extremely unlikely.

**Response:** *The discussion on transmission by fomites has been amended to include references demonstrating the role of fomites. It should be noted that references are also provided in the Technical Information section on the stability of the virus and excretion of the virus in different secretions.*

Although PRRS virus is highly infectious, given the low population density of feral pigs in Australia and the very limited contact likely to occur between feral and domestic pigs, the likelihood that PRRS virus would spread beyond the initial group of exposed feral pigs into backyard or small commercial piggeries would be very low. Similarly, the likelihood of PRRS virus spreading from backyard or small commercial piggeries to feral pigs would be very low. Even if a herd of backyard pigs or a small commercial piggery did become infected as a result of contact with feral pigs and the likelihood of further transmission of PRRS virus to other backyard or small commercial piggeries was considered to be moderate, the overall likelihood of such an event would still be very low. In this scenario a conditional relationship exists whereby contact must first occur between a feral pig and a backyard or small scale piggery before infection can pass on to other backyard or small scale piggeries.

For medium- large commercial pig units to become infected there must be effective contact with a backyard or small commercial piggery. Possible means of effective contact are stated to be by “*pigs, semen, fomites, or other means*”. It would be reasonable to conclude that the likelihood of effective contact occurring by one or more of these potential exposure pathways is at the most moderate. Medium-large commercial piggeries would be very unlikely to introduce pigs or semen from backyard herds or small commercial piggeries, primarily as a result of concerns that live animals or semen from such sources could potentially compromise biosecurity or offer little if any genetic merit. Similarly, even if it were assumed that fomites (“*inadequately cleaned vehicles, equipment or footwear*”) could transmit PRRS virus, the level of biosecurity maintained in medium-large piggeries would effectively preclude such exposure routes.

**Response:** *In the Panel’s opinion PRRS virus would spread to the Australian commercial pig herd. In Australia pigs of different ages can be marketed through regional markets and sale yards resulting in spread of the virus. Moreover, PRRS virus spread rapidly through all sections of the pig population in both North America and Europe. In addition, it is known that in other countries disease agents such as CSF and Aujeszky’s disease for which there are*

*control programs in the domestic pig population are transmitted from feral pigs to domestic pigs. In Australia, contact between feral pigs and domesticated pigs has been reported.*

It is stated on page 64 that the purpose of scenario 1 (no further establishment or spread) is “to ensure that the sum of the likelihood’s assigned to outbreak scenarios for that group [exposure group] would always be one”. If the expected values for each likelihood estimate from the probability categories given on page 28 are summed for each exposure group (feral pigs, backyard pigs or pigs in small commercial piggeries) the corresponding values are 1.2, 1.03, and 1.35. Since probabilities can only take on values of between and including 0 and 1, there is a problem with the outbreak scenario model.

**Response:** *The model is constructed so that values assigned to each outbreak scenario add up to one. The values selected lie within the probability range used in the matrix to determine likely consequences.*

Figures 6-8 provide a scenario tree for each exposure group leading to the “outbreak” scenarios of interest. Likelihood’s are assigned to each branch using the same information presented in the risk analysis but based on the preceding discussion. The likelihood of each “outbreak” is calculated by determining the joint probabilities for each end point and adding the respective endpoints for each scenario, for example for Scenario 4 for the feral pig exposure group (figure 6):

$$\text{high*low*very\_low*moderate+high*(1-low)*very\_low*moderate}$$

It is important to note that the sum of all the scenarios for each exposure group in this model sum to one. Table 1 presents the revised results for each exposure group and compares them with the original estimates provided in the risk analysis. If these revised likelihood estimates for each exposure scenario are used to estimate the “likely consequences” using AFFA’s estimates for the consequences for each scenario and applying the matrix in Table 9, page 67 and the decision rules on page 68, the overall likely consequences of entry, establishment and spread for each exposure group is very low. This compares to AFFA’s original estimate of low for each group.

**Response:** *Noted. The Panel does not agree with Canada’s estimates of the likelihood of each outbreak scenario provided in Table 1. As discussed above the Panel considers that PRRS virus would spread to the Australian commercial pig herd and has assigned a ‘moderate’ likelihood to this scenario following exposure of feral pigs, backyard pigs or pigs in small commercial piggeries respectively.*

### **13.1. Estimating the likelihood of each outbreak scenario (stated on page 63 to be “the likelihood of establishment and/or spread”)**

On page 291 it is stated that “the overall likely consequences associated with the exposure of feral pigs, backyard pigs or pigs in small commercial piggeries to infected pig meat scraps were considered ‘low’, ‘low’ and ‘low’ respectively”. This is based on the decision rules on page 68, in particular rule number 8 “where the likely consequences for one or more outbreak scenarios were ‘low’ the overall likely consequences were considered to be ‘low’”. Applying the same decision rules to the revised estimates in Table 1 for the likelihood of each scenario for each exposure group and using the same estimates in the risk analysis for consequences of each scenario results in an estimate for the overall likely consequences for each exposure group of very low.

Figure 6

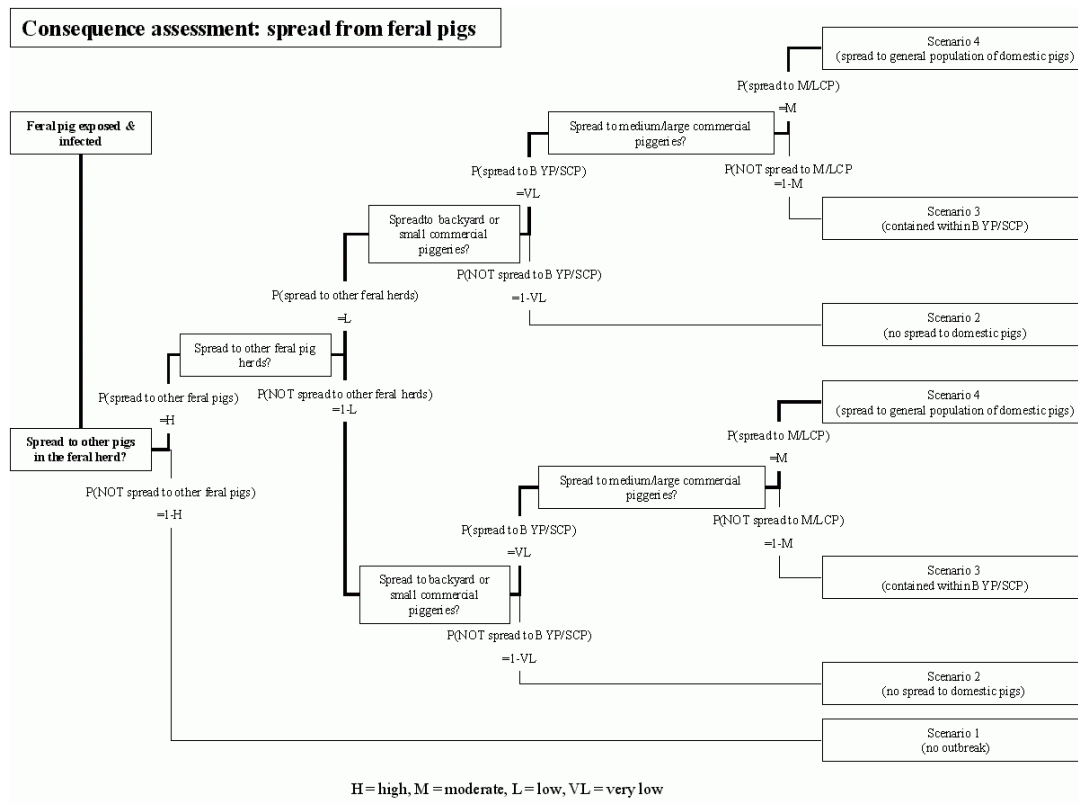
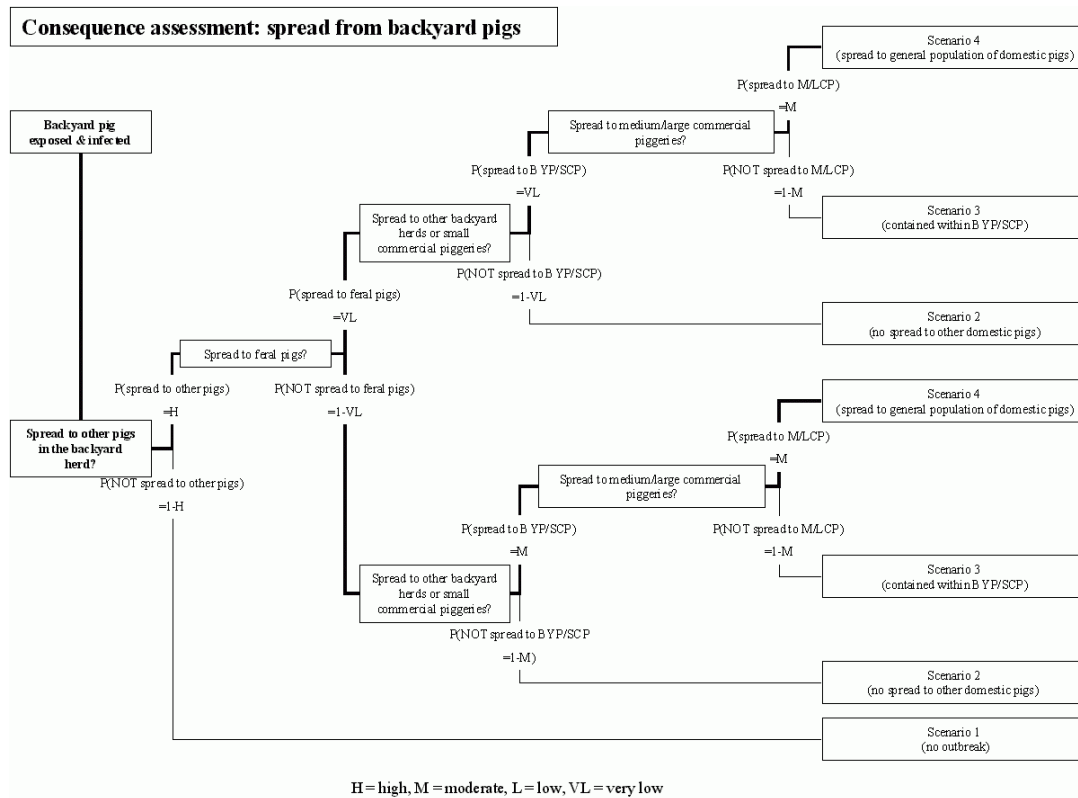
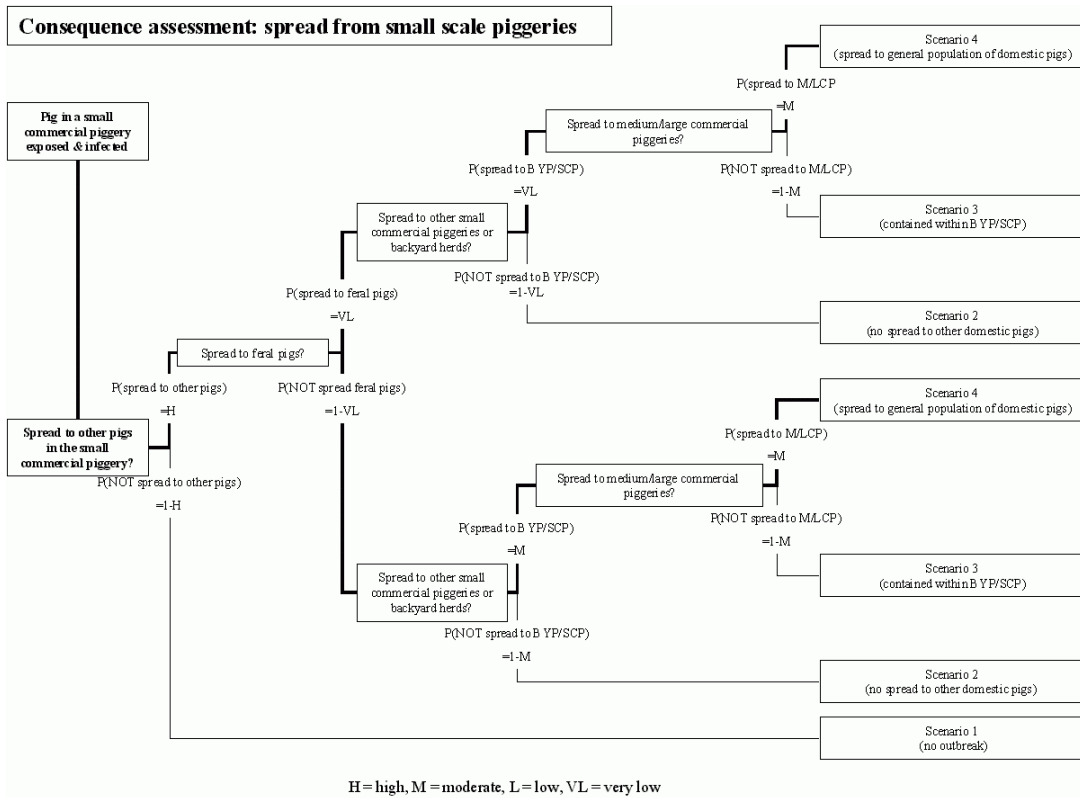


Figure 7



**Figure 8**



**Table 1:** the likelihood of each outbreak scenario. Estimates in brackets are those determined by AFFA

Scenario	Feral		BYP		SCP	
	Probability	Qualitative	Probability	Qualitative	Probability	Qualitative
1. No outbreak	0.15	Low (very low)	0.15	Low (low)	0.15	Low (low)
2. No spread to domestic pigs (feral pigs only)	0.83	High (moderate)	0.44	Moderate (low)	0.44	Moderate (low)
3. Contained within BYP/SCP and feral pig population	0.01	Very low (low)	0.21	Low (low)	0.21	Low (moderate)
4. Spread to general population of domestic pigs	0.01	Very low (low)	0.21	Low (low)	0.21	Low (moderate)

**Response:** See comment above.

**5. Estimation of the overall annual risk**

In the existing risk analysis the partial annual risk is determined for each of the exposure groups (feral pigs, backyard pigs or pigs in small commercial piggeries) using the matrix in Table 10, page 70. The results are presented in Table 46, page 293 and are estimated as ‘low’, ‘low’ and ‘low’. Using the revised estimates of the overall likely consequences for each exposure group from section 3 of this report (all very low), the partial annual risk estimates are all very low. However, this is based on the conclusion from the release and exposure assessment that the “annual likelihood of entry and exposure” for each exposure group is “high”. As has already been discussed in section 2 of this report, the existing exposure assessment is likely to significantly overestimate of the likelihood of that pigs will be exposed to PRRS virus. Once

the exposure assessment has been revised and adequate account taken of the issues such as the generation of waste prior to or after cooking in household or food service establishments and the impact of processing and/or cooking on the survival of PRRS virus, it is likely that the estimate for the annual likelihood of entry and exposure will be low rather than high. As a result the partial annual risk estimates would be negligible to very low.

The final step is to estimate the overall annual risk following the decision rules on page 70, in particular rule number 7 “*where all partial annual risks were low, the overall annual risk was considered moderate*”. Using the revised estimates of the partial annual risk (all very low), the overall annual risk according to rule number 9 would be low. However, as discussed in the preceding paragraph, once adequate account is taken of the issues raised in this report, the overall annual risk is likely to be very low to negligible.

***Response:*** *As noted above the Panel does not agree with Canada regarding the likelihoods they have assigned to each outbreak scenario. The release assessment has been amended taking into account Canada’s research. On this basis, it was concluded that there was a ‘very low’ likelihood that imported pig meat derived from an individual carcass will be infected. The overall annual risk was determined to be ‘low’. The overall annual risk is higher than Australia’s ALOP and risk management would be required. Cooking or curing to specified requirements would reduce the risk of entry, establishment and/or spread of PRRS virus to ‘very low’ which would meet Australia’s ALOP.*

## **Departamento de Protección Pecuaria, SAG, Chile**

In relation with Animal Biosecurity Policy Memorandum 2003/19 Pig Meat Import Risk Analysis Draft Report, when you talk about the risk associated with the potential presence of the disease agent porcine reproductive and respiratory syndrome (PRRS), we don't understand why Canada, Denmark and New Zealand can export to Australia uncooked pig meat then cooked it on arrival, if these countries have a similar sanitary situation with Chile, and inclusive Chile is in best sanitary position than them.

***Response:** Conditions for the importation of pig meat from Canada and the South Island of New Zealand were finalised in 1990, following consideration of their access requests. Denmark had also sought access and an import risk analysis was conducted and conditions finalised in 1997. A number of other access requests for pig meat have been received including from Chile in 2000 and this generic IRA was conducted to address these requests.*

We want to know which procedures do we have to do to export pig meat to Australia, and does Australia consider us to have the good sanitary condition as the rest of the world do?

***Response:** Once the generic conditions are adopted, and an importer applies to AQIS for an import permit for pig meat from Chile, conditions specific to Chile's health status will be developed. This may involve an evaluation of veterinary services and plant inspection. Guidelines for the approval of countries to export animals (including fish) and their products are at Attachment 3.*

According to the Animal Biosecurity, we will appreciate your kind answer about de requirements for export Chilean pig meat to Australia and the particular regulatory conditions that allow the exportation of such commodity from Canada, Denmark and New Zealand.

***Response:** The IRA sets out the conditions for importation of pig meat depending on a country's animal health status.*

*Conditions for the importation of pig meat from the South Island of New Zealand, Canada and Denmark are available on the Australian Government Department of Agriculture, Fisheries and Forestry web site <http://www.daff.gov.au>.*

## **John Riley - JCR Associates International**

Comments on the Draft IRA for the importation of Pork

I represent the interests of some 25 pig producers in Queensland and New South Wales responsible for over ten thousand sows and their progeny. Following the meeting to discuss the draft protocols on the importation of pork in Toowoomba I have been instructed to write to you regarding their concerns for national bio-security.

The protocols discussed at the meeting held in Toowoomba on Oct 1st re the "Draft IRA report" allowed for the movement of imported pork to rural areas for processing. This policy is totally unacceptable and constitutes a threat to the bio-security of the Australian industry. It is my group's considered opinion that the same controls should apply to pork as apply to that adopted for imported grain. That is that the pork should be processed in the urban areas close to the port where the product is landed.

One of the few advantages that Australian producers have over their competitors in the world market is our high health status. No policies which put that advantage at risk are acceptable to my cell. APL should take a firm stance on this to safeguard the industry's long term future. There was, as you will be aware, a case of a truck crashing and imported pork being strewn over the road. The effect of a disease on our industry would be catastrophic, would increase production costs and also put our export markets at risk.

***Response:** Revised security arrangements will apply for imported pig meat processed in rural areas. These include that the pig meat is transported from the nearest port and under appropriate security arrangements such as a refrigerated container.*

*The risk of disease introduction with imported grain and with pig meat via transport in rural areas cannot be directly compared as the specific risk factors are different.*

I draw your attention to the current concern in New Zealand regarding a possible outbreak of PMWS, a disease outbreak in weaner pigs the cause of which is not known and a cure for which has not been determined. Australian cannot reduce it's vigilance if we are to retain our high health status.

***Response:** Biosecurity Australia is aware of the situation in New Zealand. The IRA addresses the risks of PMWS with the importation of pig meat and identifies risk management measures that will provide protection to Australia.*

Whilst accepting that imports will occur we repeat our request that the imported pig meat is processed in the urban area near the point on unloading. We trust this point will be included in the next draft.

**Queensland Government, Department of Primary Industries**

**Office of the Director-General,**

**Animal Biosecurity Policy Memorandum 2003/19**

**Pig Meat Import Risk Analysis (IRA) Draft Report – request for technical comment.**

The proposed import conditions are considered appropriate to protect the Australian industry and consumers from the adverse consequences likely to ensue if diseases exotic to Australia were introduced.

The IRA appears to be thorough and comprehensive and reflects the value of the extensive consultation undertaken with relevant technical experts.

***Response: Noted.***

## **Italian Meat Manufacturers' Association**

**Object: Comments of the Italian Meat Manufacturers' Association (ASS.I.CA) on the document of the Australian Department of Agriculture, Fisheries and Forestry: "Generic Import Risk Analysis (IRA) for pig meat".**

Thank you very much for the opportunity you gave, on behalf of your Government, to interested stakeholders to express comments on the document of the Australian Department of Agriculture, Fisheries and Forestry: "Generic Import Risk Analysis (IRA) for pig meat".

The writing Association representing the Italian meat manufacturers welcomes the IRA report and wishes that its final version could lead to an opening of the Australian market to high quality pig meat products from Italy (Parma and San Daniele ham).

The specific remark ASS.I.CA would like to raise concerns the fact that in the case of Foot-and-mouth disease and Classical swine fever, the heat treatment to meet Australia's appropriate level of protection (ALOP) is higher than the OIE standards able to ensure virus inactivation (Terrestrial animal health code, Section 3.6: inactivation of pathogens and vectors).

We thank you once more for having given us the possibility to express our general views on the document in object and should you wish to receive any further information please do not hesitate to contact us.

***Response:*** *The recommendations of the OIE with regard to heating were considered for FMD and CSF. As detailed in the IRA, these risk management measures did not reduce the level of risk sufficiently to meet Australia's ALOP.*

## European Commission

### 1. Introduction – general comments

The document of the Australian Department of Agriculture, Fisheries and Forestry “Generic Import Risk Analysis (IRA) for pig meat” is presented as a generic import risk analysis. However, as drafted, it still presents major barriers to imports of pig meat, especially fresh meat.

*Response: The importation of fresh (uncooked pig meat) is permitted subject to the animal health status of a country or region. The risk management measures identified are based on a scientific risk assessment and are necessary to manage the unacceptable risks that were identified.*

The Commission notes that most of the measures proposed by Australia differ remarkably from the standards established by the relevant international bodies (OIE, Codex) and/or are not based on solid scientific grounds but rather propagate a zero-risk approach which cannot be accepted, as is against the principles of the SPS Agreement.

*Response: For each of the diseases identified in the IRA as requiring risk management, the relevant OIE recommendations for the importation of pig meat, are considered. In some instances the recommendations did not meet Australia’s ALOP, which aims to reduce risk to a very low level and other measures are required. These measures are supported by a risk assessment. Australia does not have a zero-risk approach.*

The risks posed by disease agents that could be potentially introduced into Australia via import of pig meat or pig meat products have very often been overestimated. Examples of overestimation of risks and absence of scientific grounds of the proposed measures are given below.

*Response: The likelihoods assigned in the IRA are based on available scientific information as documented. Australia would be pleased to consider any other scientific information the European Commission may have available to it.*

### 2. OIE List A diseases

Basically, a zero-risk approach has been kept for OIE list A diseases. In many circumstances the available scientific evidence indicating that the viruses in question would be inactivated by certain treatments of pig meat have been considered as insufficient or misinterpreted, despite that - at least for certain diseases - the same scientific evidence forms the basis of OIE standards, which have been accepted by the scientific community and Member Countries, whilst being disregarded by the IRA.

For **Foot and Mouth Disease (FMD)** either the pig meat must derive from a country or zone recognised by Australia as FMD free or it must be heat treated to at least 100°C, which is the only treatment considered by Australia sufficient to inactivate FMD virus in pig meat. This is excessive when compared with OIE standards on treatments of meat which are able to ensure FMD virus inactivation.

Curing and maturation of certain typical European products such as Parma Ham and Serrano Ham have not been considered by the IRA as sufficient for virus inactivation. This conclusion is not based on science. Indeed, the results of the experiments cited in the IRA concerning FMD, African and classical swine fever and swine vesicular disease, have showed that curing

and maturation of these products fully inactivate all these viruses and that - amongst the viruses above - FMD virus was the one more rapidly inactivated<sup>5</sup>.

For Parma ham – for example – these experiments<sup>6</sup> showed FMD virus persistence on samples taken up to day 96 of maturation, while full virus inactivation was shown on samples taken at 108, 136, 170 and 227 days of maturation. Despite these findings and the fact that Parma ham has a minimum maturation period of 10-14 months, the IRA concludes that there would be a “very low” likelihood that FMD virus would survive in this type of ham when cured for a minimum of 170 days. As a consequence, the IRA arrives at the conclusion that the import of Parma ham would pose unacceptable risks for Australia. This conclusion is unreasonable given the clear experimental results, which themselves are based on worst-case scenarios.

This is a very clear example of misinterpretation of scientific data and overestimation of risk. Indeed, in the light of the experiments above mentioned the likelihood of persistence of FMD virus at the end of the curing period of all products in question should be considered as “negligible” by Australian Authorities.

**Response:** *The OIE recommendations have been assessed, but did not always meet Australia’s ALOP.*

*With regard to inactivation of FMD in specific products such as Parma ham and Serrano and Iberian hams, the Panel considers that there is a ‘very low’ likelihood that virus will be present in these products (0.001 to 0.05). It should be noted that there was wide variation in virus titre of tissues from different pigs which could influence the outcome, samples from every pig were not analysed and different pooled tissue samples were inoculated into pigs.*

*Risk is a combination of not only likelihood of entry and exposure but of the likely consequences. In the case of FMD entering Australia the likely consequences were ‘Extreme’. Curing of these products alone, or in combination with pigs sourced from premises in which FMD had not occurred in the previous 3 months did not meet Australia’s ALOP.*

*With regard to the footnote that hams were produced from pigs that were moribund, or seriously sick, nowhere in the papers by Mebus et al 1993a or McKercher et al 1987 is this mentioned. The pigs were slaughtered at 2 days post-inoculation.*

For **Classical Swine fever (CSF), African Swine Fever (ASF) and Swine Vesicular Disease (SVD) under the IRA**, either: i) the pig meat must derive from a country or zone recognised by Australia as free or ii) it must be heat treated to at least 100°C or iii) it must come from farms free from evidence (clinical serological and virological) of these diseases and undergo the treatment established for certain typical European products (Parma Ham and Serrano Ham).

As for FMD, the experimental evidence that the viruses in question are fully inactivated during the curing and maturation process of these products has not been taken into account. Again the available OIE standards – for example the ones on inactivation of CSF virus in pig meat products - have not been taken into account.

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<sup>5</sup> It is to be underlined that these experiments were carried out under “extreme” conditions that are highly unlikely to occur in the field. They were carried out in parallel in two distinct laboratories, one in Europe and the other in the USA. The hams were produced from seriously sick or even moribund pigs which had very high virus titres in meat at the moment of slaughter. During the curing period virus inactivation was verified by means of pig inoculation, that is a method much more sensitive than ingestion by oral route, which would be, however, the only possible “natural” route of virus transmission via these products. The viruses in question were considered fully inactivated only after that at least two series of samples taken during the curing period at a distance of at least 30 days were found virus negative.

<sup>6</sup> McKercher et al., Can. Inst. Food Sci. Technol. J., vol 20 N.4, pp 267-272, 1987

**Response:** Where there are relevant OIE recommendations these are assessed to see if they meet Australia's ALOP. Where these recommendations met Australia's ALOP these were recommended. In the case of ASF and SVD, the OIE does not provide curing times. In the case of CSF, the OIE provides curing times, however, as discussed above, experimental work on inactivation of OIE List A viruses that can be transmitted via meat is limited to a few studies. Moreover in these studies pooled samples are used and there is significant variation between animals in virus titre of tissues.

The additional requirements proposed by the IRA before importing certain typical European pig meat products (clinical, serological and virological testing of pigs in their farms of origin during three-six months before slaughter) are very trade restrictive, in particular those on serological and virological testing and they are not justified, given that as indicated by the OIE, the incubation period for the disease in question is much shorter and clinical signs of disease would allow clinical recognition within a few weeks from virus entry into the farm.

**Response:** The Draft IRA Report stated that the pigs be sourced from premises which had been free from any evidence of ASF, CSF or SVD (be it clinical, serological or virological) for 3, 3 or 6 months respectively prior to slaughter. In the case of ASF and CSF it is not a requirement that serological or virological testing is undertaken, but if the disease has been identified by any means that premises would be ineligible to send pigs for slaughter for product to Australia for the specified time period. In the case of SVD serological testing of the herds will be required as clinical signs may not be evident as discussed by the Commission. The wording in the Final IRA Report has been clarified to state that "the pigs from which the pig meat was derived were sourced from herds serologically tested negative for SVD using either virus neutralisation or ELISA within the 6 months prior to slaughter and within the 6 months following slaughter".

A requirement for absence of any detection of clinical signs of the disease in question in the farm of origin a few weeks before and after the slaughter of the pigs from which the hams have been produced would be much less trade restrictive whilst providing the same level of protection, but still not appropriate and excessive<sup>7</sup>.

## 2. PRRS

Another example of the very restrictive approach of the IRA is in relation to **PRRS**.

The Australian measures are based on experimental data, which do not in fact reflect the field situation. Australia should take into account the very low probability that:

- slaughter pigs will be viraemic,
- after slaughter of these pigs, the PRRS virus will be present in significant amount in the meat,
- the virus will survive in the meat despite maturation, other treatments like freezing or curing<sup>8</sup> or any other exposure to environmental conditions<sup>9</sup> causing virus inactivation (this virus is very labile),
- this meat or meat products – still containing significant amount of PRRS virus - will eventually be ingested by Australian domestic or feral pigs<sup>10</sup>.

<sup>7</sup> Only in case of SVD clinical signs of disease might not be evident and therefore serological tests appropriate, see the SVD Diagnostic Manual adopted by Commission Decision 2000/428/EC.

<sup>8</sup> The PRRS virus occurs in low amount in fresh pig meat and it is very labile. As indicated in paragraph 2, viruses such as FMD, CSF, ASF and SVD, which occur in meat in much higher titres and are much more resistant than PRRS virus, are fully inactivated during the curing and maturation of certain typical European products. Therefore, the risk posed by the import of these products in relation to PRRS virus should also be considered as "negligible".

<sup>9</sup> For example, virus inactivation has been shown on 14 out of 15 tissue samples kept for 3 days at a temperature (25°C) resembling very common environmental conditions

<sup>10</sup> The issue is very well dealt in the document of the Danish Bacon and Meat Council "Assessment of the risk that the

**Response:** *These steps are taken into account in the risk assessment either in the release (R2, R4, R5, R6) or exposure assessment (L2, L3, L4, L5).*

*It is recognised that slaughter-age pigs infected with PRRS virus may not be viraemic. However, the virus can persist for long periods in tissues, in particular lymphoid tissues. In light of the research conducted by Canada, the likelihood that a slaughter-age pig from an infected herd is infected (R2) has been amended from 'moderate' to 'low'. With this new value the simulation model concludes that the overall annual unrestricted risk is 'low' and risk management is still required for PRRS virus.*

*It is known that 250 grams of meat fed over 2 days with virus at levels less than those detectable by virus isolation ( $<10^{1.8}$  TCID<sub>50</sub>/gram of tissue) can result in infection. A study conducted in Canada found that meat from slaughter-age pigs, positive by PCR for PRRS virus but not virus isolation, resulted in infection when fed to pigs. The studies used commercial slaughter and maturation procedures and in the case of the study conducted in Lelystad the meat was frozen then thawed prior to feeding.*

*With regard to Footnote 6, the submission from the Danish Bacon and Meat Council (included in this Annex) states that "we fully agree on the proposed changes and believe that this is a step in the right direction to accomplish free and unrestricted trade". The Danish and Bacon Meat Council' risk assessment of PRRS concluded that the risk of PRRS virus from heat treated Danish bone-in hams is negligible. Australia's IRA concluded that the risk of PRRS virus in bone-in pig meat heated to specified temperatures was acceptable.*

Therefore, the heat treatment requirement proposed by the IRA is excessively trade restrictive, as a more objective assessment of the risks above would lead to the conclusion that the overall risk due to the importation of pig meat from areas where PRRS occurs is "negligible". Moreover there are countries where PRRS has never been recorded, which also should be taken into account by the Australian authorities.

**Response:** *With regard to PRRS, the quarantine conditions permit the importation of fresh meat from a PRRS free country or zone.*

#### **4. Trichinella**

Excessive testing requirements are recommended by the IRA as regards Trichinella. The Commission wishes to point out that appropriate testing methods are applied in the EU, to ensure a very high level of protection against this disease agent. This legislation fully corresponds to OIE and Codex standards <sup>11</sup>.

**Response:** *Australia has based the risk management measures on the OIE Code standards for Trichinella. The likelihood assigned to R3.1 following testing of each carcass was estimated as 0.95 to 0.98 based on published scientific information. Nonetheless Australia will consider any submission from the European Commission proposing an equivalent measure. The Commission may wish to note that for countries with PRRS virus, cooking or curing will be required and pig*

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Porcine Reproductive and Respiratory Syndrome Virus may enter Australia due to the import of fresh Danish bone-in hams", which has already been brought to the attention of the Australian authorities

<sup>11</sup> The testing methods which are accepted in the European Union are: i) trichiniscopy using 0,5 g of muscle, ii) artificial digestion using 1 g per animal. These samples are pooled until a total amount of 100 g of meat is examined (pooled sample digestion method). Several pieces of equipment to support this pooled sample digestion method are described in detail and accepted after community-wide experiments (Stomacher method, Trichomatic). They are all described in detailed protocols in the annexes to Council Directive 77/96/EEC).

*meat would not need to be tested for Trichinella. Cooking at specified time/temperatures and curing are accepted as an equivalent risk management option for Trichinella.*

## **5. PWMS**

In the case of PWMS, Australia would like to take very restrictive measures such as deboning of fresh pig meat, followed by cooking or curing, in relation with the potential introduction of Porcine circovirus 2 (PCV2).

PCV2 does occur in Australia and no measures are in place to prevent pig-to-pig or farm-to-farm spread of this virus.

**Response:** *Although PCV2 is present in Australia, PMWS is not present. A surveillance program is in place for this disease. Industry funded a project where veterinarians were asked to submit samples from pigs with clinical signs suggestive of PMWS such as ill thrift. Despite the wide coverage of this project, and veterinarian awareness, few herds had pigs with clinical signs suggestive of PMWS. None of the samples submitted met the criteria for PMWS. There is a continuing awareness program on PMWS and its clinical signs for veterinarians working in the pig industry.*

The measures recommended by the IRA are based on the assumption that the unrestricted import of pigmeat containing “exotic” PCV2 would lead to the occurrence of PWMS in Australia, whilst the “local” PCV2 does not cause this disease. No scientific finding supports this assumption, except the claim that “PMWS has been described in most countries but not in Australia”. Furthermore:

a) PMWS is a multifactorial disease whose occurrence depends on several biological, environmental and management factors and not only the occurrence of PCV2. The claimed absence of PWMS in Australia is not substantiated by any scientific study. If this absence can be substantiated, then it should also be demonstrated that this relates to the absence of PCV2 of exotic origin and not with the absence of the other disease co-factors.

**Response:** *It is considered that a difference in virulence of strains of PCV2 is one potential explanation. Another potential explanation is the presence of an unknown disease agent which acts as a trigger for PCV2. A preliminary study in which an Australian PCV2 isolate in conjunction with immunoenhancers were inoculated into pigs did not result in PMWS or PMWS type lesions in tissues (Buddle, et al., 2003). Further work is underway.*

b) it is legitimate to assume that PCV2 is widespread in Australian pigs at the same or at a similar extent as in the rest of the world. A significant part of the pig population in Australia is likely to have developed antibodies and to be immune against any PCV2. This has not been taken into account in the scenarios following introduction of “exotic” PCV2, leading to an overestimation of the consequences of this introduction

**Response:** *In countries with PMWS, the presence of PCV antibodies does not appear to have reduced the impact of the disease. Porcine circovirus has been present in countries for many years. It is recognised that previous tests could not differentiate antibodies to PCV1 or PCV2, however, retrospective examination of tissues and sera have demonstrated the presence of PCV2 for several years prior to the recognition of PMWS. In Australia, a preliminary study examining herds with clinical signs suggestive of PMWS, congenital tremors or PDNS found that of 27 herds, 33% were positive for PCV1, 39% positive for PCV2 and 11% positive for PCV1 and PCV2 by multiplex PCR for PCV1 and/or PCV2 (Buddle et al., 2003). However, no cases met all criteria for the diagnosis of PMWS.*

c) there is no evidence that ingestion of pigmeat containing PCV2 is a risk factor of any importance in the occurrence and spread of PWMS and no country in the world imposes trade restrictions on pig meat to protect itself against PWMS.

**Response:** *Most countries have PMWS with no official control measures in place domestically. PCV2 has been found in lymphoid tissues, particularly peripheral lymph nodes and bone marrow for prolonged periods. It is also known that the virus is hardy and hence is likely to persist in the environment. Recently it has been postulated that PMWS may have entered New Zealand via imported uncooked pig meat which was fed to pigs.*

Within this technical context, the current insufficient knowledge on the pathogenesis of this disease cannot be used as a legitimate reason to propose the suggested measures that would have a very negative impact on pig meat imports, without guaranteeing Australia any protection against the disease.

**Response:** *A risk assessment has been conducted demonstrating that risk management measures are required. Biosecurity Australia will continue to monitor new information about this emerging disease.*

## Conclusions

As regards the OIE list A diseases mentioned above, the Commission wishes to point out that the whole European Union is free from FMD, and most Member States are free from CSF, ASF and SVD. In those Member States which are not disease-free, disease control, zoning and regionalization measures are in place. The Commission therefore requests that:

- as regards those Member States wishing to export pig meat and pig meat products to Australia and which have presented an application in this regard, their free status (of the whole country or of the free regions within the country) should be rapidly recognised by Australia,

**Response:** *Australia would consider submissions from the European Union or those countries seeking recognition of their disease status including regionalisation.*

- pending the recognition above and in the case of those Member States which have not produced an application for the recognition of their status, Australia authorises the import of pig meat and pig meat products in accordance with the available OIE standards or, where they are not available, with the comments above.

**Response:** *Australia is under no obligation to accept product from a zone of unknown animal health status.*

As regards PRRS, the Community requests Australia to take fully into account the comments above. Moreover there are countries where PRRS has never been recorded, which also should be taken into account by the Australian authorities.

**Response:** *With regard to PRRS, Australia will permit the import of fresh meat from PRRS free countries or zones, subject to successful consideration of a submission seeking recognition of that status.*

As regards Trichinella, the Commission requests that Australia consider the measures in place in the EU as equivalent to the ones recommended by the IRA.

***Response:*** Australia would consider an equivalence submission from the Commission regarding the measures it has in place for *Trichinella*. As discussed above the Commission may wish to note that testing of carcasses will not be required for countries with PRRS virus due to the cooking/curing requirement for this disease agent.

As regards PWMS, Australia is requested not to apply any restrictions to import of pig meat, as the proposed measures are not based on sound scientific evidence.

***Response:*** The measures are based on the risk assessment for PMWS that takes into account the available scientific information and provide the level of protection required by Australia.

Finally, as a general comment, under the IRA, only meat from pigs born and bred in the exporting country would be allowed to be exported to Australia. The EU is composed of many Member States and pigs are often traded from one Member State to another in accordance with the health requirements of Community legislation on intra-Community trade. Procedures are in place to ensure that movements between Member States cause no risks as regards transmission of animal disease agents. Therefore, the Commission requests that imports be allowed for any pig meat which is derived from pigs of EU origin or imported into the EU under its import rules.

***Response:*** As Member States differ in their disease status, different import requirements may apply. Hence this request would need to be considered on a Member State by Member State or zone basis.

The Commission is available to provide further information to Australia on the issues above, as appropriate.

## **Australian Pork Limited**

### **Response to the Draft Import Risk Analysis Report for Pig Meat**

Australian Pork Limited (APL) welcomes the opportunity to comment, on behalf of the Australian pig producers, on the Review of the Generic Import Risk Analysis for Pig Meat Draft Import Risk Analysis Report

APL contends that there continue to be significant risks inherent in the importation of pig meat that have not been adequately addressed by the Draft IRA Report. These must be addressed if the industry is to have confidence that the estimates and calculations and resulting risk management measures do indeed provide an appropriate level of protection to the Australian pork industry, the environment, economic activity and human life. In particular APL opposes the importation of uncooked pig meat from PMWS and/or PRRS affected herds 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's concerns and comments on the draft IRA Report are provided in detail in the attached submission.

APL acknowledges and is appreciative of Biosecurity Australia's 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

I look forward to further advice from Biosecurity Australia on the progress of the issues.

## **Australian Pork Limited**

### **Review of the Generic Import Risk Analysis for Pig Meat**

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

##### **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.

The continuation of our unique high health status is the principle competitive advantage of the Australian pig industry. It is a marketable commodity; 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 high health status becomes even more desirable and an increasing competitive advantage.

In the Draft Import Risk Analysis Report for pig meat (“Draft IRA”) Biosecurity Australia (BA) has proposed changes to quarantine policies for Pig Meat Imports. While APL agrees with the risk management proposed for some of these diseases notably FMD, African Swine Fever, Classical Swine Fever, Rinderpest, Swine Vesicular Disease, Nipah Virus and Vesicular Exanthema, we are seriously concerned and object to the measures proposed for PMWS and PRRS on the basis that the revised protocols do not limit the level of quarantine risks to an acceptably low level i.e. Australia’s “low risk categorization”.

APL has significant concerns about several aspects of the proposed importation of pig meat, including:

- 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 several other countries
- Inadequate proposed risk management procedures due to deficiencies of understanding of PMWS
- Inadequate proposed risk management procedures for PRRS; without consideration of on shore cooking as a control measure *separate* from off shore cooking and deboning, there is no basis to conclude that risks will be acceptably managed through on shore cooking.
- Apparent errors in the estimate of the likelihood of entry for some diseases which has led to R4 estimates at a lower than justified level
- Unsound methodology regarding the quantitative approach applied to consequence assessment and risk estimation
- Underestimation of the total impact of diseases due to the annualised calculation methodology used to assess the likelihood of entry and exposure.
- Underestimation of the volume and market penetration levels used in simulations affecting the overall annual risk
- Insufficient explanation as to why likelihood distribution models were based on the 50<sup>th</sup> percentile instead of the 95<sup>th</sup> percentile; the effect of choosing 50<sup>th</sup> percentile is to move away from the use of conservative assumptions which is inappropriate
- Difficulties in applying the rules of the Impact Score Tables to reach the outcomes identified in the draft IRA
- The appraisal of the execution of risk management is as important as design of the risk management measures and should be addressed in the draft IRA.

APL contends that there continue to be significant risks inherent in the importation of pig meat that have not been adequately addressed by the Draft IRA. These must be addressed if the industry is to have confidence that that the estimates and calculations and resulting risk

management measures do indeed provide an appropriate level of protection (ALOP) to the Australian pork industry, the environment, economic activity and human life. APL, therefore, continues to oppose the importation of uncooked pig meat from PMWS and/or PRRS affected herds 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 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.

***Response:*** *Noted. The comments are addressed in the following submission.*

## **Australian Pork Limited**

### **1. Australian Pork Industry**

APL wishes to take this opportunity to correct certain information and data reported in the Draft Import Report. The errors in each of the following matters contained in the Draft IRA affect the modelling, analysis of the outcomes and proposed risk management measures proposed in the Draft IRA.

According to the latest ABS statistics (30 June 2002) the industry comprises 2,642 pig farmers not 2,500 as reported on pp19-20.

According to APL analysis of ABS data per capita consumption in Australia has increased from December 2001 to June 2003 from 18.99kg/head to 21.46kg/head. That is an increase of 13% in an 18 month period. That is a very significant change and not "little changed" as reported on p20.

- In the Exposure Assessment on p36, according to APL figures sourced from the ABS <sup>12</sup>:
  - Pig meat imports were 49,000 tonnes in the year ending August 2003 (APL figures) and not as reported at approximately 40,000 tonnes.
  - Total pig meat production in 2001 was 378,530 tonnes and not as reported 377,889 tonnes and has increased to 421,750 tonnes in the year ending August 2003. That is significantly more than 400,000 tonnes.
  - APL have been advised by the NZ Pig Industry Board that the most recent NZ Customs records identified imports last year as comprising 36% of total product consumed in that market and not 28% as reported.

***Response:** The specific data in the IRA has been amended to reflect the figures provided by APL. In developing the model the Panel recognised that figures relating to pig meat imports, number of pig farmers etc are not static. Hence distributions were used to model values, not precise individual values as these may change and would be then incorrect. Nonetheless the Panel recognised that pig meat imports have increased significantly in the last 12 months and accordingly has increased the minimum and most likely values of imported pig meat. The annual volume of imported pig meat has been assigned a minimum value of 50,000 tonnes, most likely value of 90,000 tonnes and maximum value of 151,150 tonnes. It should be noted the proportion of pig meat imported into New Zealand quoted in the IRA is based on the annual volume of imports prior to New Zealand's imposition of processing requirements for pig meat from countries with PRRS virus. This point is clarified in the Final IRA Report.*

- The proportion of pig meat purchased by households and discarded as waste as reported on p40 refers to an informal survey of government personnel. APL questions the statistical validity of this survey and requests that details be provided as to the number of households surveyed, the survey methodology, whether the households were located within cities or in areas in which piggeries are located and whether there was anything that might suggest that the government personnel who responded might have been more aware of food processing and handling issues than the population in areas in which piggeries operate. APL contends that a more thorough scientific study must be conducted before valid conclusions can be made regarding waste, particularly in respect of the assertion that processing reduces waste to one tenth.

***Response:** Twenty-five people were surveyed, single persons and families with up to 4 children. These people either lived in urban environments or in semi rural areas. The distribution used in this model also concurs with the results of a small survey in the United Kingdom as detailed in the IRA. Information was also sought from industry on this matter, but unfortunately none could be provided.*

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<sup>12</sup> ABS Export Document #00473 & ABS Import Document # 01763

- APL believes that smallgoods manufacturers should not be excluded as a source of waste. Up to 5% of imported pork would be discarded as trim, some before and some after processing. As acknowledged by BA, this trim finds its way into composite product (ie. sausage). It then becomes subject to wastage in either the food service establishments or household sectors. It therefore seems inappropriate that this source of waste is not factored into the waste estimates.

**Response:** *Any smallgoods including sausages that end up as human consumption are included in the proportion purchased by households or food service establishments and discarded.*

- APL considers that the maximum value for a waste unit reported on p42 is underestimated. Lactating sows may consume as much as 10kg of feed per day, based on industry standards (R Smits, pers comm.), and not the 5kg reported. It is therefore a reasonable inference that the most likely value, at 250 g, is too low, with a value of at least 500 g being more logical.

**Response:** *The value of 250g was considered by the Panel to be the most likely quantity of pig meat waste to be discarded and is not directly related to the maximum quantity a pig would consume in a day. The maximum value of 5kg is based on a study with feral pigs as referenced in the IRA.*

- APL also questions the estimates used for illegal swill feeding. APL asks that BA provide a more substantiated reasoning as to why the estimate of “very low” for illegal swill feeding should be viewed as a conservative estimate.

**Response:** *The proportion of backyard and small commercial piggeries that illegally feed swill was based on the number of prosecutions or warnings, taking into account the difficulty in identifying and convicting perpetrators. For example in 2002 there were two prosecutions in Queensland and one in NSW, one prosecution and one warning letter in Victoria, and three warning letters in Tasmania.*

## **2. Appropriate Level of Protection (ALOP)**

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’.<sup>13</sup> 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.<sup>14</sup>

As noted by APL in previous submissions and as a matter of record, APL reiterates that the approach used in the Draft IRA to setting the 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

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<sup>13</sup> Australia – salmon case.

<sup>14</sup> Senate Rural and Regional Affairs and Transport Committee Interim Report on the Proposed Importation of Fresh Apple Fruit from New Zealand at 8.9

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 Import Risk Analysis (IRA) for Pig Meat on the whole has been a more transparent process than previous IRAs with opportunities provided for all stakeholders to comment on an Issues Paper, a Technical Paper and a Draft Methods Paper. It also attempts to be more quantitative in its approach to assessments, although as noted in the Section 4.2 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.

**Response:** *This issue has been addressed in response to comments on the Methods Paper, however, they are reiterated here to assist the reader. It is Biosecurity Australia's opinion that the qualitative approach to consequence assessment and risk estimation is designed to accommodate uncertainty, due to the very broad and general categories used to rank consequences. Because risk is the combination of likelihood (a probability) and consequences (a qualitative ranking) then risk will also be expressed in qualitative terms. This is desirable, because risk is evaluated against Australia's (similarly qualitative) statement of ALOP. Australia's ALOP "is currently expressed as providing a high level of sanitary or phytosanitary protection aimed at reducing risk to a very low level, but not to zero."<sup>15</sup>*

### **3. 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 on the Issues Paper and Draft Methods Paper. There are numerous instances where the Draft IRA does not adequately address specific points raised in APL's submissions leading APL to question whether those points have been considered by BA. APL continues to rely on those submissions. For convenience some of our concerns are raised again in the following sections.

**Response:** *The Panel has responded to all stakeholder comments, see Annexes re Draft Import Risk Analysis Report.*

#### **3.1 Likelihood of entry**

APL's analysis indicates that within the Draft IRA Report there are errors in respect of the estimates of R4. Within the Draft Report, R4 is defined as 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. On this basis APL requests that BA review R4 estimates. 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

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<sup>15</sup> IRA Handbook, section 2.1.1, page 5.

to viraemic pigs (i.e. reduce R4). 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.

APL also questions the supposition that the removal of the head and neck for risk management of Aujeszky's Disease does in fact reduce R4. If the disease has a predilection for neurological tissue, as stated in the Draft IRA Report, then there seems no reason why peripheral nerve tissue that is inseparable from muscle is less likely to be infected than trigeminal nerve tissue. Whilst virus numbers will be higher in trigeminal tissue, this will bear on L2 and not R4.

APL requests that BA review the R4 estimates, particularly in respect of risk management.

**Response:** *Some viruses have a predilection for certain tissues. In the example above with swine influenza, most slaughter-age pigs will not be viraemic, if these pigs are infected the virus will be present in respiratory tissues that are discarded. This has a direct effect on the likelihood of R4 (i.e. the likelihood that the pathogenic agent will be present in meat harvested for export). It is recognised that in the few pigs that may be viraemic bleeding the carcass will reduce the viral load but not eliminate all the virus and hence the likelihood was assessed as 'extremely low' not 'negligible'. The reduction in viral load is considered at step L2.*

*In the case of risk management, by removing certain tissues that the virus has a predilection for, such as lymphoid tissue in the case of PRRS virus and PMWS, R4 is influenced. This is particularly the case for pigs that are persistently infected and are not viraemic, i.e. the virus has localised in certain tissues.*

More generally, regarding the total likelihood (R\_tot) distribution, APL has difficulty in identifying the scientific justification for building a model to make precise estimates, then making the estimates less precise 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 unnecessary approximation of the total release likelihood. In the draft report, a semi-quantitative estimate of the total release likelihood (R\_tot) distribution has been carefully obtained. However, following from this BA only use the category (for example 'low') into which this 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.

In preference APL recommends that all simulations are performed using the 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).

**Response:** *A qualitative value was provided for the release assessment to assist in the readability of the document. However, the simulation model uses all numerical data from the release and exposure assessment to determine the annual likelihood of entry and exposure. Estimates are not converted back to qualitative values at the intermediate steps when the simulation is run.*

### **3.2 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 seriously to distort the outcome of the risk assessment. APL argues that both logically and statistically this has the potential to have a significant and major impact on the likelihood and consequence assessments. It fails to consider the totality of the impact of diseases.

In addition the Quarantine Act and the Quarantine Proclamation do not confine any likelihoods or risks on 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. The methodology is flawed in failing to extrapolate annual exposure or outbreak risks to the risks attendant on long periods of imports. Instead, the approach of the Draft IRA is to 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 measures considered beyond a time frame of one year.

There is a failure in the Draft IRA to take the next logical step forward from an estimate of annual risk. 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; 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 0.31 (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 19<sup>th</sup> 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 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 the likelihood of 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 being 100%<sup>16</sup>.

The disease outbreak expectations results indicate that under the Draft IRA Australia's existing quarantine measures will not meet Australia's Appropriate Level of Protection. The results show that on the balance of probability there will be one or more outbreaks within the next two years under the proposed protocols.

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<sup>16</sup> Refer to Table 1 in Appendix A

**Response:** *This issue has been addressed in response to comments on the Methods Paper, however, they are reiterated here to assist the reader. The basic tenet of the comment is that, all things being equal, risk increases with the volume of product imported. As the volume imported increases, the likelihood of pest or disease introduction gets closer to one. Australia has a managed risk policy for biosecurity risks, it is not a zero risk based policy. The ALOP is based on annual risk, thus it is appropriate to compare the calculated annual risk to the ALOP. The Panel notes that a risk assessment model is a useful guide for decision making but should not be considered in isolation. Importantly as new information on diseases becomes available and as the technology for detecting and managing them changes, quarantine policy will be reviewed.*

*It should be noted that pig meat has been imported into Australia for 13 years from countries where both PRRS and PMWS occur, with no exotic disease outbreak occurring.*

### **3.3 Likelihood distribution models based on 50<sup>th</sup> percentile instead of 95<sup>th</sup> percentile**

It is unclear from the Draft IRA as to why the approach stated in the Draft Methods Paper (p18) which adopts “a conservative (95<sup>th</sup>) percentile“ is changed to the “median value (50<sup>th</sup>) percentile” in the draft 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, although APL does note the objection raised in the US submission, “...that the proposed approach seems to promote the use of conservative assumptions” (Annex B p47). APL requests that an explicit explanation be provided 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 50<sup>th</sup> percentile has been to move away from “the use of conservative assumptions” and that that is inappropriate.

The Draft IRA demonstrates that using the 50<sup>th</sup> percentile as opposed to the 95<sup>th</sup> percentile in the case of PRRS has the effect of reducing the estimated overall annual risk from ‘Low’ to ‘Very Low’.<sup>17</sup>

**Response:** *In assigning likelihoods to the steps in the pathway appropriately conservative assumptions are made to take into account uncertainty and variability in the available data. As stated in the response to comments on the Methods Paper the output distribution from an import risk analysis model tends to be strongly right-skewed – i.e. it has a long ‘tail’ which, if a probability, tends towards 1. Relatively few iterated values contribute to this tail which, as a result is quite ‘imprecise’. Thus, it is believed that a more robust estimate of likelihood can be obtained from a measure of central tendency – the most appropriate in this case being the median value, or 50<sup>th</sup> percentile.*

### **3.4 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 to reach the outcomes proposed by BA from applying the ‘rules’. For example, the outcomes from applying both Rules 3 and 5 appear not to be possible in terms of the table provided.

This raises serious doubts about the methodology generally and must be addressed by BA.

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<sup>17</sup> Refer to Table 2 and Table 3 in Appendix A

**Response:** *There are no mathematical rules underlying the table, the combination of impacts must depend on decision rules. All the rules are possible including rule 3 and rule 5 depending on the assessment of the impact for each direct and indirect consequence criteria.*

#### **4. Risk Management for Quarantine Diseases**

##### **4.1 PRRS**

The position taken by BA on the measures to prevent the entry of PRRS virus is in general supported by APL. Analysis conducted by the CSIRO, however, does show that the overall annual risk level from PRRS increases from ‘very low’ to ‘low’ when errors detailed in Section 2 with respect to pig meat import volumes and total imports consumed are corrected.<sup>18</sup>

**Response:** *As discussed previously, taking into account the increase in imported pig meat in the last 12 months the Panel has increased the minimum value to 50,000 tonnes and most likely value to 90,000 tonnes with a maximum value of 151,160 tonnes. The current volume of imports provides an indication of the current trend and this is reflected in the distribution chosen. Using these figures and applying risk mitigation of cooking or curing the risk of entry, establishment and/or spread of PRRS virus is ‘very low’ which would meet Australia’s ALOP.*

In the case of countries in which both PRRS virus and porcine circovirus Type 2 (PCV2) are present as manifested by PMWS, APL strongly supports the position of off-shore cooking as necessary to protect Australia from both diseases. Both disease conditions can lead to significant production losses within a pig herd and this is borne out but observations in the EU, Canadian and US pig herds. The absence of effective vaccines means that control measures, as currently practised in those countries, are costly and in many cases of questionable value.

BA should require exporting countries to demonstrate that pig meat being sent to Australia is free from porcine circovirus and PRRS virus. In the absence of known protocols, the exporting country must show the cooking method will lead to the total inactivation of porcine circovirus. It is not sufficient, nor acceptable as argued by the 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” Draft IRA Vol 2 (p743). APL contends that further research work 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.

**Response:** *The risk management measure for PMWS is to reduce the volume of waste discarded and remove tissues most likely to be a risk such as bone and major peripheral lymph nodes. The Panel concluded that cooked and cured deboned pig meat would result in a significant reduction in the volume of waste. Options were examined to identify the least trade restrictive measures which would reduce risks to within Australia’s ALOP.*

There is no justification provided in the Draft IRA for on-shore processing. The key 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. As freedom from both PRRS and PMWS is important for the industry’s future, APL contends from these first principles that cooking and deboning on shore cannot be 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.

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<sup>18</sup> Refer to Table 4 in Appendix A

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 that waste from the onshore processing plants cannot be accessed by feral pigs, birds, insects, rodents or other animals.

While APL welcomes the tightening of the security arrangements surrounding the movement of uncooked imported pork into a rural area, we continue to contend as stated in past representations that the treatment of all imported pork should be restricted to the urban area of the port at which it is imported.

**Response:** *Cooking on-shore whilst under quarantine control to manage the risk is an appropriate measure. In the case of PMWS pig meat will be required to be deboned and major peripheral lymph nodes and head and neck removed prior to export. Any wastes produced on-shore from processing will be treated as quarantinable waste as is the case for shipping and airline food wastes i.e. incineration or deep burial or other approved method.*

*Smallgoods processors cooking imported pig meat will need to enter a compliance agreement with AQIS and be subject to audit. A model of the current compliance agreement is at Attachment 2.*

#### 4.2 PMWS

Recent developments worldwide indicate that PMWS is becoming a disease of major significance and of even greater concern than originally estimated. Reports have emerged that potentially PMWS is of similar economic magnitude to PRRS. While PMWS has been prevalent in the US and Canadian pig herds for some time, the current epidemic in the UK and France and its virulence raises questions concerning the epidemiology, infection and transfer of this disease. More recently, there appears to be evidence in NZ of how less than conservative import policies, for both pig meat and semen, may be failing to protect local industry. 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 herds.

A study carried out in Ireland in 1994 (GM Allan et al J. Vet. Med. B 41 (1) 17-26) 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.

**Response:** *The Draft IRA Report provided information on the stability of porcine circovirus and the Panel recognised the stability of the virus. The risk management measure for PMWS is to reduce the volume of waste discarded and remove tissues most likely to be a risk such as bone and major peripheral lymph nodes. Only cooked or cured bone-out product from affected countries will be permitted for retail sale. As PCV2 has been shown to result in persistent infections, has been isolated from many tissues, is a hardy virus and is likely to be transmitted orally, the Panel considered that if an unknown disease agent was involved in PMWS, the risk management measures requiring removal of bone, major peripheral lymph nodes, head and neck and cooking or curing would also act to reduce the risks associated with that agent.*

The aetiology of PMWS is still not completely understood and currently there is no specific treatment for PMWS. APL notes that while a strain of PCV2 has been identified in Australia the disease PMWS has not been observed in Australia. While it is understood that the virus PCV-2 is involved in the disease, other factors are required to lead to the manifestation of the disease PMWS. More important, however, is critical emerging evidence that suggests not all PCV2 strains are of equal pathogenicity and that strains from different countries vary in their virulence.

**Response:** *The Panel would appreciate any information APL has on “the emerging evidence that suggests that not all PCV2 strains are of equal pathogenicity and that strains from different countries vary in their virulence.” However, the Panel has considered that one potential explanation for the presence of PMWS is that PCV2 isolates may differ in virulence.*

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. Similar interpretations have been expressed to APL by other stakeholders including the National Farmers Federation. 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).

As stated above there is no justification provided in the Draft IRA for on-shore processing. The key 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 cannot be equivalent to off shore processing. As stated in previously in Section 4.1, *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.*

**Response:** *Cooking on-shore would be permitted provided that an equivalent level of biosecurity can be achieved by processing off-shore. On-shore cooking is currently allowed for imported pig meat from Canada and Denmark, by requiring processors to enter a compliance agreement, which is subject to audit. As stated above bone, major peripheral lymph nodes and the head and neck must be removed prior to the export of pig meat to Australia.*

Further the Draft IRA makes clear that cooking will not appreciably inactivate the PCV2 virus. 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, then this does nothing to inactivate PCV2 virus, and consequently R4 for PMWS should be "moderate" rather than "low" (as argued by APL in section 4.1 “Likelihood of Entry.”)

**Response:** *The risk management measure for PMWS of cooking or curing and deboning and removal of major lymph nodes is designed to remove risk tissues and reduce the volume of waste discarded hence no cooking schedule is provided. Nonetheless as most countries with PMWS also have PRRS, the cooking or curing specifications for PRRS will apply. Options were examined to identify the least trade restrictive measures which would reduce risks to within Australia’s ALOP. The step R4, which describes the likelihood that the pathogenic agent would be present in meat harvested for export, was reduced from ‘moderate’ in the unrestricted risk estimate to ‘low’ following removal of major peripheral lymph nodes, the head and neck and bone, areas of the carcass where the virus has a predilection. Cooking has not been proposed as an inactivation step (R7) for PMWS. Nevertheless the Panel notes that many other viruses are sensitive to heat leading to a decrease in virus titre or inactivation.*

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.

With respect to the Outbreak Scenario 4, as reported on page 400 of the Draft IRA, APL cannot verify or understand the conclusion of the panel rating PMWS as a “D” for its impact at

national and state level. Where it acknowledges that “mortality rates can be high as in the case of the United Kingdom” how does the Draft IRA conclude that “the direct impact on animal health is unlikely to be discernible at the national level”? APL questions this categorisation. Is there a more direct impact on animal health than high mortality rates? APL asks that BA either change the rating or provide reasons for it.

**Response:** *The Panel recognises that PMWS can cause significant mortalities and this would be significant on affected pig enterprises. However, the assessment of consequences for all diseases for both animals and plants is considered on a national basis i.e. on the national economy or the Australian community not solely pig producers or that industry. Hence a rating of ‘D’ was assigned for this criterion.*

As PMWS is not an OIE notifiable disease, the Draft Report fails to address a number of critical issues that will impact on how the proposed risk management measures will operate in practice. APL requests that BA publish draft protocols 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?

**Response:** *Countries claiming freedom or zone freedom from PMWS will need to provide a submission to Biosecurity Australia with the basis of this claim. In the case of country freedom this would need to be equivalent to Australia’s basis for its claim to freedom from this disease which would include a case definition of PMWS, an active surveillance program in place for PMWS, the disease is notifiable and diagnostic capability. A submission on zone freedom should take into account the principles of zoning at Attachment 1. If a country or zone is accepted as being free from PMWS, certification to that effect will need to be provided with exported product. If PMWS occurs in an exporting country, that country can no longer certify to the conditions and Australia is notified. This system is in place for all imports where country or zone freedom is required and also applies when Australia certifies to its exports.*

#### **4.3 Other comments**

For a number of diseases namely African Swine Fever, Classical Swine Fever, Swine Vesicular Disease and PRRS, Parma type hams and/or Iberian type hams, loins or shoulders and/or Serrano type hams are proposed depending on the disease as appropriate risk management measures. However the Report fails to explain the difference in curing times for each disease and the source of this information.

**Response:** *The different curing times are based on the published research and properties of the virus. This is documented in the Draft and Final IRA Reports.*

APL is surprised that the unrestricted annual risk for TGE is estimated as “very low”. While we have no specific suggestions, APL would like assurance from BA that its assumptions are soundly based. Moreover if cooking of imported pork were ever abandoned, we would request reassessment of the risk management for TGE.

**Response:** *The likelihoods assigned in the risk assessment were based on published scientific information. It should be noted that cooking has never been required as a risk management measure for TGE. The risk management measure introduced in 1990 for TGE virus was to require removal of the head and neck. The cooking requirement introduced in 1992 was to address the risk of PRRS virus.*

### **5. 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. For example, are import protocols properly executed, are foreign governments reporting findings of disease, and are assumptions in the protocols justifiable, eg are countries making invalid claims of freedom or equivalence?

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. Once the IRA is approved, appraisal of risk management in practice will become as important as scrutiny of the risk management measures.

Appraisal of the execution of risk management is therefore as important as the design and should be addressed in the Draft 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.

The US Food Safety and Inspection Service (FSIS) a division of the USDA carries out inspections of abattoirs in Australia that are currently approved to export to the USA and abattoirs that have been identified by AQIS as being up to FSIS standards. (The last inspection was carried out in May 2003; the latest report on the FSIS web site is for 2002). Australia's program effectiveness was assessed by evaluating five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) systems and the E. coli testing program, and (5) enforcement controls, including the testing program for Salmonella species. Exports of pork products to the USA are minimal with one shipment being made in the past 18 months.

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 BA how it intends to satisfy itself that overseas abattoirs and processing plants conform to Australian standards and that audits by Australian authorities are of an equivalent 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.

***Response:*** *An audit of the auditing system of the exporting country will occur annually. In addition, opportunistic audits of overseas plants will be undertaken unless a problem is detected which may trigger an audit.*

APL also requests that BA provide advice in the Draft Report on whether there is a zero tolerance for lymphatic tissue in meat. In particular, if inspection of a consignment demonstrates any lymphatic tissue, would that consignment be ineligible for export to Australia?

***Response:*** *The risk management measure for PMWS requires removal of major peripheral lymph nodes (not all lymph nodes) and certification to that effect must be provided. Major peripheral lymph nodes would include the popliteal, iliac, inguinal, axillary, ventral, middle and dorsal superficial cervical and those in the region of the head and neck. Imported cuts of*

*meat found on inspection to contain any of these nodes would be directed for further processing under quarantine supervision.*

## **6. Conclusion**

While APL agrees with the proposed risk management changes to BA's Draft IRA for pig meat imports regarding FMD, African Swine Fever, Classical Swine Fever, Rinderpest, Swine Vesicular Disease, Nipah Virus and Vesicular Exanthema, we do not believe that the revised protocols limit to an acceptably low level the quarantine risks relating to PMWS and PRRS. There continues to be significant risks inherent in the importation of pig meat, as detailed above, that have not been adequately addressed by the Draft IRA Report.

APL has specific methodological concerns regarding the quantitative approach applied to consequence assessment and risk estimation and also the apparent underestimation of the total impact of diseases due to the annualised calculation used to assess of likelihood of entry and exposure. In addition, we believe that there has been underestimation of the volume and market penetration levels used in simulations and that this in turn impacts on the overall annual risk. The use of the 50<sup>th</sup> percentile instead of the 95<sup>th</sup> percentile is also inappropriate, while the rules for of the Impact Score Tables appear arbitrary and it is therefore not possible to reached the outcomes identified in the Draft Report. The final report should also document the appraisal techniques intended to be used to ensure proper execution of risk management procedures.

APL is particularly concerned about substantial risk of introducing PMWS in the context of the limited available knowledge about the disease and its current rapid and uncontrolled spread in several other countries. We are of the view that the proposed risk management procedures are inadequate due the deficiencies of understanding about PMWS. Similarly for PRRS, APL believes that the proposed risk management procedures are insufficient. Without consideration of on shore cooking as a control measure separate from off shore cooking and deboning, APL see no basis for concluding that risks will be acceptably managed through on shore cooking.

Until these issues are resolved and the revised protocols 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>19</sup>, APL will continue to oppose changes to the risk management measures particularly as they relate to PMWS and PRRS.

***Response:*** *Noted. Comments on these issues are provided in the above submission.*

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<sup>19</sup> Australia – salmon case.

## Appendix A

Table 1 - Disease outbreak expectations for 1, 10, 25 and 50 years  
Restricted risk (assuming cooking and 10 fold reduction in waste) for PMWS

Exposure group	Annual Likelihood		
	5th %ile	50th %ile	95th%ile
Feral pigs	5.77%	31.43%	97.62%
Backyard pigs	0.02%	0.11%	1.06%
Small piggeries	2.42%	10.07%	27.60%
Overall	8.07%	38.41%	98.29%

Likelihood of one or more outbreaks

Years	5th %ile	50th %ile	95th%ile
1	8%	38%	98%
10	57%	99%	100%
25	88%	100%	100%
50	99%	100%	100%

Table 2

Summary –Components of the **restricted risk for cured** PRRS Virus  
with BA tonnes Pert (41569, 75580, 151160) & using 50<sup>th</sup> percentiles

Exposure group	Likelihood of entry	Annual likelihood	Likely Conseq.	Annual Risk
Feral pigs	Very low	Low	Low	Very low
Backyard pigs	Very low	Very low	Low	Negligible
Small piggeries	Very low	Low	Low	Very low
Overall annual risk				<b>Very Low</b>

Table 3

Summary –Components of the **restricted risk for cured** PRRS Virus  
with BA tonnes Pert (41569, 75580, 151160) & using 95<sup>th</sup> percentiles

Exposure group	Likelihood of entry	Annual likelihood	Likely Conseq.	Annual Risk
Feral pigs	Very low	<b>High</b>	Low	Low
Backyard pigs	Very low	Low	Low	Very low
Small piggeries	Very low	<b>High</b>	Low	Low
Overall annual risk				<b>Low</b>

\*Note that there is an additional release step (R7). This step reduces the entry (release) likelihood and therefore also influences the three exposure group annual likelihoods.

**Table 4**

**Summary of Restricted risk calculations – Comparing CSIRO & BA’s results**

Disease	Who's simulation	Overall annual risk	Explanatory Notes
<b>PRRS cured &amp; median</b>	BA	Very low	1 strategy applied- using median cured (R7=very low, L2=low)
	CSIRO	Low	
		<b>Different</b>	<b>due to different tonnes only</b>
<b>PRRS head &amp; neck off</b>	BA	Low	1 strategy applied <b>head &amp; neck off</b> (R4 low, L2=mod)
	CSIRO	Moderate	
		<b>Different</b>	<b>due to 95th percentile likelihoods</b>
<b>PRRS cured</b>	BA	Very low	1 strategy applied <b>cured</b> (R7=very low, L2=low)
	CSIRO	Low	
		<b>Different</b>	<b>due to 95%ile &amp; APL tonnes</b>
<b>PRRS cured &amp; head off</b>	BA	Very Low	2 strategies, <b>cured+head/neck</b> (R4 low, R7=very low, L2=low)
	CSIRO	Low	
		<b>Different</b>	<b>due to 95th percentile likelihoods</b>

## Windridge Pig Farm, Dugald Walker

### Comments on Draft Pigeat Import Risk Analysis

Thank you for your presentation in Young and the opportunity to make comments on the draft IRA for pigeat.

Our industry is highly dependant on our high health status for a number of reasons.

1. Our high health status contributes to lower costs of production than we would otherwise have. Other factors, including protection of the market for our biggest input – cereal grains, result in our production costs being otherwise higher than many of our competitors. Our high health status is our only real cost advantage and thus is critical to our future ability to compete.
2. Our clean, green disease free image is also the single most important component of our marketing advantage over our competitors.
3. We are able to use much lower levels of anti-biotics than many of our competitors. This is critical as due to human health fears our access to anti-biotics is likely to decrease in the future. We will struggle to compete if we have to face more disease whilst being given fewer options to manage disease.

As a result we cannot afford to lose our clean, green, disease free environment nor perception of this situation.

Our concerns with the current draft IRA centre around a few major points:

- a) Protocols.

The IRA does not provide any evidence that the existing import protocols will be adequately implemented, nor any reason to believe future protocols will be adequately implemented. I understand from your presentation in Young that this is part of your terms of reference. For us to have confidence in a final IRA we would need to see this evidence.

**Response:** *Certification must accompany pig meat imports testifying to the specified import conditions. The Official Veterinarian must certify the conditions. Uncooked pig meat imported from Canada or Denmark must be processed in Australia in accordance with a compliance agreement. All processors using imported pig meat are audited on a regular basis by AQIS. The consolidated audit findings are made available to Australian Pork Limited yearly on request.*

*“Guidelines for the approval of countries to export animals (including fish) and their products to Australia” have been published. A copy is attached for your information (Attachment 3).*

What evidence is there that major systemic problems with implementation of general import protocols have been fixed? For example, the inadequacies in the system, which have allowed entry with significant spread of fire ants and wheat streak mosaic virus in recent times.

**Response:** *If major inadequacies with import protocols are identified, these protocols are amended or suspended. Existing import protocols are under constant review.*

*It should be noted that Australia does not implement a zero risk policy. To do so would preclude all cargo and passenger movement. As you mentioned above, Australia has a very good record in maintaining its animal health status. The Australian Quarantine Review Committee(1996) showed that the rate of pest and diseases has not increased over the past 25 years with the possible exception of weed incursions. It should also be noted that there has recently been a considerable boost to border programs by Government with increased interventions, port surveillance programs and post border surveillance.*

With regard to pigmeat specific import protocols: what sort of corrective actions have been taken when audits have uncovered inadequate practices in both domestic and foreign processing plants and transportation practices? Do these corrective actions appear to be working? What changes are proposed to auditing procedures and corrective actions in the new protocols? Can the industry appoint an independent individual to attend a proportion of these audits to give us some confidence that they are adequately carried out?

**Response:** *As discussed above AQIS provides a report to Australian Pork Limited of the audit findings. Corrective actions can include amendments, increased audits, or if a major corrective action, suspension. Current auditing procedures and corrective actions will apply to new protocols.*

*There would be commercial-in-confidence issues with an independent individual appointed by industry attending some of the audits. AQIS operational arrangements for audit of processing imported Canadian and Danish pig meat have been assessed independently.*

Cooking is a critical part of the protocol. Do on and off shore processors have to have completely foolproof equipment and processes for cooking of pigmeat?

**Response:** *Processors are required to have records of cooking times and temperatures and data loggers to automatically record this information. Ovens must be calibrated.*

b) PMWS

PMWS is not an OIE-listed disease. It is an emerging disease and is present in all of the applicant countries other than New Zealand. In many of these countries the impact of the disease has been devastating for producers. Given we know so little about this disease, how can we be confident that the suggested protocols will be adequate to prevent importation of it?

**Response:** *The Panel notes that PMWS has now been diagnosed in the North Island of New Zealand. The Panel recognises that PMWS is an emerging disease and as with all diseases new information will be evaluated. A Technical Working Group on PMWS with expertise in virology and epidemiology assisted the Panel in its consideration of the risk of PMWS and imported pig meat.*

c) Access to adequate medicines

If we are choosing an adequate level of risk for these diseases and there is some chance of their importation, then we also need to have pre-arranged access to adequate medicines to deal with them. (Note: Many medicines used for animals in other countries are unavailable in Australia.) Will this be arranged by AFFA?

**Response:** *Measures provide a high level of quarantine protection against introduction, establishment or spread of diseases of quarantine concern. However, as with any exotic disease outbreak, the Australian Pesticides and Veterinary Medicine Authority has the ability to grant the emergency registration for vaccines and other therapeutic agents needed to combat the disease.*

The future of our industry depends on the strength and quality of your decision and report. Please ensure we have the opportunity to fulfil the enormous potential our industry holds.

## **National Farmers' Federation Limited**

Thank you for the opportunity to comment on Animal Biosecurity Policy Memorandum (ABPM) 2003/19, "Pig Meat Import Risk Analysis, Draft Report".

The National Farmers' Federations (NFF) Quarantine Animal Health Task Force (QAHFT) has considered ABPM 2003/19 and has recommended that NFF support the conclusions reached in the Draft IRA on pigmeat which includes risk-management practices aimed to prevent the introduction of exotic animal diseases into Australia.

However, QAHFT has noted that no scientific information is presented in the Draft IRA on the likelihood of cooking of imported pig products reducing the risk of the introduction of Postweaning Multisystemic Wasting Syndrome (PMWS) into Australia from countries having this disease. The draft IRA assumes, probably correctly that cooking of pork imports will reduce the likelihood of the introduction of PMWS from "low risk" to "very low risk", thereby meeting Australia's appropriate level of protection (ALOP).

However, the main aetiological agent implicated in this disease, porcine circovirus 2 (PCV 2), is a relatively robust virus and there is some scientific evidence that it can resist heating to temperatures that will inactivate say porcine respiratory and reproductive syndrome (PRRS) virus (70 degrees Celsius for 15 minutes). In the absence of definitive data, it seems in Australia's best interests to commission studies into the effect of cooking of the types of product to be imported on the survivability of PCV 2. Such studies, if shown to reduce the infectious titre of the virus, will go along way towards deflecting criticism from exporting countries against the requirement for cooking pork to reduce the likelihood of the introduction of this disease into Australia's pigs.

***Response:** The IRA included information on the physicochemical properties of porcine circovirus. Risk management for PMWS did not rely on the effect of cooking on inactivation of PCV2, although it is recognised that many other viruses are inactivated by cooking. The risk management measures are designed to remove certain tissues where the virus has an affinity i.e. major lymph nodes and bone marrow and reduce the volume of waste discarded i.e. the product is bone-out, major peripheral lymph nodes removed and cooked or cured. These measures reduce the risk to a sufficient extent to meet Australia's ALOP. The Panel also considered that should an unknown agent be required to trigger expression of PCV2 leading to PMWS the risk management measures requiring removal of bone, major peripheral lymph nodes, head and neck and cooking or curing would also act to reduce the risks associated with that agent.*

## Government of the People's Republic of China

The Chinese government appreciates very much for the chance to review and comment on G/SPS/N/AUS/150 regarding Import Risk Analysis (IRA) for Pig Meat. After consideration, China would like to comment as follows. Please deliver it to your competent authority to take into consideration carefully.

1. Two special technical groups working for PRRS and PMWS were established under the Australian risk analysis work group, and indicated clearly that the unprocessed pig meet from countries and regions experiencing the two diseases not be imported. However, PMWS is neither included in List A or List B of OIE, nor in type I or type II Infectious and Parasitic Diseases of Animals Entering the People's Republic of China, So, China doesn't think that the risk management measure for this disease is in compliance with the minimum trade effect principle of WTO SPS Agreement.

**Response:** *Australia identified PMWS as a hazard. This disease does not occur in Australia. A risk assessment was completed and risk management is required. Australia therefore believes that this is in full compliance with the SPS Agreement.*

2. China suggests that EC fulfill the principle in Article 6 of SPS Agreement and the relevant standards of OIE concerning regionalization, and implement regionalization policy.

**Response:** *The Risk Management section of the IRA provides for a free country or zone for all diseases requiring risk management. Australia will consider submissions requesting recognition of disease status.*

3. The draft stipulates "Pig meat may be imported from any country if the meat is canned (sealed container) and all portions of the contents have been heated to at least 100°C", however, the duration of heat treatment, and whether 100°C is the maximum temperature or the average are not clear. Please give explanations.

**Response:** *In the course of manufacture, every portion of the contents of the batch of cans or containers must be heated to a temperature of 100°C. Cans can be heated to a higher temperature. The minimum temperature is 100°C. No time is specified. Conditions for the importation of canned pig meat are available on the Department of Agriculture, Fisheries and Forestry web site (<http://www.daff.gov.au>).*

4. Because discussions regarding meat inspection and quarantine regulations are to be organized by CAC on February 2004, we suggest extending the comment period of this notification to March 31, 2004. Hope the draft will be referred to as risk analysis document on the meeting and be modified.

**Response:** *Australia provided all stakeholders with a 60 day comment period as required under SPS notification and domestic requirements. The comment period cannot be extended until March 31, 2004.*

## **The Danish Veterinary and Food Administration**

With reference to the Australian Government, Department of Agriculture, Fisheries and Forestry release of the draft import risk analysis (Generic Import risk Analysis (IRA) for Pig Meat), the Danish Veterinary and Food Administration has the following comments.

The Australian Generic Import Risk Analysis (IRA) for pig meat has been on its way for five years. Australia has, with reference to the fact that new import conditions would be based on the IRA, rejected Danish requests for further access to export pig meat bone-in and pork meat products. We find it very unsatisfactory that the process has taken so long.

Our main reservations to the IRA are connected to the proposed restrictions on import of pig meat from countries with PMWS and the proposed demands for canning and heat treatment of pork to at least 100°C when pork is imported from countries with Rinderpest, Foot and mouth disease, Classical swine fever, Swine vesicular disease and African swine fever.

Furthermore, we fully agree on the proposed changes relative to previous sanitary measures in relation to PRRS, which we believe is a step in the right direction, as specified below.

### Postweaning Multisystemic Wasting Syndrome (PMWS)

In our opinion, the proposed restriction on import of pig meat with reference to PMWS are a violation of the International Trade Obligations according to the SPS agreement under the WTO.

Australia wishes to impose very restrictive import regulations on pig meat from countries with PMWS, even though Australia has demonstrated that Porcine circovirus 2 (PCV2) is present in their own pig population and no measures in place to prevent the spread of the virus. In our opinion, this is an arbitrarily and unjustifiable discrimination between their own territory and that of other countries, and therefore a violation of article 2.3 in the SPS agreement.

The following argument underpin that the proposed restrictions are unjustified.

- PMWS is a multi-factorial disease. PCV2 is the key factor for developing the disease, but other factors are also involved.
- As indicated in the IRA, Australia is not free from infection with PCV2.
- PCV2 virus is believed to spread by direct contact between live animals. So far there is no scientific evidence or indication of PCV2 being meat-born. It does not make sense to keep the virus out of Australia by controlling import of meat, as PCV2 is already present in Australia. PMWS itself, which is multifactorial, cannot under any circumstances be claimed to be meat-born.

With regard to the proposed connection in the IRA between the development of PMWS and the presence of PRRS, it is documented that PRRS is not a causal factor in PMWS. In Denmark, it is assumed that approximately 70% of all herds are affected by PRRS, and among the first 45 cases of PMWS in Denmark only 70% were infected with PRRS. For more information on PMWS with references please see the attached letter from the Danish Bacon & Meat Council. Our own scientists at the Danish Veterinary Institute have validated this information.

**Response:** *Although PCV2 is present in Australia, PMWS has not been reported. It is considered that a difference in virulence of strains of PCV2 is one potential explanation. Another potential explanation is the presence of an unknown disease agent which acts as a trigger for PCV2. A surveillance program is in place for PMWS and Australian veterinarians are aware of the disease. A preliminary study in which an Australian isolate of PCV2 together with immunoenhancers were inoculated into pigs did not result in PMWS or PMWS type lesions*

*in tissues (Buddle, et al., 2003). Further work is being conducted. Several researchers have suggested that PCV2 strains may differ in virulence (Ladekjaer, et al., 2002; Segales & Domingo, 2002). A difference of only a few amino acids could be significant. An example where this is the case is Newcastle disease virus.*

*As PMWS is an emerging disease, the mechanism of transmission has not been fully elucidated. Interestingly PRRS virus (a virus that also has an affinity with lymphoid tissue, and may result in persistent infections) was originally considered unlikely to be transmitted via meat (Larochelle & Magar, 1997), but this has since been shown not to be the case. The available evidence suggests that PCV2 associated with persistent infection would be present in lymphoid tissues associated with muscle and during viraemia in blood perfusing muscle. Recently it has been postulated that PMWS may have entered New Zealand via imported uncooked pig meat which was then fed to pigs.*

*The IRA references several studies where PMWS could be induced experimentally by co-inoculation of PRRS virus and PCV2 or porcine parvovirus and PCV2. The IRA does not conclude that PRRS virus is required for the development of PMWS.*

#### Canning and heat treatment of pig meat in relation to relevant OIE list A diseases

The Danish Veterinary and Food Administration fully support the European Commissions draft comments on this subject in the document SANCO / 10559 / 2003R1 (*see comments on Draft IRA Report from the EU Commission*).

**Response:** *Noted. Refer to the Panel's comments on the EU Commission's submission.*

#### Porcine Reproductive and Respiratory Syndrome

In the IRA the recommendations for Quarantine Requirements for importation of pig meat from countries with PRRS, it is proposed to allow the import of bone-in and pork products (Heat treated in accordance with specific Australian demands for inactivation of PRRS virus). We fully agree on the proposed changes relative to the previous sanitary measures, and believe that this is a step in the right direction to accomplish free and unrestricted trade. Please also see the enclosed Danish Assessment of the risk that Porcine Reproductive and Respiratory Syndrome Virus may enter Australia due to import of fresh Danish bone-in hams and the enclosed report from Danish Meat Research Institute regarding PRRS elimination by heat treating – Documentation of the temperature course in bone marrow and the centre temperature in meat by smoking and heat treating cured bone-in hams.

If the recommendations are implemented, it will be possible to gain access to the Australian market as we have requested. Nevertheless we reserve our rights for further comments on the draft import requirements for post entry control and processing requirements for pig meat from countries with PRRS, as we are collecting information among stakeholders on the economical and practical impact of the proposals.

**Response:** *Noted.*

#### Conclusion

The Danish Veterinary and Food Administration believes the IRA recommendations, for Quarantine Requirements for importation of pig meat from countries with PRRS, is a step in the right direction to accomplish free and unrestricted trade. The major improvement is the possibility to export pig meat with bone, and it is also important that the heat treatment can be performed in the country of origin. Unfortunately these improvements may turn out to be unimportant due to the proposed restrictions on import of pig meat from countries with PMWS, which we believe to a violation of the International Trade Obligations according to the SPS agreement under the WTO.

***Response:*** *The quarantine requirements for PRRS and PMWS allow for the processing of product in the country of origin or on-shore in Australia.*

## **Danske Slagterier (Danish Bacon and Meat Council)**

### **Main reservations regarding the Draft Import Analysis for pig meat released by the Australian Government, Department of Agriculture, Fisheries and Forestry**

#### Background

On August 13, 2003, the Australian Government, Department of Agriculture, Fisheries and Forestry released the Draft Import Risk Analysis (IRA) for pig meat:

(<http://www.affa.gov.au/content/publications.cfm?ObjectID=EAA47406-D373-4205-AC85A3D6A8AA7046>)

The IRA has been on its way for five years. Australia has, with reference to the fact that new import conditions would be based on an IRA, rejected Danish requests for further access to export pig meat bone-in and pork meat products. We find it very unsatisfactory that the process has taken so long. We also find it very unacceptable that there is only given a 60 days' comment period for stakeholders on a document of almost 800 pages.

***Response:** As the Danish Bacon and Meat Council (DBMC) note the Draft IRA Report is extensive, covering 26 disease agents. The Panel notes that the PRRS risk assessment undertaken by the DBMC commenced in February 2001 and was not finalised until June 2003, a period of 28 months for one disease.*

*Under Australia's administrative process for import risk analysis and in line with our SPS notification requirements 60 days comment is provided.*

#### Our main reservations

##### *PMWS*

Our main reservations are connected to the proposed recommendations for quarantine Requirements for importation of pig meat from countries with PMWS.

In our opinion, restrictions on import with reference to PMWS are a violation of the International Trade Obligations according to the SPS agreement under the WTO.

Australia claims having fulfilled international obligations under the SPS agreement by conducting this IRA. We do not agree since the proposed import quarantine restrictions on PMWS are not based on scientific principles (See article 2, section 2 in the SPS agreement).

The fact that Australia imposes very restrictive import regulations on pig meat from countries with PCV2 and clinical symptoms of PMWS, even though Australia cannot demonstrate freedom of PMWS and has demonstrated that the virus is present in their own pig population, is a violation of article 2, section 3 in the SPS agreement.

We do not find that the Australian import restrictions due to PRRS are justified and in accordance with international agreements and recommendations.

The following arguments underpin that the proposed restrictions regarding PMWS are unjustified:

- PMWS is a multifactorial disease. Porcine circovirus type 2 (PCV2) is the key factor for developing the disease, but other factors are also involved.

- As indicated in the IRA, Australia is not free of infection with PCV2. The virus can be isolated in pig herds without any clinical symptoms of PMWS.
- Virus strains and their pathogenic characteristics in for example Europe would not differ from the virus strains and pathogenic characteristics of virus found in Australia.
- PCV2 virus is believed to spread by direct contact between live animals. So far there is no scientific evidence or indication of PCV2 being meat-borne. It does not make sense to keep the virus out of Australia by controlling import of meat, as PCV2 is already present in Australia. PMWS itself, which is multifactorial, cannot under any circumstances be claimed to be meat-borne.
- With regard to the proposed connection in the IRA between the development of PMWS and the presence of PRRS, it is documented in several papers that PRRS virus is not absolutely conditional for PMWS. In our opinion, papers, which have found an association between these two infections, were all based on a “loose” case definition. The diagnosis was based only on clinical symptoms of PMWS and was not complemented by histopathology and identification of the virus. Internationally, the diagnosis of PMWS is agreed to be based on three factors: 1) clinical symptoms, 2) histopathological findings in lymphoid tissue including depletion and 3) presence of PCV2 by immuno-histochemical procedure. It is a big mistake to base the diagnosis on clinical symptoms alone because the clinical symptoms of PMWS cannot be distinguished from those of PRRS.

For further information please see appendix A.

**Response:** *Noted. Please refer to the Panel’s response to the Danish Veterinary and Food Administration on this matter.*

#### *PRRS*

In the IRA recommendations for Quarantine Requirements for importation of pig meat from countries with PRRS, it is proposed to allow the import of pork bone-in and pork products (heat treated in accordance with specific Australian demands for the inactivation of PRRS virus). We fully agree on the proposed changes and believe this is a step in the right direction to accomplish free and unrestricted trade. Please also see our proposed changes of the risk management with reference to the enclosed *Danish Assessment of the risk that Porcine Reproductive and Respiratory Syndrome Virus may enter Australia due to the import of fresh Danish bone-in hams* and the enclosed report from Danish Meat Research Institute regarding *PRRS elimination by heat treating – Documentation of the temperature course in bone marrow and centre temperature in meat by smoking and heat treating cured bone-in hams*.

If the recommendations are implemented, it will be possible to gain access to the Australian market as we have requested. Nevertheless we propose that the Danish Veterinary and Food Administration reserve their rights for further comments on draft import requirements for post entry control and processing requirements for pig meat from countries with PRRS, as we are collecting information among stakeholders on the economical and practical impact of the proposals.

**Response:** *Noted. The Panel appreciates the DBMC submissions, in particular the report of heat treatment of bone marrow.*

#### *Demands for heat treatment*

We also have reservations regarding demands for canning and heat treatment of pork to at least 100°C when pork is imported from countries with Rinderpest, Foot and mouth disease, Classical Swine fever, Swine Vesicular disease and African Swine Fever. For further information please see appendix B.

***Response:*** *Noted. Refer to the Panel's comments on the EU Commission's submission.*

We ask the Danish Veterinary and Food Administration to take our comments into consideration in connection with submission of the official comments before October 13, 2003.

## **Appendix A. More information on PMWS with references**

The exact cause of PMWS is unknown. Porcine circovirus type 2 (PCV2) is believed to be the causative agent in PMWS, but unknown factors are also involved. The PCV2 virus is widespread all over the world. The virus has been present in the swine population long before the first case of PMWS was recognised in Canada in 1991 (Magar et al., 2000).

The diagnosis of PMWS is based on:

- 1) Presence of clinical symptoms including unthriftiness and increased mortality among pigs after weaning.
- 2) Histopathological findings in the lymphoid tissues including depletion of lymphocytes.
- 3) Detection of PCV2 virus by immunohistochemical procedures in the lymphoid tissue.

This is accepted all over the world (Segales et al., 2003).

This means that the diagnosis depends on the presence of clinical symptoms despite that none of the clinical symptoms of PMWS is essential for PMWS. This means that if a herd only has a few clinical signs of that could be due to PMWS, it is not certain that the herd would be investigated for PMWS. It is therefore impossible to have a surveillance program on PMWS.

The causative agent, PCV2 is also found in Australia (IRA report, page 383). A lot of work has been carried out to see if PCV2 isolates from herds affected by PMWS and hers without PMWS is different. To date all research has shown no difference among isolates, and the homology ranges between 95-98%. (Boisseson et al., 2003). PCV2 virus is believed to spread by direct contact between live animals (Hassing, personal communication, 2003).

The correlation between PRRS and PMWS has not been proven scientifically. In Denmark, it is assumed that about 70% of all herds are affected by PRRS, and among the first 45 cases of PMWS in Denmark only 70% of the cases were infected by PRRS. (Hassing et al., 2003). In one Dutch paper describing the results of a case-control study, it was found that a PRRS infection is a risk for PMWS (de Jong et al., 2003). Unfortunately, the case definition of PMWS in this investigation was only based on clinical findings of PMWS without any laboratory confinement. Hence, in some cases the clinical symptoms could be due to another infection e.g. PRRS.

There is no evidence of a zoonotic aspect of PCV2 infection; porcine circovirus has only been isolated from pigs (Allan et al., 1994).

PCV2 is already present in Australia and according to the SPS agreement under WTO article 2 section 3 it is a violation to ban import of meat from countries if the causative agent is already present in the importing country.

### Reference:

Allan G.M., Phenix K.V., Todd D., McNulty M.S.; Some biological and PhysicoChemical properties of Porcine Circovirus. J. Vet. Med. B41, 17-26 (1994).

Boisseson C., Beven V., Bigarre L., Thiery R., Rose N., Eveno E., Madec F., Jesten A.,; Characterization and comparison of porcine circovirus sequences from Postweaning Multisystemic wasting syndrome affected and non affected herds. Proceedings 6<sup>th</sup> International Congress on Veterinary Virology, 24-27. August 2003. p. 92.

De Jong M.F.m Elbers A., Wellenberg G.J.; Factors associated with PMWS and PDNS: A case-control study. Proceedings 4<sup>th</sup> International Symposium on Emerging and Re-emerging pig diseases, June 29<sup>th</sup> – July 2<sup>th</sup>, 2003, p.215.

Hassing A.-G., Danish Bacon and meat Council, 2003

Hassing A.-G., Botner A., Ladekjaer-Mikkelsen A.-S., Kristensen C.S., Jorsal S.E., Bille-Hansen V., Baekbo P.: Characterization of the first cases of PMWS in Denmark. Proceedings 4<sup>th</sup> International Symposium on Emerging and Re-emerging pig diseases, June 29<sup>th</sup> – July 2<sup>th</sup>, 2003, p.211.

Magar R., Muller P. Larochelle R.; Retrospective survey of antibodies to porcine circovirus type 1 and type 2. Canadian Journal of Veterinary Research, 64, 184-186, 2000.

Segales J., Calsamimiglia M., Domingo M.; How we diagnose Postweaning Multisystemic Wasting Syndrome. Proceedings 4<sup>th</sup> International Symposium on Emerging and Re-emerging pig diseases, June 29<sup>th</sup> – July 2<sup>th</sup>, 2003, p.149-151.

## **Appendix B. More information on demands for heat treatment of pig meat from countries with quarantine diseases**

Australian demands to heat treatment are very restrictive. Only shelf stable canned meat, all portions of meat in a can have been heated to at least 100°C, can be imported despite international recommendations (OIE) for lower temperature requirements. It is unfortunate that even international recommendations are questioned in this way in the IRA.

OIE recommends the following inactivation procedures (OIE, Terrestrial Animal Health Code, 11<sup>th</sup> edition, 2003):

### *Foot and Mouth disease*

For the inactivation of viruses present in meat, one of the following procedures should be used:

**Canning:** Meat subjected to heat treatment in a hermetically sealed container must reach an internal core temperature of at least 70 °C for a minimum of 30 minutes or subjected to an equivalent treatment which has demonstrated inactivation of the FMD virus.

**Thorough cooking:** Meat, previously deboned and defatted, shall be subjected to heating so that an internal temperature of at least 70 °C or more is maintained for a minimum of 30 minutes.

### *African Swine Fever*

Meat products have been processed to ensure the destruction of the ASF virus. The requirements according to the OIE pave the way for dialogue regarding demands for different measures.

### *Rinderpest*

Meat products must be processed to ensure the destruction of Rinderpest virus in conformity with one of the below-mentioned procedures (the same demands as for inactivation of the FMD virus).

**Canning:** meat subjected to heat treatment in a hermetically sealed container must reach an internal core temperature of at least 70 °C for a minimum of 30 minutes or subjected to an equivalent treatment which has demonstrated to inactivate the Rinderpest virus.

**Thorough cooking:** Meat, previously deboned and defatted, must be subjected to heating so that an internal temperature of at least 70 °C or more is maintained for a minimum of 30 minutes.

### *Classical swine fever*

Meat must be subjected to one of the following treatments:

- a) Heat treatment in a hermetically sealed container with  $F_0$  value 3.00 or more
- b) Heat treatment at a minimum temperature of 70 °C, which must be reached throughout the meat

### *Swine vesicular disease*

Meat products have been processed to ensure the destruction of the SVD virus. The requirements according to the OIE pave the way for dialogue regarding demands for different measures.

### References:

OIE, Terrestrial Animal Health Code, 11<sup>th</sup> edition, 2003.

**Assessment of the risk that Porcine Reproductive and  
Respiratory  
Syndrome Virus may enter Australia due to import of fresh  
Danish bone-in hams**

**DANISH BACON & MEAT COUNCIL  
Veterinary and Food Advisory Service  
June 2003**

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### **Preface**

In January 2001, the Australian authorities released a hazard identification entitled “Generic Import Risk Analysis for Uncooked Pig Meat”. According to the report it is envisaged to carry out a risk assessment for each hazard identified. Since The Danish Bacon & Meat Council (DBMC) is interested in exporting fresh pork to Australia, DBMC decided to undertake a risk assessment of the risk that Porcine Reproductive and Respiratory Syndrome Virus may enter Australia due to import of fresh Danish pork bone-in. In February 2001, a task group was appointed to carry out the risk assessment, which was finalised in June 2003.

The members of the group were:

Lis Alban

Nina Blom

Sten Mortensen (Since 2002 employed with the Danish Veterinary & Food Administration)

## 1. Summary

Australia is concerned that Porcine Reproductive and Respiratory Syndrome (PRRS) Virus might enter Australia due to import of fresh pork from countries like Denmark, where PRRS is endemic. At present, import of pork from Denmark into Australia is permitted, only if the pork is deboned and destined for processing at an approved Australian processing facility. Here, the pork is heat-treated until it reaches a core temperature of 56°C for a minimum of 60 minutes or an equivalent combination of time and temperature.

The Danish Bacon & Meat Council wishes to export bone-in hams with subsequent heat treatment in Australia if a risk assessment shows that the risk is below the acceptable risk level. Therefore, DBMC undertook a risk assessment to estimate the risk of introducing PRRS Virus into Australia due to import of this commodity.

The assessment is qualitative and carried out according to present international standards for risk assessment. It contains information on the prevalence of PRRS in Danish herds as well as in pork. Furthermore, the processing methods applied for bone-in hams are used to document that AQIS' demands for heat treatment have been reached in both meat and bone marrow of pork bone-in.

It is concluded that the probability that PRRS would enter Australia due to import of *fresh Danish bone-in hams, heat-treated upon arrival to Australia*, is negligible because:

- The prevalence of PRRS virus in Danish pork at slaughter is very low despite PRRS being endemic in Denmark, and freezing reduces the prevalence further by 75%,
- If present, virus is in low titers,
- Any virus is inactivated when pork is processed at 56°C for 60 minutes or an equivalent combination of temperature and time
- Our pilot plant experiments have demonstrated that the required temperature in the bone is obtained to the same degree as in the muscle
- A HACCP-based quality assurance programme at the processing plants guarantees that the required time/temperature combination has been reached
- In Australia, the use of swill is restricted by law
- It is questionable how likely PRRS virus is to be transmitted through pork naturally infected with PRRS virus

The consequences of introducing PRRS are by no means devastating since there is no risk for humans, and the swine production will only experience temporary production losses due to an increased number of abortions and decreased fertility during introduction of the virus. Finally, a country with PRRS can continue export of pig meat since only a limited number of countries have demands regarding PRRS.

Risk is a combination of the probability and the consequences of the adverse effect. Since the probability is negligible, and the consequences are limited to production losses over a short time period, the risk associated with import of *Danish bone-in hams heat treated upon arrival to Australia* seems to be below the acceptable risk level.

## 2. Background

Since 1980 Denmark has requested full access to the Australian market for fresh pork against the background that no OIE list A disease has been present in Denmark for several years. However, PRRS is endemic in Denmark, whereas it is non-occurring in Australia, and Australia is concerned that PRRS might be introduced because of import of fresh pork. Therefore, the Australian authorities refuse the Danish request.

Despite that PRRS virus is on OIE's list of group B diseases, there are no international guidelines or veterinary conditions limiting the trade in pork from countries with PRRS virus (<http://www.oie.int>). Therefore, Australia is obliged - due to the SPS agreement - to base any veterinary requirements for Danish pork intended for export on an import risk assessment (<http://www.wto.org>).

In 1993, Australia started conducting an Import Risk Analysis on Danish Pig Meat (Anon., 1994a), and in 1994 AQIS evaluated the Danish Veterinary Services (Anon., 1994b). This provided the setting for Australia to open its market for import of fresh pork from Denmark under certain conditions (Anon., 1996). Accordingly, pork could be imported from Denmark, only if de-boned and destined for processing at an approved Australian processing facility. The processing facility should guarantee that the meat would be heat-treated to a core temperature of 56°C for minimum 60 minutes or another equivalent combination of time and temperature (Anon., 1997). In 1999, the Danish Veterinary and Food Administration approved the veterinary certificate specifying the conditions for import of Danish pork (Anon., 1999). Until 2002, approximately 50,000 tonnes of pork at a value of approx. 135 million EURO have been exported from Denmark to Australia.

In August 1999, a Danish request for exporting pork bone-in from Denmark to Australia was rejected against the background that the Australian authorities wanted to carry out further PRRS risk assessments in relation to import of bone-in-cuts of pork. Subsequently, the Australian authorities released a hazard identification entitled "Generic Import Risk Analysis for Uncooked Pig Meat" in January 2001 (Anon., 2001). The report dealt with several hazards and envisaged to carry out a proper risk assessment for each hazard identified.

As the Australian hazard identification focuses on PRRS as 'the' hazard in relation to export of pork from Denmark, The Danish Bacon & Meat Council decided to undertake a risk assessment specifically on the risk of introducing PRRS to Australia due to import of fresh Danish bone-in hams, heat-treated in Australia. As the hazard identification has already been made (Anon., 2001) we only address this shortly and focus on the risk assessment itself.

The assessment is qualitative and – whenever possible - carried out according to international standards (Anon., 1998). Available information from the literature as well as from the manufacturers is presented. If information was missing or of poor quality, assumptions have been made and these are listed in the report. A pathway was set up describing the series of events necessary for exposing Australian swine for PRRS virus originating from Danish pork. For each event the probability of the event occurring was assessed by use of an ordinal scale with 5 levels: negligible (<0.1%), very low (>0.1-1.0%), low (>1-10%), medium (>10-50%), and high (>50%) The probabilities were derived from the detailed description of each event.

### **3. Hazard identification**

#### **3.1 The virus**

PRRS is a small, enveloped, single stranded RNA virus from the arterivirus group, classified within the Togavirida family. In 1991, the virus was isolated in both the Netherlands and in the USA. The use of modified live vaccines, based on American strains of PRRS virus, in Europe, has resulted in American strains occurring in Europe.

##### **3.1.1 Virus distribution in tissues**

The target cells of PRRS replication are matured monocytes/macrophages. Infected cells are primarily found in the lung, thymus, tonsils, lymph nodes, and serum (Mengeling et al., 1995). The carrier state for PRRS virus is characterised by predilection and maintenance of the virus in tissues other than meat, that is the tonsils and lungs (Farez and Morley, 1997).

### **3.1.2 World distribution**

PRRS occurs in domestic, feral and wild porcines only. At present, PRRS is endemic in North America, most European countries, Russia, the Philippines, Korea, Taiwan, and Japan. Countries that are believed to be free of PRRS include Australia, New Zealand, Norway, Finland, and Sweden.

### **3.2 The disease**

The majority of the herds will either be endemically infected or non-infected, leaving a small fraction to be acutely infected. Incubation time is usually 2-5 days. Typically, the herd will experience an acute disease episode lasting 2-4 months (acute phase) followed by a gradual return to normal production (endemic phase) (Christianson and Joo, 1994; Meredith, 1995). The infection usually persists for years in herds (Albina et al., 1994) unless specific measures are taken to eliminate the infection. A recent simulation study showed that the average time to extinction in a herd with 115 breeding sows would be 6 years, and 80 years in a herd of twice the size (Nodelijk et al., 2000). The disease symptoms vary from none to severe (see below) upon the infection of previously un-infected herds (Christianson and Joo, 1994).

#### **3.2.1 Naive adult pigs**

The symptoms in boars and non-pregnant sows are mild and transient (fever, inappetence) although some strains of the virus have been associated with increased mortality in sows (Lager et al., 1998). The infection may cause abortion in late-term pregnant sows, prolonged farrowings, the birth of stillborn and weak-born piglets andagalactia (Christianson and Joo, 1994).

Pigs initially exposed to PRRS virus will generally have antibodies detectable by indirect fluorescent antibody (IFA) or ELISA within ten days of post infection (Wensvoort, 1994). The disease is highly infectious with an estimated basic reproduction ratio of 3 (Nodelijk et al., 2000). Within a susceptible herd, an average of 85% of exposed adults will sero-convert during the acute phase (Swenson et al., 1994). After recovery, the vast majority of pigs appear to be immune to further expression of the disease. The duration of the viraemia in experimentally infected 6-week old pigs varied from 2-35 days (Farez and Morley, 1997), and it is estimated that peak viraemia occurs after 11 days (Anon., 2000). However, experimental studies have indicated that clinically healthy animals might infect susceptible animals for prolonged periods, up to 99 days post infection (Albina et al., 1994; Dee et al., 1994). Stress or immune suppression may play a part in inducing viraemia in pigs with neutralising antibodies and without clinical signs (Albina et al., 1994). These authors reported the sero-conversion of pigs placed in contact with non-viraemic, non-clinical, seropositive piglets that had been given exogenous corticosteroids and submitted to transport stress.

#### **3.2.2 Piglets**

During the acute phase of an outbreak, piglets might be weak-born and viraemic. Increased pre-weaning and post-weaning mortality are common results. The clinical signs include respiratory symptoms in young pigs and increased susceptibility to secondary infections (Christianson and Joo, 1994). However, mild symptoms might also be seen, e.g. in a recent Dutch experiment, the only symptoms of disease were lethargy, mild respiratory distress, fever, and inappetence for a short period of time - and only among a part of the animal (only 3 out of 81 needed antibiotic treatment) (Anon., 2000). Likewise, the diagnosis of PRRS is difficult as sub-clinical infections are common in all age groups. According to Murray (2001) it is probable that most finishing herds in infected areas are infected without clinical signs, and PRRS may only be detected when respiratory diseases are being investigated among weaners.

Piglets born from sows that became infected in late gestation might have antibodies to PRRS virus at birth. Piglets might also obtain maternal antibodies in colostrum or sero-convert following a challenge by PRRS virus in the farrowing room or nursery (Albina et al., 1994). Titres of maternal antibodies progressively decrease and might be absent at weaning although

titres subsequently rise where PRRS is endemic in the growing and fattening herds (Dee and Joo, 1994; Stevenson et al., 1994). In this situation, 80-100% of the piglets will be positive on IFA by 8-9 weeks of age, although the sero-prevalence in finishing pigs (5-6 months) may vary from 25-50% (Dee and Joo, 1994).

### **3.2.3 Endemic situation**

During the endemic phase, clinical signs may disappear in all stages of the production. In some herds reproductive failure of first parity sows may occur, and endemic infection in the nursery sections may result in increased death losses (Dee and Joo, 1994). In Danish herds, weaners in the nurseries usually become sero-negative due to the decline of maternally derived antibodies. Virus circulation seems to persist among growers when they are introduced into growers and finishers units (Nymark et al., 1998). By the end of the finishing period, 83% of the animals in 1,603 infected herds were seropositive (Mortensen et al., 2001).

*In conclusion, infection will occur 2-4 months before slaughter following the introduction of 25-30 kg pigs in grower-finisher units. Viraemic pigs at slaughter could possibly occur as a consequence of a new introduction of the virus in a previously non-infected herd or as sporadic cases in endemically infected herds. The probability of a swine being viraemic exactly at slaughter is considered to be low, whereas in a newly infected herd the probability is considered to be medium to high.*

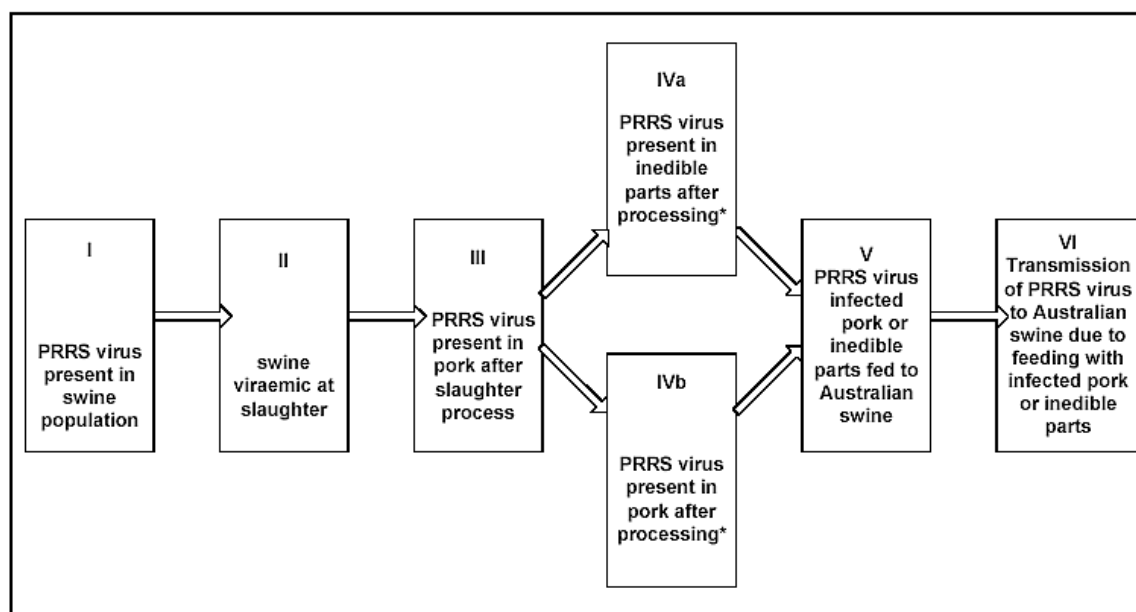
### **3.2.4 Transmission**

In general, PRRS virus is transmitted within a susceptible herd or population at a high rate. However, the rate appears to vary with the viral strain and with the structure and density of the pig producing enterprises in the region (Halbur et al., 1992). The primary vector in the transmission is the infected pig (Dee et al., 1994). Transmission by direct contact has been demonstrated both experimentally (Collins et al., 1992; Christianson et al., 1992) and in field observations, where the spread of PRRS virus by movement of infected stock into susceptible herds has produced epidemic diseases (Dee, 1991). Aerosol transmission of PRRS virus has been reported, particular in conditions of high humidity, low wind speed, and low ambient temperature (Edwards et al., 1992; Mortensen and Madsen, 1992; Dee and Joo, 1994; Lager and Mengeling, 2000). PRRS virus may be spread by semen from infected boars (Meredith, 1992; Yaeger et al., 1993; Swenson et al., 1994; Christopher-Hennings et al., 1995). Experimental transmission of PRRS virus by certain waterfowl species has been reported (Zimmerman et al., 1997); the magnitude of this effect has not been substantiated however. According to Hooper et al. (1994) rats and mice are not a reservoir for the virus. Vomites may play a part (Yoon et al., 1993; Dee and Joo, 1994; Dee et al., 1994).

The above-mentioned ways of transmission are not relevant for the present risk assessment, which deals with export of fresh Danish bone-in hams. Therefore, we have only dealt with *infected pork* as a way of transmission (Section 3.2.2).

## **4. Risk Assessment**

The series of events necessary for fresh Danish bone-in hams to expose Australian swine to PRRS virus is described in Figure 1. Firstly, PRRS virus must be present in the Danish swine population, secondly in swine at slaughter. Thirdly, virus must be present in the pork after the entire slaughter process. Fourthly, virus must survive in pork, i.e. in heat treated bone-in hams or in bits and pieces not undergoing processing. Virus could also survive in inedible parts, i.e. refuse, waste, packing material and effluents. Fifthly, pork or inedible parts containing PRRS virus should be fed to Australian swine. Finally, Australian swine should develop infection to PRRS due to the feeding of pork or inedible parts containing PRRS virus. The risk assessment consists of 3 parts: 1) Release assessment (steps I-III), 2) Exposure assessment (steps IV-VI), and 3) Consequence assessment, here combined with Risk estimation. In the risk assessment, the probability of the specific event occurring is assessed qualitatively.



\* Processing includes heat treatment and takes place in Australia

**Figure 1** Pathway describing the series of events needed for PRRS virus to pass from an infected swine population via export of infected pork to the Australian swine population.

#### 4.1 Release assessment

##### 4.1.1 Prevalence in Danish swine herds

The pig industry in Denmark maintains a voluntary programme that monitors the PRRS status of about 4,100 participating herds, 3,700 in the SPF-system (SPF=Specific Pathogen Free) and 400 non-SPF. The aim of the programme is to reduce dissemination of the virus among herds. Breeding and multiplying herds (genetic herds) are required to maintain their status by monthly blood samples. Production herds participating in the programme are required to maintain their status by yearly blood samples (Mortensen et al., 2001). The SPF & PRRS-programme covers approximately 60% of the national sow population and about 45% of the finishing herds. 60% of the national finishing pig population originate from participating sow herds. Most of these finishing herds are following the same regulations as the SPF system, but without control-obligations. There are approximately 2,000 herds declared free of PRRS in Denmark. (Jensen, H. K., personal communication, 2003). The annual incidence is estimated to 8% (we expect that 8% of the *non-infected* herds become infected each year) Mortensen et al. (2001). Both the American and European type of PRRS virus is prevalent in Denmark.

*In conclusion, there is a high probability that an individual Danish pig gets infected with PRRS virus during its life span. Usually, this will occur 2-4 months before slaughter following the introduction of 25-30 kg pigs in grower-finisher units.*

##### 4.1.2 Transport of Danish swine to slaughter

Pigs are slaughtered at approximately 6 months of age, when they weigh around 100 kg. In general, pigs are delivered for slaughter in special trucks, and the transport is as short and comfortable as possible. Typically, pigs are only transported for two hours due to short distances from farms to slaughterhouses. Thereafter, pigs are stabled for approximately two hours before slaughter. Occasionally, pigs are stabled overnight (personal communication, Gade, 2001).

*In conclusion, the stress level among the transported pigs is relatively low, and transport time and lairage are short in general. Hence, there is a low probability that a pig, which was previously infected with PRRS virus, would develop PRRS during transport and lairage.*

#### **4.1.3 Slaughter of Danish swine**

The slaughter process includes: Stunning -> Bleeding-> Scalding -> Flaming -> Rinsing -> Evisceration -> Meat inspection -> Chilling. The carcasses weigh around 76 kg after dressing. The carcasses are chilled as quickly as possible after slaughter in order to optimize the yield and quality of the meat. During the first part of the chilling process, the carcasses are in the chilling tunnel, where the temperature is freezing (-18 to -25°C) and the air velocity is high (2-3 m/s). After approximately 60 minutes, the carcasses are shell frozen and put in storerooms at a temperature at 5°C until the core temperature of the carcasses has reached a maximum of 7°C. The carcasses are stored and chilled for at least 24 hours (24-72 hours with a mean period of 48 hours) before cutting (Kyrme, personal communication, 2003). After cutting, the meat is packed and frozen to -18 to -25°C within 1-2 days. Most of the carcasses are cut at the slaughterhouses in 3 or 4 primal cuts (fore-end, pork leg, pork belly and pork loin) (Danish Bacon and Meat Council, 2001).

#### **4.1.4 pH in pork after slaughter**

The ultimate pH, measured 24 hours post mortem, was on average 5.6 in ham (sd=0.1) (Maribo et al. A and B, 1998; Aaslyng and Gade, 2001).

*In conclusion, the pH of bone-in hams is 5.6 on average, measured 24 hours post mortem. Hence, if PRRS virus is present in the pork at slaughter, it will be reduced, but not fully eliminated since the pH is not low enough during the maturing period, which can be as short as 24 hours.*

#### **4.1.5 PRRS virus in pork from experimentally infected pigs**

Several researchers have examined the role of pig meat in the transmission of PRRS virus. In a study conducted by Bloemraad et al. (1994), 4 pigs were infected experimentally. The pigs were slaughtered 5 days (2 pigs) and 10 days (2 pigs) post infection, respectively. Carcasses were stored at 4°C and samples of muscle and bone marrow were collected from the carcasses 0, 24, or 48 hours after slaughter. PRRS virus was recovered sporadically from muscle samples 0 and 24 hours after slaughter, but not 48 hours after slaughter. No virus was recovered from the bone marrow samples. Likewise, Duan et al. (1997) did not find PRRS virus in the bone marrow of any of 16 experimentally infected pigs, which were euthenased at day 3, 14, 21, 28, 35, 42, or 82 post infection. Mengeling et al. (1995) exposed 21 pigs to one of three PRRS virus strains, with one pig exposed to each virus strain euthenased on days 3, 7, 14, 22, 35, 49, and 70 post infection. PRRS virus was isolated from the ham muscle from one pig only (several muscle groups were sampled), which was euthenased seven days post infection. Frey et al. (1995a) demonstrated PRRS virus (both European and American strains) in pooled samples of ham muscle and bone marrow in pigs slaughtered six days post infection. Hence, it is not known whether PRRS virus was actually present in the bone marrow. The pooled muscle bone marrow samples retained infectivity for several weeks when stored at 4°C and at least for one month when stored at -20°C. Magar et al. (1995) found that PRRS virus was isolated in muscle samples from 2 out of 2 pigs seven days post infection, but not 14 days post-infection. Bloemraad et al. (1994), Mengeling et al. (1995), and Magar et al. (1995) all suggested that low levels of PRRS virus detected in muscles were due to residual infected blood, not because the muscle cells were actively infected with the virus.

#### **4.1.6 PRRS virus in pork from naturally infected pigs**

Several groups have investigated the presence of PRRS virus in commercially slaughtered pork. Frey et al. (1995b) examined 1,049 sample pools taken from 178 lots of fresh pork (40,000 lbs per lot) for PRRS virus, finding 6 of the sample pools positive for virus (prevalence 6/1049=0.6%). In the positive samples virus levels were low. In another study, Magar et al.

(1995) collected muscle samples from 44 abattoir pigs derived from seropositive herds. No virus was isolated and no viral antigens were detected by immunogold silver staining. This same research group subsequently expanded the study to 73 lots of frozen packaged pig meat, each sampled by six pools of meat samples. All samples were negative both by virus isolation and reverse transcription – polymerase chain reaction (RT-PCR) (Larochelle and Magar, 1997). Likewise, a Danish study examined the presence of PRRS virus in pork from 22 herds, where PRRS virus was active up to six months previously. A total of 234 pools of muscle samples were collected at slaughter from approximately ten pigs per herd. All samples were negative by virus isolation. For that reason, the authors concluded that pork does not retain detectable amounts of PRRS virus in endemically infected herds (Olsen, personal communication, 1998). However, it cannot be ruled out that this might occur occasionally. If 234 pools were sampled from a population consisting of 10,000 pigs, this would correspond to a 95% confidence interval for the prevalence from 0.0-1.3% in the population – which includes the prevalence of 0.6% obtained by Frey et al. (1995b). There are probably several reasons explaining the difference in prevalence found in experimental and observational studies:

1. High doses of virus are used in experimental set-ups, whereas in real life the virus levels are probably lower because the animals are infected weeks to months before slaughter.
2. Usually pigs in a viraemic phase are febrile. Febrile pigs cannot be slaughtered according to Danish (and EU) meat inspection rules. The producer, the transport driver and the meat inspector (veterinarian at the abattoir) are each responsible for only slaughtering healthy pigs.
3. During the maturing of the pig meat, any virus being present will gradually be reduced, so that no virus (or close to no) is present after 48 hours. In the example, a Dutch study showed that while PRRS virus could be found in 12 out of 24 muscle samples analysed directly after slaughter, PRRS virus could only be found in 3 out of the same 24 samples after freezing. Hence, a 75% decrease in the prevalence (Anon., 2000).

*In conclusion, PRRS virus has been isolated from muscles of experimentally infected pigs, primarily in the early stages of infection where the pigs usually are febrile. Contrary, PRRS virus has been isolated from slaughterhouse pork seldomly, and if virus was present, it has been in low levels, which decrease further during maturing and freezing (prevalence dropped by 75%). Therefore, the probability that a commercial pork carcass contains PRRS virus is assessed to be very low, around 0.6%.*

## **4.2 Exposure assessment**

### **4.2.1 Oral transmission of PRRS virus due to infected pork**

Transmission under experimental conditions following administration of doses of  $10^7$  TCID<sub>50</sub> virus has been reported previously (cited from Farez and Morley, 1997). The oral transmission of PRRS virus by feeding infected pork to pigs has been investigated recently (Anon., 2000). A preliminary study included 24 eight weeks old pigs infected by intranasal inoculation with either a European or an American strain of PRRS virus. The pigs were slaughtered 11 days post-inoculation, and the semimembranosus muscle was assayed to determine PRRS viral titres. PRRS virus was detected in the muscle of 12 pigs (50%) after slaughter ( $10^{3.3}$ - $10^{4.3}$ TCID<sub>50</sub>/g). The muscle was frozen until it was used in the feeding experiment, and muscle titres were determined before feeding. In most samples, titres decreased during freezing (below  $10^{1.8}$ - $10^{3.8}$ TCID<sub>50</sub>/g) and virus could only be found in 3/24 pigs, hence a 75% reduction in prevalence. 500 g of raw muscle from each experimentally infected pig were fed over a 2-day period (250 g/day) to each of two receiver pigs (48 pigs). Sera were collected for virus isolation and antibody detection for 3 weeks post feeding. Horizontal transmission occurred

since sentinel pigs in contact with receiver pigs became infected, probably a result of group housing. Oral transmission was demonstrated. However, some reservations remain as PRRS virus could be isolated from all receiver pigs even though PRRS virus was not detectable in muscle samples. This could be because the detection level was not low enough, but it could also indicate horizontal transmission.

In general, the oral pig infective dose 50% (PID<sub>50</sub>) for PRRS virus is expected to be considerably higher for feeding of infected pork than for instilling virus in culture media on the tongue of a pig, feeding the virus suspended in a liquid medium such as milk or force-feeding homogenized infected tissue (Farez and Morley, 1997). Additionally, as the predilection sites are other than pork, it might be expected that virus titres are low in pork with PRRS virus making it questionable whether transmission might occur under natural conditions. According to Farez and Morley (1997), uncooked waste of pork or pork products have been incriminated in the transmission of classical swine fever, African swine fever, swine vesicular disease, and foot and mouth disease, but never of PRRS.

*In conclusion, oral transmission of PRRS virus due to infected pork is possible under experimental conditions. However, it is not known how likely this is to occur under natural conditions where the virus titers in infected pork are lower than under experimental conditions. It is assessed that the probability of the event under natural conditions is very low.*

#### **4.2.2 Description of bone-in hams**

Danish exporters have a special interest in exporting Danish bone-in hams for further processing in Australia.

The specific type of bone-in ham, intended for export, is described as pork leg round cut (standard cut) without tailbone, flank fat and flank meat. It contains the aitch bone (os ischium), leg bone (femur) hind shank bone (fibula and tibia) and hock bones (tarsus). A ham weighs 10 kg on average. The product contains approximately 10% bone (1 kg bone) (DANISH CROWN, Randers, Denmark).

The Danish bone-in hams will be sent frozen (- 18°C during transport), wrapped in plastic and packed in cartons, weighing approximately from 20-30 kg. The cartons will be marked with the following information: package no., produced at (name, address), authorization number, type of product, description of goods, production date(s) / lot no, species of animal, net weight and health mark (DANISH CROWN, Randers, Denmark).

It is estimated that Denmark can export 5,000 tonnes bone-in hams to Australia annually at a value of 8 million EURO (Funch, personal communication 2001).

#### **4.2.3 Heat treatment of the raw bone-in hams**

Australia requires that the core temperature should be 56°C for 60 minutes or an equivalent combination of time and temperature in order to inactivate PRRS virus.

The ham is heat-treated to the required temperature by monitoring the core temperature of the ham. It has been questioned whether the heating required for inactivating any PRRS virus will be reached in the bone. Therefore, we set up an experimental study with the aim of demonstrating whether there were any differences between the temperature in the bone and the meat during the heating process. The experiment was conducted twice; at first, four hams were measured during pre-trial, secondly ten hams were measured during the study itself. The results showed that in fact the temperature in the bone was higher than in the meat during the entire heating process for each of the six hams. The reason is that the bone is placed laterally in the ham, not centrally, and hence more exposed to the heat (Frøstrup et al., 2002).

*In conclusion, when heat-treating bone-in hams, the temperature in the bone is higher than in the meat during the heating process. Hence, there is no excess risk associated with bone-in hams compared with hams without bone, provided the cooking procedure has been carried out adequately.*

#### **4.2.4 Quality assurance programme**

The Quality Assurance Programme at the meat producing plants handling Danish pork should secure that PRRS virus is inactivated. The programme should describe both the processing (heat treatment) of pork (de-boned as well as bone-in) as well as the handling of bits and cuts and the inedible parts from the production.

An Australian meat-processing factory (1995) has a detailed Quality Assurance Manual, based on HACCP principles, for the processing of uncooked pig meat (deboned) imported from Canada and Denmark. The manual describes the total process flow of Danish pork, e.g receipt of uncooked meat, identification of the product during processing, heat treatment of pork (including heat treatment of edible trimmings), sterilisation of equipment, heat treatment of refuse, disposal and treatment of waste, packaging material and effluents. The manual is based on AQIS's quality and quarantine requirements with regard to the handling and processing of uncooked pig meat from Denmark and Canada. The manual is approved by AQIS.

An Australian meat processing factory imports over 70 % of the total amount of pork from Denmark and Canada to Australia. The company is also interested in importing Danish pork bone-in for further processing. The company is aware that import of Danish pork bone-in implies amendments to their manual concerning cooking programmes for pork bone-in and disposals including pork bone. The company is interested in participating in "field tests" in connection with general import approval of Danish pork bone-in by AQIS.

*In conclusion, it is assessed that the probability is negligible that a pork cut or inedible parts contain PRRS virus when leaving the processing plant.*

#### **4.2.5 Swill-feed**

Animal Health Australia reports that all states in Australia have imposed legislation restricting the use of swill feed, and the farmers will be punished if they feed swill to pigs. As part of a national publicity programme, a special video has been prepared on the penalties for feeding swill to pigs (<http://www.aahc.com.au/status/ahiareport/1994/aahr9407.htm>). Presumably, compliance is high, but we have no information on the subject.

*In conclusion, it is assessed that the probability is low that pork or other inedible parts will be fed to Australian swine.*

### **4.3 Consequence assessment**

There is no risk associated with PRRS for humans or any other species than porcines. If PRRS virus should be introduced extensively into the Australian pig population, the same series of event are expected as in other countries where PRRS virus is now endemic.

#### Direct consequences

Production and economical losses as a result of infection with PRRS were examined in 28 sow herds and 15 finisher herds. In Danish Farrow – to – finisher herds the losses, as a result of acute PRRS symptoms, have been calculated to amount to 119 Euro per year sow. The costs include losses as a result of a decrease in production of weaners and finishers. For pure sow herds the losses was 47 Euro per year sow and for pure finisher herds 4 Euro per finisher (Anon., 1994 c). As gross margin over time is constant, the average losses described from 1994 are acceptable estimates for losses today (Udesen, personal communication, 2003).

The clinical expression of PRRS varies greatly, and the losses sustained in the herds also differ. This is mainly due to the infection load of other production diseases in the herds. Herds that are declared free of specific production diseases and follow management programmes to ensure low infection load, experience fewer production losses than conventional herds (Anon., 1994 c).

It has been established that to ensure a low infection load during an outbreak of PRRS implementation of management programmes has a positive effect on the production rate during the endemic phase. The positive effect of these management programmes has been found to outweigh the negative effect of PRRS during the endemic phase (Christensen, personal communication, 2003).

Mortensen et al. (2001) have estimated that 8% of non-infected herds become infected each year.

#### Indirect consequences

According to OIE no special measures (including eradication) are required in relation to introduction of PRRS virus into a country (<http://www.oie.int>). So far, none of the countries affected by PRRS has chosen to eradicate the disease after introduction. The costs of controlling the disease (eradication, compensation, surveillance and control costs) vary depending on the measures against PRRS.

In the Danish National Pig Breeding Programme, under the National Committee for Pig Production, there is a demand for testing for PRRS in the nucleus and multiplying herds. The tests are done on a monthly basis (10 samples). The owners of these herds have a so-called Health Advisory Contract with their veterinary practitioner. The contract comprises minimum 12 visits per year, and the blood samplings are done in connection with these visits. The costs of the samplings amount to EURO 3.80 per test, and the analysis EURO 7 per test (Rønn, personal communication 2003).

Since the mid 90ies, the Danish pig industry has implemented a voluntary programme that monitors the PRRS status of the participating herds (Mortensen et al., 2001).

The cost connected with declaration on PRRS free status is due to sampling and analysis of 20 blood tests yearly (122 EURO per year). The clinical examination for presence of PRRS in the herd is normally done under the health advisory contract with the veterinary practitioner. Approximately 80% of all swine producers have signed a health advisory contract.

Piglets/weaners free from PRRS are sold at an additional price of 4-6 %. The high price is an incentive to keep the herd free from PRRS (Jensen, personal communication 2003).

In case PRRS virus is introduced into Australia and becomes endemic, restrictions in export to other countries are expected to be the same as for other countries with PRRS. Denmark exports pork to many countries. Access to markets are not denied with reference to PRRS, but there are special demands regarding PRRS in connection with export to Argentina, Cyprus, New Zealand, Russia, Ukraine, Belarus, Lithuania, and Australia. The financial impact of the restrictions on exports to the specified markets depends on the kind of products exported, the volume and the price of the products (Danish Bacon and Meat Council, 2003).

The most important export restrictions due to PRRS are imposed on exports to Australia and New Zealand which both are high price markets (Danish Bacon and Meat Council, 2003).

Based on Danish experience in fulfilling export conditions to countries with specific demands for PRRS (bilateral agreements with Russia and Argentina), there are also different costs in

connection with the administration of pigs under slaughter restrictions for PRRS. These costs are mainly due to transport of pigs to special abattoirs in order to fulfil the export conditions. The costs for slaughtering pigs under PRRS restrictions are estimated to be 9 EURO for each pig (DANISH CROWN, Randers 2002).

In 2001, Australia exported approximately 13% of their total pork production. Singapore and Japan constitute Australia's biggest markets in volume and value. These markets account for 71 % of the total pork export (76 % of the export value). Trade in pig meat to countries imposing restrictions on PRRS (New Zealand, Russia) accounts for 7% of the total pork export (5 % in value) ([www.apl.au.com](http://www.apl.au.com)).

Denmark exports breeding pigs to many countries. There are no requirements for freedom from PRRS in the country of origin, but demands for freedom from PRRS in the herd of origin and in the animal. (Bramsen, personal communication, 2003).

It is presumed that there will be the same demands for import of live pigs from Australia.

*In conclusion, there are no international demands for eradication of PRRS virus after introduction. The introduction and spread of PRRS virus will only affect export of meat to few markets. This will be in the context of special demands for attestations for PRRS in connection with export. Export of live animals will not be affected if a declaration and monitor system of PRRS is set up to meet the special demands of each importing country. There will be no import ban.*

#### Comments to Australia's assessment of the financial consequences:

Australia has assessed the expected financial impact of PRRS virus entering Australia (Garner et al., 2001). The assessment forms part of a report, which also deals with Nipah virus (serious zoonosis and classical swine fever (OIE List A disease)). The report demonstrates that the consequences associated with the introduction of PRRS virus will be dramatic, not only for Australian pig production but also for Australia as such.

We do understand the uniqueness of Australia's disease-free status with respect to PRRS virus. However, it is interesting to learn about the experiences of the countries in which PRRS is endemic. These countries did not observe the devastating consequences described in the Australian report. In the following we will briefly explain where we have other viewpoints than those stated in the Australian report.

We do not believe that the financial impact on Australia as such will be detrimental because the pig industry in Australia is small compared to international standards (Garner et al. (2001) state that Australia has around 304,000 sows). In comparison, a small country like Denmark (43,000 km<sup>2</sup>) has 1,344,000 sows (Eurostat, 2002).

As stated above under "Indirect consequences", only few countries have special demands regarding PRRS virus, and in most cases export of breeding pigs and pig meat is allowed if certain conditions are followed (certification of the fact that the pig meat originates from a herd without clinical symptoms of PRRS). The Australian report states that some consumers would be likely to stop buying pig meat. This might be the case for Nipah virus, which has a serious zoonotic aspect, and for classical swine fever, where infected pig meat has been incriminated in relation to outbreaks several times (Farez and Morley, 1997). However, a consumer ban on pork is unlikely in relation to PRRS virus since only porcines will be affected by the virus (no zoonotic aspect). Furthermore, it is highly debatable whether the virus can be transmitted by pork under natural conditions (Garner et al. 2001).

For years, Denmark has exported approx. 20,000 tonnes pig meat to Sweden. Despite this, Sweden is still considered free from PRRS. This real-life example demonstrates that the probability that PRRS virus should be transmitted via infected pig meat is negligible under natural conditions.

#### 4.4 Risk estimation

The consequences that PRRS virus might enter Australia are not devastating since primary concerns are production losses. Table 2 lists the events describing how PRRS virus might infect Australian swine on account of import of Danish bone-in hams, heat-treated upon arrival to Australia.

**Figure 2**

List of events that may lead to PRRS virus infecting Australian swine due to import of Danish bone-in hams, heat treated upon arrival to Australia.

Event in pathway	Description of event	Dealt with in Section	Assessment of Probability
I	PRRS virus present in Danish swine population	3.1.1	High
II	Swine viraemic at slaughter	2.2.2 2.2.3 3.1.2	Low (endemic infected herds) Medium-high (newly infected herds)
III	PRRS virus present in pork after slaughter process	3.1.4 3.1.5 3.1.6	Very low <sup>a</sup>
Iva	PRRS virus present in inedible parts <sup>b</sup> after processing	3.2.3 3.2.4.	Negligible <sup>a</sup>
Ivb	PRRS virus present in pork <sup>c</sup> after processing	3.2.3 3.2.4	Negligible <sup>a</sup>
V	Pork <sup>c</sup> and inedible parts <sup>a</sup> fed to Australian swine	3.2.5	Low
VI	Transmission of PRRS virus to Australian swine due to feeding with infected pork <sup>c</sup> or inedible parts <sup>a</sup>	2.2 3.2.1	Very low <sup>a</sup>
<b>I-VI</b>	<b>All events happening</b>		<b>Negligible</b>

a: The probability of the event is conditional on PRRS virus being present in the pork/swine

b: Inedible parts comprise waste, refuse, packing material and effluents

c: Pork comprises bone-in hams as well as pieces and cuts

Before PRRS virus enters Australia because of import of *fresh Danish bone-in hams, heat treated upon arrival to Australia*, all six events in the pathway must happen. This probability may be described by the combined probability of each of the events I-VI. It is concluded that this probability is negligible. The most important reasons are:

- Even though PRRS is endemic in Denmark, the prevalence of PRRS in Danish pork is very low, and further reduced during freezing
- Virus is present in low titres
- Any virus is eliminated when pork bone-in is processed at 56°C for 60 minutes or a similar combination of time and temperature

- Our pilot plant experiments have demonstrated that the required temperature in the bone is obtained to the same degree as in the muscle
- A HACCP-based quality assurance programme on the processing plants guarantees that the required time/temperature combination is reached
- Swill-feed in Australia is restricted by law
- It is questionable how likely PRRS is to be transmitted through pork naturally infected with PRRS virus

Since there is no risk for humans, the consequences of having PRRS introduced are by no means devastating, and the swine production will only experience temporary production losses due to an increased number of abortions and decreased fertility. Risk is a combination of probability and the consequences of the adverse effect. Since the probability is negligible and the consequences are limited to short-term production losses, the risk associated with import of *Danish bone-in hams heat treated upon arrival to Australia* is below the acceptable risk level.

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**PRRS elimination by heat treating  
Documentation of the temperature course in bone marrow and the  
centre  
temperature in meat by smoking and heat treating cured bone-in  
hams**

by

Ann-Britt Frøstrup, Hardy Christensen, Jens Stoumann Jensen

**Summary**

*Background*

Because of fear of introduction of the swine disease Porcine Reproductive and Respiratory Syndrome (PRRS), Australia only allows import of boned Danish pork for further processing at Australian processing plants. The Australian Quarantine and Inspection Service (AQIS) has rejected import of bone-in hams for further processing in Australia among other things on the grounds that PRRS can occur in bone marrow. AQIS believes that heating of the meat part of the ham to the temperatures and holding times required by AQIS that ensure inactivation of possible PRRS virus in meat is not necessarily achieved in the bone marrow.

*Objective*

Studies have been conducted to clarify the effect of heat treatment of bone-in hams and to document whether it is possible to reach a temperature that satisfies AQIS' requirements for temperatures and holding times both in the centre of the meat and in the bone marrow. The studies have shown that during the entire heating process the temperature measured in the bone marrow in the centre of the leg (*femur*) corresponds to or is higher than the temperature in the centre of the meat. This was anticipated because bone and lean fresh meat have almost the same thermal characteristics and because the bones are not situated in the centre of the ham.

*Conclusion*

If bone-in hams are heat treated so that the centre temperature in the meat reaches the minimum temperature and standing times required by AQIS, one can in other words be certain that the temperature and the holding time in the bone marrow have been the same or higher.

## **Introduction**

### *Background*

Because of fear of introduction of the swine disease Porcine Reproductive and Respiratory Syndrome (PRRS) into the Australian swine population via import of Danish pork, Australia only allows import of boned Danish pork for further processing at Australian processing plants. PRRS prevails in swine populations in most of the world, including Denmark, but has not been detected in Australia.

Exporters and importers of Danish pork wish to export whole Danish bone-in hams to Australia. Back in 1999 and 2000 the Danish Food and Veterinary Administration therefore applied for the authorisation of the Australian Quarantine and Inspection Service (AQIS) to export bone-in hams for further processing in Australia. AQIS rejected the applications among other things on the grounds that PRRS virus can occur in bone marrow. AQIS believes that heating of the meat to the temperatures and holding times required by AQIS that ensure inactivation of possible presence of PRRS virus in the meat will not eliminate possible presence of PRRS virus in the bone marrow.

Since it is difficult to measure the temperature in the bone marrow in heat treated bone-in hams, the industry must control the heat treatment by measuring the centre temperature in the meat. The objective of the present study is to document the possible difference in temperature course in meat and bone marrow. The study is based on Australian recipes and procedures for drying/smoking of whole cured bone-in hams.

### *Objective*

The objective of the study is to clarify the effect of smoking and heat treatment of bone-in hams and to document whether it is possible to reach a temperature in the centre of the meat and in the bone that satisfies the requirements for temperature and holding times laid down by AQIS. The documentation must be used in the argumentation that control of heat treatment can be achieved by measuring the temperature and holding time in the centre of the meat.

Two studies have been conducted of which the first was a study of the process, including the placing of temperature measuring probes. Four and ten hams were used in the two trials, respectively. The objective of the last-mentioned trial was to create realistic conditions in the boiling tank.

### *Raw materials*

Danish exporters wish to export frozen ESS FOOD 1203 hams. ESS FOOD 1203 is a bone-in ham including collar bone (Os ischium), leg bone (Femur), shank (Fibula and Tibia) and hock (Tarsus). The ham is round cut without tail bone, flank fat and flank meat. This type of whole bone-in ham is used in the studies with a weight from 9.22 kg to 10.84 kg.

The two-stage thawing was performed in a boiling tank according to the following programme:

1. At 12°C to -0.5°C in the centre
2. At 6°C to 2°C in the centre

### *Curing*

The studies were based on Australian recipes and procedures for the production of cured, smoked whole bone-in hams. With a multi-needle the hams were injected with pickle to 20% weight gain. The pickle was composed of the following:

### *Pickle ingredients*

	%
Water	84.50
Vacuum salt	4.25
Nitrite salt	5.75
Lactage Purasal S/SP 60	4.50
Dextrose	1.00
Total	100.00

### *Drain*

After the multi-needle injection the hams were drained at 4°C.

Table 1: Thawing and curing data for the 14 hams that were included in the two studies:

Id	Frozen Weight, Kg	Thawed weight Kg	Thawing loss, %	Weight after injection, kg	Weight gain, %	Weight after drain, kg	Curing weight gain, %
A**	-	9.22	-	10.83	17.5	-	-
B	-	10.84	-	12.97	19.6	-	-
C*	-	9.80	-	11.62	18.6	-	-
D*	-	10.43	-	12.26	17.5	-	-
1*	9.41	9.26	1.59	10.64	14.9	10.45	12.9
2*	9.57	9.31	2.72	10.81	16.1	10.44	12.1
3	10.47	10.31	1.53	11.92	15.6	11.63	12.8
4**	10.72	10.57	1.40	12.45	17.8	12.16	15.0
5	10.19	9.97	2.16	11.46	14.9	11.20	12.3
6	9.73	9.32	4.21	10.91	17.1	10.61	13.8
7*	10.27	10.13	1.36	11.95	18.0	11.62	14.7
8*	10.26	10.01	2.43	11.81	18.0	11.49	14.8
9	9.77	9.48	2.97	11.16	17.7	11.03	16.4
10	9.99	9.78	2.10	11.68	19.4	11.42	16.8

Id: A, B, C and D are hams from the pre-trial, 1-10 are from the study itself

\* Hams with temperature measuring probes in leg bone and meat

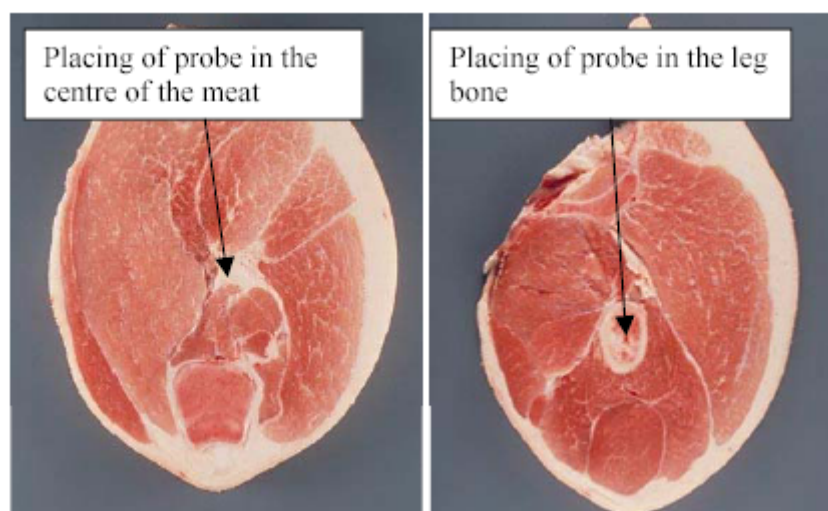
\*\* Hams with the centre temperature probe of the oven

### *Hanging*

The hams were equipped with a hanger in the shank and hanged on a smoking and cooking rack.

### *Calibration of thermic probes*

Temperature measuring probes of the NiCr type were used. Right before use, the temperature measuring probes were calibrated against a Risø-certified temperature measuring probe of same type. The calibration report may be obtained on application to the authors.



*Placing of temperature measuring probes*

The temperature in the bone marrow was measured in the leg bone being the largest bone in the ham and situated the most centrally in the meat.

To record the temperature course in meat and leg bone, the temperature in 6 hams was measured (2 in study 1 and 4 in study 2).

The optimum measuring points were determined by means of the pictures in appendix 1 showing that the leg bone is not centrally situated nor is it situated in the deepest place in the ham. The deepest spot is situated in the meat (see above).

Placing of temperature measuring probe in leg bone (see above and appendix 1):

The meat on the collar bone was cut off. Using a 3 mm drill a hole was drilled into the leg bone. After drilling through the head of the bone, room for the temperature measuring probe was made by means of an awl approx. 8 cm inside the bone marrow of the leg bone (measured from the collar bone). After placing the probe the hole was sealed with finely chopped meat from the collar bone. All temperature measuring probes were connected to a data logger that recorded the temperature every minute.

The temperature measuring probe in the meat was placed in the centre of the ham, see appendix 1 and the examples in appendix 2.

The temperature probes in the smoking and boiling tank were stuck into the hams from the inside of the leg and also placed on the thickest spot in the middle of the 2 and 4, respectively, largest 14 hams that were used in the studies.

*Smoking & heat treatment*

The hams were smoked according to the following programme:

Step	Smoke	Temp,	Time	Ventilation
		°C	min	High/Low
1	-	65	30	High
2	-	70	120	High
3	+	70	20	High
4	-	70	5	High
5	-	75	15	High
6	+	75	20	High
7	-	75	5	High
8	-	74	10	High

After smoking the hams were heat treated and cooled down in a Danfotech cooking cabinet according to the following programme:

1. At 74°C to 69°C in the centre of the meat
2. At 74°C for 10 minutes
3. Cooling at 2°C for 24 hours

**Results and discussion**

*Temperature data*

The temperature data recorded during the two cooking trials are shown in the data files in appendix 3 and 4.

*Documentation of the placing of temperature measuring probe in leg bone*

The leg bone from the hams with probes (C and D; and 1, 2, 7, and 8; see above) was cut out and sawn through to control the actual measuring spot in the leg bone.

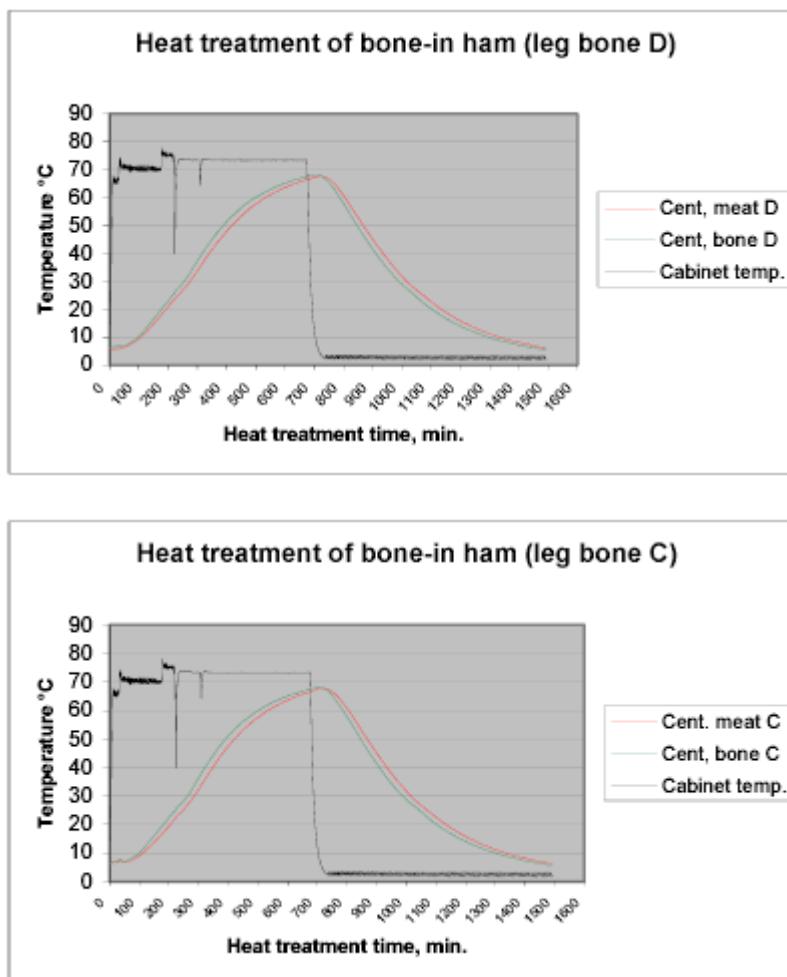
The leg bones with probes were then documented photographically and the result is shown in appendix 2.

Please note that the probe in the leg bone was placed too deep into the bone in study 1 (probe C). The temperature course recorded in the two leg bones in study 1 (probe C and D) was nevertheless identical, see figure 1.

*Study 1*

Four hams were used in study 1. The temperature was recorded in the largest and second largest ham.

**Fig. 1.** Temperature course in leg bone and centre of the meat during heat treatment of 2 bone-in hams (C and D; see table 1 above) at 74°C



*Result and discussion*

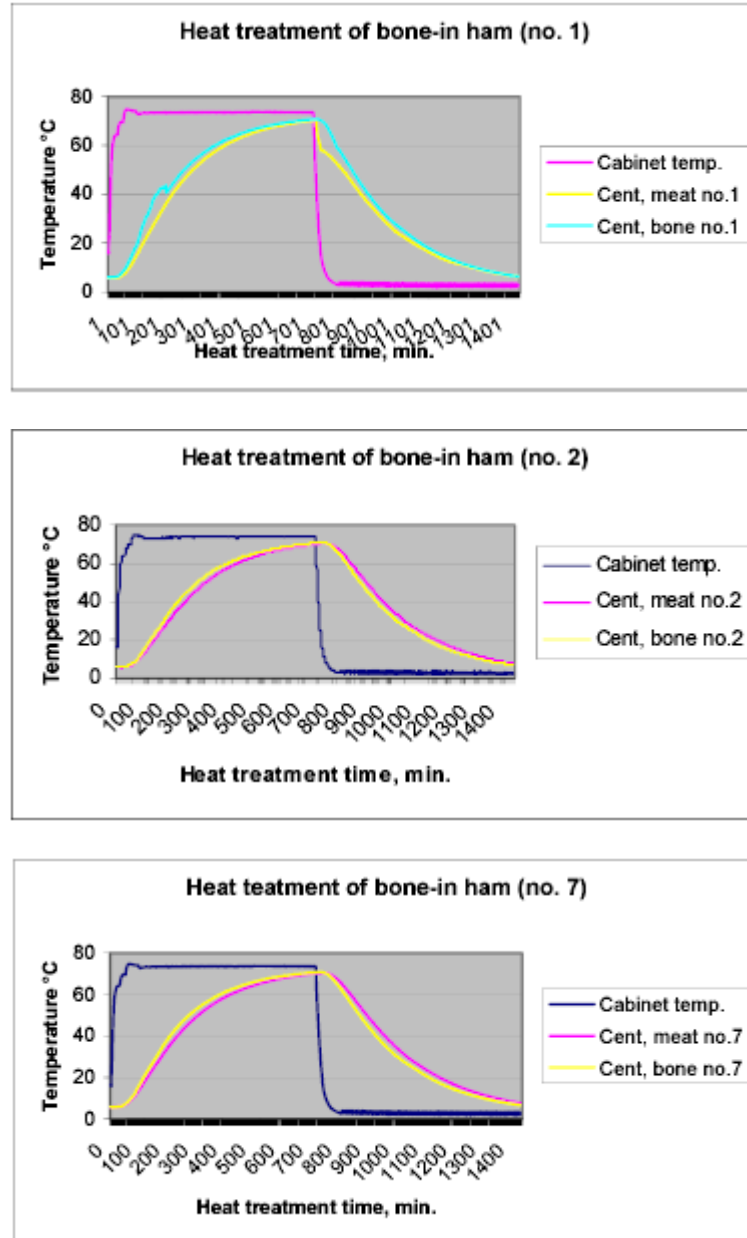
The ultra-short drop in treatment temperature to almost 40°C occurred when the hams were taken from the smoking oven to the cooking cabinet.

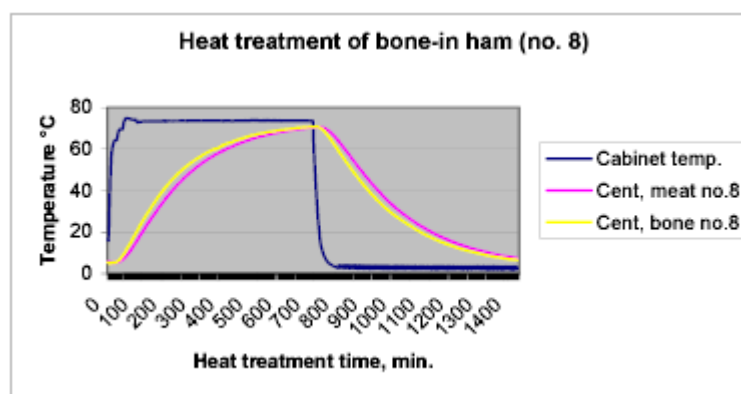
As it appears from the data set in appendix 3 and figure 1, the temperature in the centre of the leg bone is the same or higher than the centre temperature in the meat during the entire heating process, which can be explained by the fact that the temperature measuring properties in meat and bones are very much alike (lean meat:  $0.49 \pm 0.05 \text{ W/m}^\circ\text{C}$ ; bone:  $0.56 \pm 0.02 \text{ W/m}^\circ\text{C}$ ; marrow:  $0.22 \pm 0.02 \text{ W/m}^\circ\text{C}$ ) and as shown in appendix 1 that the leg bone does not lie in the centre of the ham. As the temperature in the ham draws nearer to the temperature in the tank, the difference between the temperature in the leg bone and temperature in the meat is minimised. During the cooling process the temperature in the leg bone is similarly a bit lower than in the meat.

Study 2

Ten hams were examined in the second cooking trial. The temperature in the leg bone and in the centre of the meat was recorded in 4 hams (no. 1, 2, 7, and 8; see figure 2-5) that represented the two smallest (no. 1 and 2) and the two largest (no. 7 and 8) hams. The placing of the probes is shown on the pictures in appendix 2.

**Fig. 2-5.** Temperature course in leg bone and centre of the meat during heat treatment of 4 bone-in hams (no. 1, 2, 7, and 8; see table 1 above) at 74°C





*Result and discussion*

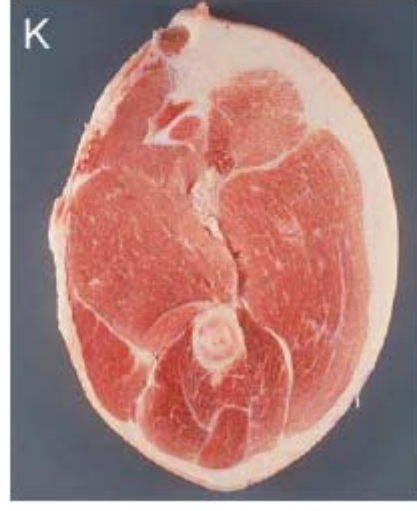
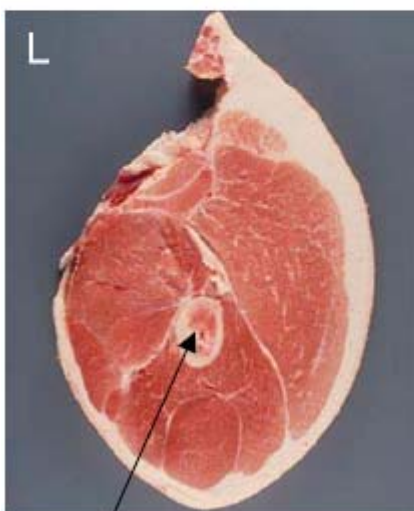
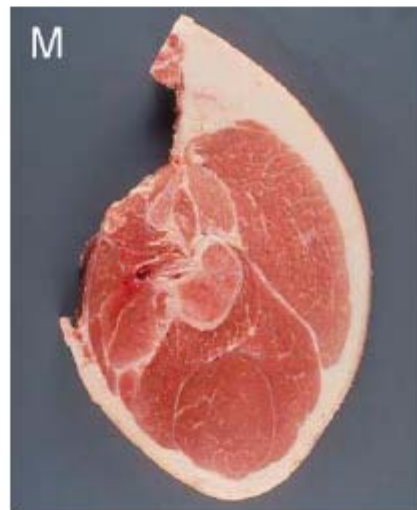
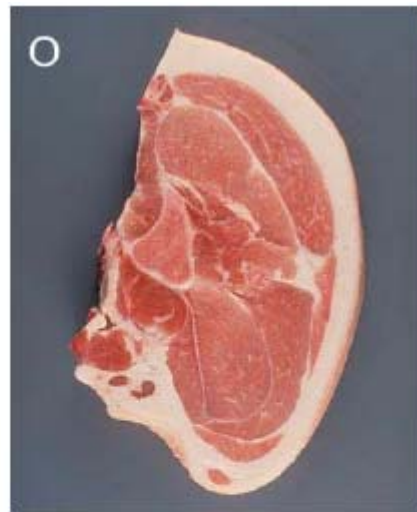
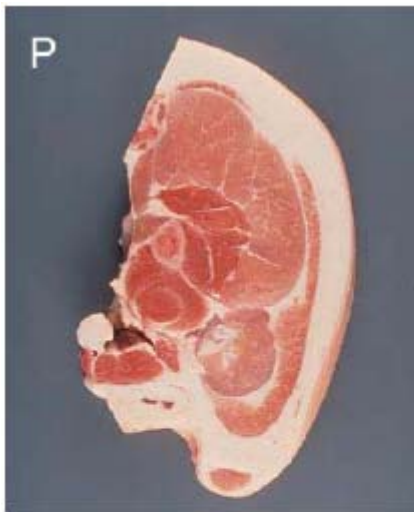
As it appears from the data set in appendix 4 and figure 2-5, study 2 shows the same results as study 1 with two measurements: during the entire heating process the temperature recorded in the centre of the leg bone was the same or higher than the centre temperature in the meat. As the difference between the temperature in the cabinet and the ham was reduced, the difference between the temperatures measured in the leg bone and in the centre of the meat was also minimised. During the cooling phase the temperature in the leg bone was similarly a bit lower than in the meat.

*Conclusion*

The studies demonstrate that during the entire heating process the temperature measured in the bone marrow in the centre of the leg bone (femur) was the same or higher than the temperature in the centre of the meat. This was anticipated because bone and meat have almost the same temperature measuring characteristics and because the leg bone is not situated in the centre of the ham.

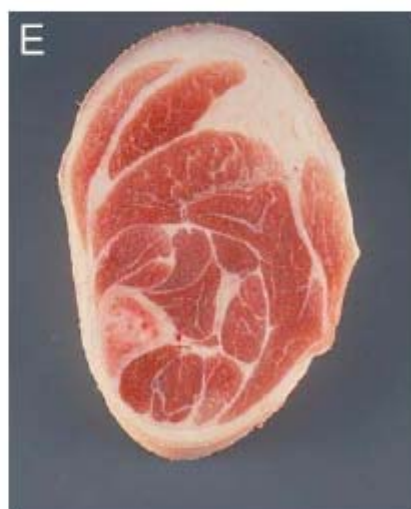
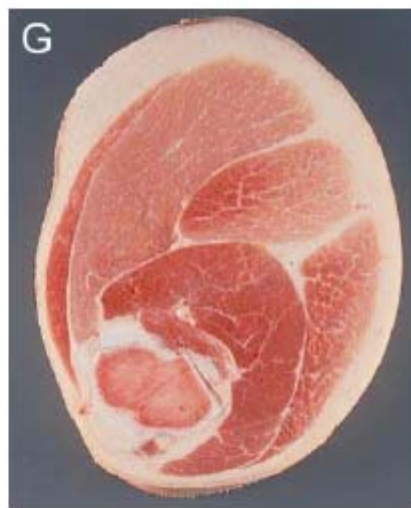
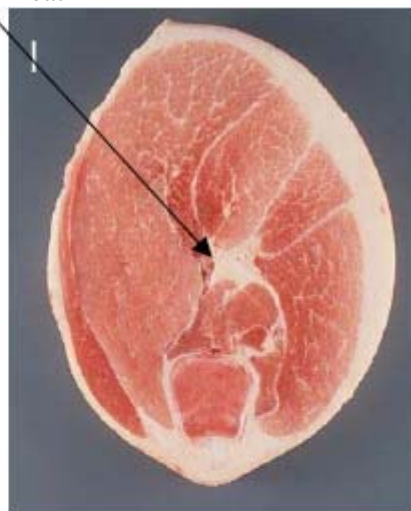
If bone-in hams are heat treated so that the centre temperature in the meat reaches the minimum temperature and holding times required by AQIS, one can in other words be sure that the temperature and holding time in the bone marrow have been the same or higher.

Transverse section through a ham starting from the hip (collar bone):



Measuring point for temperature measuring probe in leg bone

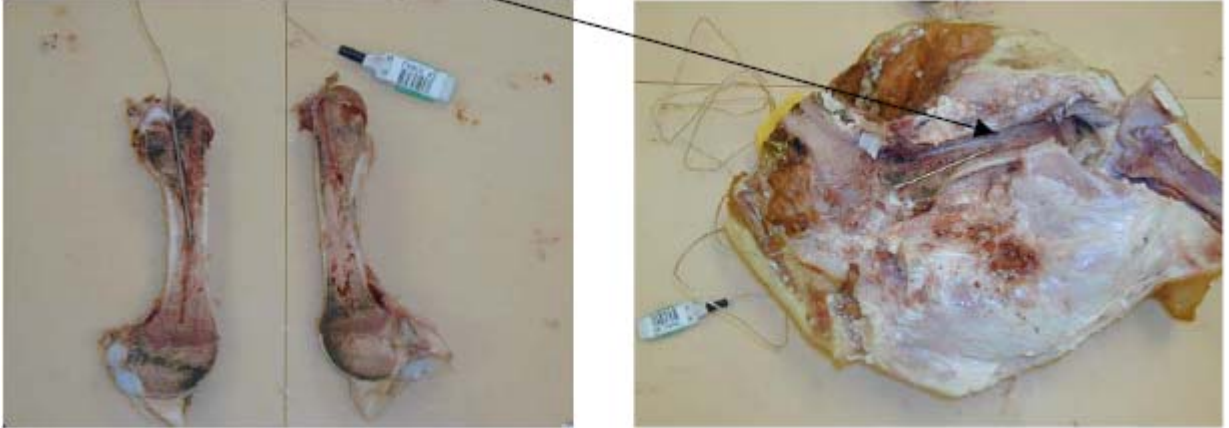
Measuring point for centre temperature probe of the oven in meat



## Appendix 2

Placing of temperature measuring probes

**Study 1:** Placing of temperature measuring probe in ham C . Please note that the probe is placed too deep into the leg bone compared to the centre of the ham.

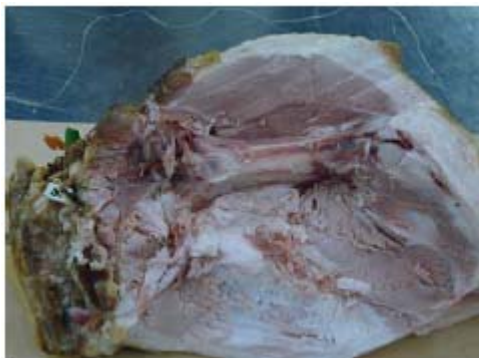


**Study 2:** Placing of temperature measuring probes in the leg bone of each of the 4 hams measured

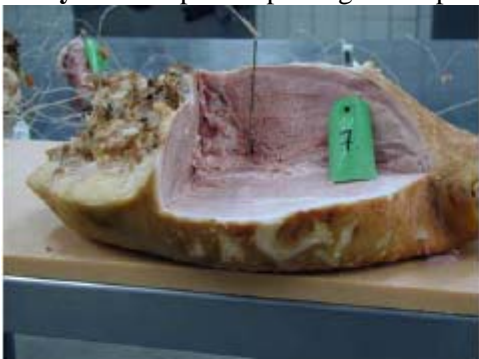


**Appendix 2 - continued**

**Study 2:** Temperature measuring probes in leg bone. Placing of probe in leg bone and probe placed on leg bone, respectively, to illustrate where the probe is placed compared to the centre of the ham



**Study 2:** Examples of placing of temperature measuring probes in the centre of the meat



**Department of Primary Industries, Victoria**

**Animal Biosecurity Policy Memorandum 2003/19**

**Pig Meat Risk Analysis: Draft Report**

I refer to the above Memorandum seeking comment on the Executive Summary of the Draft Import Risk Analysis (IRA) Report for pig meat and the attached Draft Quarantine Requirements for the Import of Pig Meat.

Victoria generally endorses the measures proposed to address the quarantine risks associated with the importation of pig meat as presented in the draft IRA report. Disease agents of quarantine concern have been covered thoroughly and comprehensively.

One area of concern relates to the proposed controls over the transport of imported pigmeat outside urban areas. Modern systems of transportation and packaging can readily manage the already low risks of disease transmission during the course of product transport. While there is no detail provided on just what “special security arrangements” AQIS may impose in this regard, I hope and trust that these will be sensible and reasonable and not unnecessarily discriminate against businesses located in regional centres. The proposed wording of section 4.2 of the draft protocol serves, in my view, to exaggerate the risks associated with transport of product “outside urban areas”.

I trust these comments will receive your serious consideration.

***Response:*** *Noted. With regard to the security arrangements for transport, imported pig meat that is required to be processed will need to be transported directly from the nearest port of entry, and in the case of processors located in regional areas transport will be by refrigerated container or an equivalent secure means.*

## National Food Agency, Finland

### EXPORT OF PIG MEAT FROM FINLAND TO AUSTRALIA

Based on the Generic Import risk Analysis (IRA) for pig meat, Finland seeks approval to be recognised as an exporting country.

In addition, the following Finnish slaughterhouses and cutting plants would like to be approved as eligible to export pork to Australia.

No.	Name	Address
18	HK Ruokatalo Oy	Teollisuuskatu 17, 30420 Forssa
22	Atria Oy	P.O. Box 117, 60101 Seinäjoki
62	Oy Snellman Ab	Kuusisaarentie 1, 68600 Pietarsaari
73	Pouttu Oy	P.O. Box 4, 69101 Kannus
85	Koiviston Teurastamo Oy	P.O. Box 3, 32301 Mellila

**Response:** *Once the generic conditions are adopted, and an importer applies to AQIS for an import permit for pig meat from Finland, conditions specific to Finland's health status will be developed. This may involve an evaluation of veterinary services and plant inspection. Guidelines for the approval of countries to export animals (including fish) and their products are at Attachment 3.*

## REFERENCES

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- Sorden, S.D. (2000). Update on porcine circovirus and postweaning multisystemic wasting syndrome. *Swine Health and Production*, **8**, 133-36.
- Buddle, J.R., Muhling, J., Raye, W., Raidal, S.R. & Wilcox, G.E. (2003). Porcine circovirus in Australia. *Proceedings, Australian Association of Pig Veterinarians*, Cairns, pp 67-77.
- Ladekjaer-Mikkelsen, A.S., Nielsen, J., Stadejek, T., Storgaard, T., Krakowka, S., Ellis, J., McNeilly, F., Allan, G., & Botner, A. (2002). Reproduction of postweaning multisystemic wasting syndrome (PMWS) in immunostimulated and non-immunostimulated 3-week-old piglets experimentally infected with porcine circovirus type 2 (PCV2). *Veterinary Microbiology*, **89**, 97-114.
- Segales, J., & Domingo, M. (2002). Porcine circovirus type 2 infection: Postweaning multisystemic wasting syndrome and other conditions. *Proceedings of the 17<sup>th</sup> International pig Veterinary Society Congress*. Ames, Iowa, USA. **1**, 35-42.
- Lager, K.M., & Mengeling, W.L. (2000). PRRS: nature of the RNA virus and how it causes disease. *Proceedings of the 16<sup>th</sup> International pig Veterinary Society Congress*. Melbourne, Australia, pp 538-43.
- Larochelle, R., & Magar, R. (1997). Evaluation of the presence of porcine reproductive and respiratory syndrome virus in packaged meat using virus isolation and polymerase chain reaction (PCR) method. *Veterinary Microbiology*, **58**, 1-8.

## **Australian Pork Limited – Second Submission**

### **APL Response to the draft Import Risk Analysis Report for Pig Meat – Second Submission**

Australian Pork Limited (APL) wish to take the opportunity to comment, on behalf of the Australian pig producers, on the various stakeholder comments submitted to Biosecurity Australia (BA) regarding the draft Import Risk Analysis Report for Pig Meat.

One of the purposes of this document is to provide support to BA with answering claims made by other stakeholders. This submission also expresses concern with a number of assertions made in the Canadian correspondence.

APL wishes to emphasise that we continue to oppose the importation of uncooked pig meat from PMWS and/or PRRS affected countries. We believe these diseases pose a significant threat to the future viability of the Australian pork industry. 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 acknowledges and is appreciative of Biosecurity Australia's 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 is implemented.

I look forward to further advice from Biosecurity Australia on the progress of the issues.

## **Australian Pork Limited**

### **Generic Import Risk Analysis for Pig Meat, Draft Import Risk Analysis Report – Second Submission**

#### **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 (TCID50)**

APL notes that APHIS (p6) criticises the Tissue Culture Infected Dose (TCID50) 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  $<10^{1.8}$  to  $10^{5.3}$ . APHIS subsequently infers that doses greater than those established in the Lelystad study ( $<10^{1.8}$  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 L<sub>2</sub> (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>20</sup> for the past 3 years and also at Elizabeth Macarthur Agricultural Institute (EMAI)<sup>21</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.

<sup>20</sup> APL Project # 1538 & # 1824 - projects into porcine circovirus

<sup>21</sup> APL Project # 1840.

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>22</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>23</sup>.

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

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<sup>22</sup> Proceedings of 2003 Leman Conference; pg. 118)

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

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>24</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

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<sup>24</sup> John Deen, 'What's New with Circovirus?' [International Pigletter](#), October 20, Vol. 23, No. 8a

to the 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>25</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.

**Response:** *Biosecurity Australia appreciates APL's contribution to the IRA process. Biosecurity Australia strongly refutes APL's suggestion that a different Draft IRA Report or different information was provided to the Government of Canada. All stakeholders received the same information. The Panel wishes to draw APL's attention to page 62, Annex B of the Draft IRA Report. In commenting on APL's submission on the Draft Methods Paper regarding the Custom distribution the response states 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))".*

*With regard to the comment from APL that the Draft IRA fails to assess the rise of bioterrorism in light of the incident at Portland, Biosecurity Australia and the Panel are unable to see the relevance of this issue in relation to legal pig meat imports. In the case at Portland, ham was added to the feed of sheep intended for export to a Muslim country. APL's comments on bioterrorism have been forwarded to the area within the Department responsible for this matter. The Department is working closely with security agencies on the issue of food chain security. This cooperation is assisting in the clarification of threat levels and agents and the development of counter terrorism response capability. Since 11 September 2001, Australian border and security agencies (Australian Customs, AQIS and the Australian Federal Police) are aware of the potential risks of product entering Australia and have implemented enhanced measures.*

*The Panel has responded to individual points raised above in the relevant submission.*

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5 Australia – salmon case

## Principles of Zoning and Regionalisation

Article 1.3.5.1 of the Office International des Epizooties (OIE) Code (2002) describes zoning as a procedure implemented by a country to define geographical areas of different animal health status within its territory for the purpose of international trade (in accordance with relevant Chapters in the Code). Regionalisation refers to the application of this concept to a territory comprising more than one country.

Article 1.3.5.2 states that *'requirements necessary to preserve the special health status of a zone must be appropriate to the particular disease. The requirements will differ and size, location and delineation of a zone will depend on the epidemiology of the disease, environmental factors, and surveillance and control measures applicable. The extent of zones and their limits should be established by the Veterinary Administration on the basis of natural, artificial or legal boundaries and made public through official channels.'*

The relevance of each point depends on the epidemiology of the disease in the area in which zoning is applied:

- 1) Geographical or other delineation of the zone - including free zone to be separated by a surveillance or buffer zone or physical or geographical barriers
- 2) Quality of veterinary services administering the zone
- 3) Animal health legislation supporting the establishment and maintenance of the zone
- 4) Quality of disease reporting - including
  - a. notifiable
  - b. public awareness
  - c. records of investigation
  - d. trace forward
  - e. history of disease occurrence
- 5) Level of knowledge of the epidemiology of the disease within the country or region - including
  - a. stability of pathogen or vector systems within the country or region
- 6) Reliability of laboratory procedures - including
  - a. agent detection
  - b. sensitivity and specificity of tests
- 7) Level of surveillance (active/passive/herd or flock health programs) in the zone - including
  - a. early investigation of clinical disease
    - i investigation of the suspicion of *cases* of animal disease (in the free zone)
  - b. agent surveillance
    - i surveys for evidence of the agent
    - ii routine sampling on farms, markets and abattoirs
    - iii sentinel programs (animals and vectors)
    - iv banking of samples for retrospective surveys
    - v analysis of laboratory records
  - c. host population
    - i demographics

- ii movement patterns
    - iii interaction between domesticated and free-living animals
    - iv management factors
    - v animal identification systems
  - d. environmental factors
    - i air/water quality
    - ii topography
    - iii meteorology
    - iv vector distribution
    - v vector competence
    - vi data on feed, marketing and distribution, slaughter, pharmaceutical and other relevant industries
    - vii degree of uniformity of environmental factors
- 8) Disease controls present in the zone or buffer zone (such as vaccination)
- 9) Control of the entry of animals - including
  - a. entry point
  - b. import controls
    - i animals
    - ii genetic materials
    - iii animal products
    - iv fomites
    - v animal feeds including swill
    - vi biologics
    - vii border audit
- 10) Level of biological security - including
  - a. safety of vaccines used
  - b. Safety of therapeutics used
- 11) Safety of measures taken before export from the zone can occur
- 12) Quality of certification for export
- 13) OIE ratification (where applicable)

## Model of Existing Compliance Agreement for Canadian and Danish Pig Meat

# AQIS

AUSTRALIAN QUARANTINE AND INSPECTION SERVICE  
DEPARTMENT OF AGRICULTURE, FISHERIES AND FORESTRY

## SCHEDULE

Reference Number 7003

### THE PROCESSING OF IMPORTED UNCOOKED CANADIAN AND DANISH PIG MEAT.

#### 1. PURPOSE

- 1.1 To specify the scope, pre-requisites and requirements applying under this schedule for *the processing of imported uncooked pig meat from Canada and Denmark* at an AQIS Registered Pig Meat Processing Premises to prevent the introduction, establishment and spread of diseases or pests that will or could cause significant damage to human beings, animals, plants, other aspects of the Australian environment.

#### 2. SCOPE

- 2.1 The management and processing of imported uncooked Canadian and Danish pig meat product at an AQIS Registered Processing Premises approved for the purpose and under the direct control of the Other Party in accordance with the requirements of this Schedule and specific import permit conditions.
- 2.2 The storage of imported uncooked pig meat from Canada and Denmark for processing at the AQIS Registered Processing Premises covered by this Compliance Agreement.
- 2.3 The processing of imported uncooked Canadian and Danish pig meat product solely for human consumption.
- 2.4 The management and treatment of the waste material associated with the importation and processing of imported uncooked Canadian and Danish pig meat product.

#### 3. DEFINITIONS

- 3.1 In this Schedule:

**AQIS Registered Processing Premises -**

**AQIS Accredited Person** - Suitably trained/skilled/informed person authorised by give assurance that the processing of imported uncooked Canadian and Danish pig meat product has been undertaken in accordance with the requirements of the Schedule.

**Compliance Agreement** - as described in Section 66B of the *Quarantine Act 1908*.

**Disease** – includes a micro-organism, a disease agent, an infectious agent and a parasite.

**Import Permit** – The permission signed by the Director of Quarantine (or delegate) that authorises the import of a particular shipment of goods.

**Equipment** – any inanimate object which is within the AQIS Registered Processing Premises such as cages, trolleys, receptacles etc.

**Imported uncooked pig meat** – Unprocessed meat from Canadian or Danish pigs

**Other Party** – The non-commonwealth party to the agreement.

**Pest** – Includes any animal or any plant that is a pest.

**Pre-entry conditions** – The conditions that need to be satisfied before entry of a shipment of goods of a specific kind from a particular place can occur.

**Processing** – The cooking of imported uncooked pig meat for human consumption and treatment of any waste materials associated with the storage, preparation and cooking of imported pig meat.

**Quarantine Approved Premises (QAP)**– A place approved for goods of a specified class that are subject to quarantine and may be treated or otherwise dealt with in accordance with section 46A of the *Quarantine Act 1908*.

**Segregation** – the physical separation or isolation of imported uncooked pig meat product. Physical segregation maybe achieve using impervious barriers, - ie thawing tubs, shrink wrapping of unopened cartons or by physical separation where the minimum distance between products should be not less than 0.5 metres.

**Waste material** – any and all materials, including but not limited to: liquids, meat, spoiled pig meat product, packaging, and other material that have come into contact with imported uncooked pig meat product and are to be disposed of for any purpose other than human consumption.

#### **4. LEGISLATION APPLICABLE**

4.1 Quarantine Act 1908 and the Proclamations and Regulations made under the Act:

**Section 70B**

**Section 66B – Compliance Agreement**

***Quarantine Regulations 2000***

**Regulation 72 - Documentation and undertakings**

**Regulation 73 -Who may sign compliance agreements**

**Regulation 74 - Other provisions of compliance agreements not affected**

**Section 38**

**5. PREREQUISITES**

- 5.1 This Schedule is only valid if the following pre-requisites are met by the Other Party:
- 5.1.1 The Other Party is registered as an AQIS Registered Processing Premises for the purposes of processing of imported uncooked Canadian and Danish pig meat product.
  - 5.1.2 The Other Party will ensure that during processing that the imported uncooked Canadian and Danish pig meat products is cooked to a minimum of 56°C, core temperature, for 60 minutes or equivalent.
  - 5.1.3 The cold storage used by the Other Party for the storage of imported uncooked Canadian and Danish pig meat product is approved by AQIS as a Quarantine Approved Premises – Class 2.5.
  - 5.1.4 That prior to the transfer of any imported uncooked Canadian and Danish pig meat product either too or from the AQIS Registered Processing Premises subject to this Schedule that the Other Party notify AQIS and obtain a Quarantine Movement Order.

**6. REQUIREMENTS**

- 6.1 The following mandatory requirements will be complied with by the Other Party under this Schedule to the Compliance Agreement.
- 6.1.1 The Other Party will ensure that all imported uncooked Canadian and Danish pig meat product stored at the AQIS Registered Processing Premises is stored in a secure manner so as to maintain the product integrity and traceability throughout the processing process.
  - 6.1.2 The Other Party will maintain an inventory of all imported uncooked Canadian and Danish pig meat product stored at the AQIS Registered Processing Premises.
  - 6.1.3 The Other Party will ensure that all waste materials associated with processing imported uncooked Canadian and Danish pig meat product are securely contained with in the AQIS Registered Processing Premises prior to treatment.
  - 6.1.4 The disposal of liquid waste materials may be direct to the municipal sewage system where such systems are directly linked to a sewage treatment works. No liquid waste will be discharge to external settling, recycling or effluent ponds.
  - 6.1.5 The Other Party will maintain and regularly calibrate all equipment associated with the processing of uncooked imported Canadian and Danish pig meat product in accordance with limits specified in the Process Management System.

- 6.1.6 The Other Party will ensure that any product that comes in direct contact with imported uncooked Canadian or Danish pig meat is processed in accordance with the requirements for imported uncooked pig meat.
- 6.1.7 The Other Party will maintain an appropriate segregation and hygiene regime to prevent the cross contamination of domestic product with imported uncooked Canadian and Danish pig meat product.
- 6.1.8 Where the Other Party simultaneously processes both imported uncooked pig meat and domestic pig meat product all product and associated waste materials will be treated in accordance with the requirements of Schedule as imported pig meat product.

## 6.2 Outcomes

- 6.2.1 That through the management and processing of imported uncooked Canadian and Danish pig meat product in accordance with the Schedule - *the processing of imported uncooked pig meat from Canada and Denmark* to the Compliance Agreement will prevent the potential introduction of exotic disease to Australia.

## 6.3 Compliance with Operational Procedure Statements (OPS)

- 6.3.1 The Other Party is required to implement and operate the system of procedures described in the Operational Procedures Statements relating to this Schedule (as listed in the Table of Schedules) to ensure that the outcomes specified above are achieved.

## 6.4 Specific critical procedural requirements

- 6.4.1 That the Other Party ensures that all waste materials, either liquid or solid, are disposed of either through the municipal sewage system or through an AQIS approved licensed commercial waste contractor.
- 6.4.2 All untreated solid waste materials, including spoiled product and packaging associated with the processing of imported uncooked Canadian and Danish pig meat product are to be disposed of through an AQIS approved licensed commercial waste contractor in a manner approved by AQIS.

The Other Party will ensure that the AQIS approved licensed commercial waste contractor takes all such waste to the AQIS approved waste treatment facility.

Waste materials will not be either sold or recycled for any other purpose unless specifically approved by AQIS.

## 6.5 Record keeping

- 6.5.1 The Other party is required to ensure that the following categories of records and documents, relating to the procedures for goods covered by this Schedule, are maintained and kept up to date:
  - Operational Procedures Statements relating to this Schedule (as listed in the Table of Schedules)

- Inventory storage records
- Release of cooked produce records
- Cooking records
- Equipment calibration records
- Quarantine movement records
- Import permit

6.5.2 The Other Party is required to ensure that the following categories of records and documents, relating to supervising, monitoring and testing compliance with the procedures for goods covered by the Schedule, are maintained and kept up to date.

- Oven electronic thermographic printouts
- NATA accredited reference thermometer calibration records
- Oven calibration records

6.5.3 The Other Party is required to keep records and documents mentioned in sub-paragraphs 6.5.1 and 6.5.2 at the Quarantine Approved Premises where procedures authorised by this Schedule are conducted. These records and documents will be made available on request by AQIS for the purpose of the audit.

6.6 Examinations or services conducted by the Commonwealth for which a fee will be charged

(i) The Other Party acknowledges that failure to maintain either the integrity of the AQIS Registered Processing Premises or processing of imported uncooked pig Canadian and Danish pig meat product and associated waste materials may compromise the quarantine integrity of Australia and therefore an auditing system is necessary to monitor performance. Should a non-conformity occur, a compliance system is necessary to ensure additional action is taken to monitor performance, assist the Other Party to address matters of quarantine concern and establish compliance.

(ii) The Other Party acknowledges that this Schedule entails the conduct by the Commonwealth of examinations or services for which fees are chargeable under section 86E of the Act:

- (a) Standard documentary reviews, random documentary reviews and compliance audits (For guidance refer to OPS - Audit Policy)
- (b) Reviews in response to non conformities (For guidance refer to *OPS Compliance Policy*)

*Note:* The inclusion of the above requirements in relation to record keeping and examinations or services satisfy regulation 72(1) of the *Quarantine Regulations 2000*.

## **7. PERSON AUTHORISED TO GIVE CERTIFICATION OR ASSURANCE**

7.1 The AQIS Accredited Person will at the completion of each cooking process review the cooking records for the processed imported Canadian or Danish pig

meat product to verify that the cooking process has been met the minimum criteria of the Schedules, and sign and date, the cooking records, including oven records.

**8. REVIEW DATE**

8.1 This Schedule is valid, subject to all other requirements and pre-requisites being satisfied on an ongoing basis by the Other Party for a period of 18 months from its publication date, 31 March 2003.

8.2 Prior to this time AQIS in accordance with the AQIS Review Policy may either amend or require the Other Party to amend or require the Other Party to amend the Operational Procedures Statements to meet either additional or amended AQIS requirements.

**9 EXECUTION.**

Note: "Giving false or misleading information is a serious offence"

I am a director, manager, or senior executive of ----- ('the Other Party') who:

- a) has responsibility for the business operations of the Other Party; and
- b) is authorised to enter into contracts for the Other Party.

SIGNED for and on behalf of	)	.....	)
<i>Company Name and Address</i>	)	<i>Signature</i>	)
ACN	)		)
on:	)	.....	)
	)	<i>Name of signatory</i>	)
.....	)		)
<i>Date</i>	)	.....	)
by:	)	<i>Position of signatory</i>	)
	)		)

## TABLE OF SCHEDULES

Company (Address)	Schedule	Operational Procedures Statements
Parent company address covered by the CA.  Schedules approved for the parent company site to be listed opposite  AQIS Company CA ref No Q/ ABN No /1/1 for parent company	<b>Schedule title:</b> <i>the processing of imported uncooked Canadian and Danish pig meat</i> <b>Schedule ref:</b> 7003 <b>Start date:</b> 1/01/03 <b>Review date:</b> 1/7/05	<b>OPS title:</b> <i>Process Management System for the processing of imported uncooked Canadian and Danish pig meat</i> <b>OPS ref:</b> 7003 <b>Start date:</b> 31/03/03
		<b>OPS title:</b> Audit Policy <b>OPS ref:</b> 7003 <b>Start date:</b> 31/03/03
		<b>OPS title:</b> Compliance Policy <b>OPS ref:</b> 7003 <b>Start date:</b> 31/03/03
		<b>OPS title:</b> Appeals Policy <b>OPS ref:</b> 7003 <b>Start date:</b> 31/03/03
		<b>OPS title:</b> Review Policy <b>OPS ref:</b> 7003 <b>Start date:</b> 31/03/03



# PROCESS MANAGEMENT SYSTEM

to the

Schedule

For

## **THE PROCESSING OF IMPORTED, UNCOOKED CANADIAN AND DANISH PIG MEAT.**

OPS Ref. No: 7003

**1. MANAGEMENT RESPONSIBILITIES**

1.1. I \_\_\_\_\_  
\_\_\_\_\_ being the Manager of \* \_\_\_\_\_  
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hereby declare that I understand that in agreeing to meet the requirements set out in the Process Management System, *The processing of imported uncooked Canadian and Danish pig meat* and associated Australian Quarantine and Inspection Service (AQIS) policies, that this in no way diminishes my responsibilities and obligations under the *Quarantine Act 1908*.

Signed \_\_\_\_\_ Date \_\_\_\_\_

**2 COMPANY ORGANISATION**

**Duty Statements**

The following positions must be identified under this agreement with persons occupying these positions identified on the **Company Organisation Chart** (Appendix 1)

- 2.1 The \* \_\_\_\_\_ is responsible for ensuring the implementation and compliance with the requirements of the Schedule and associated Operation Procedures Statements.
- 2.2 The \* \_\_\_\_\_ will ensure that all persons undertaking activities directly relating to the Process Management System (herein named) are appropriately trained and aware of their responsibilities.
- 2.3 The \* \_\_\_\_\_ will ensure that all day to day duties and activities are performed and recorded in accordance with the requirements of the Process Management System.
- 2.4 The \* \_\_\_\_\_ will ensure that all imported pig meat product is clearly identified and stored in a secure manner in accordance with Appendix 2 prior to processing.
- 2.5 The \* \_\_\_\_\_ will ensure that they transport all imported pig meat under a quarantine direction between premises, and that it is

palletised, shrinkwrapped (if no longer in its original container), identified as subject to quarantine and clearly labelled with an AQIS contact officer in case of accident.

- 2.6 The \* \_\_\_\_\_ will ensure that records documenting stock control, processing and waste disposal for imported pig meat product are maintained
- 2.7 The \* \_\_\_\_\_ will ensure that all waste associated with the processing of imported pig meat product is disposed of in accordance with procedures described in Appendix 3.
- 2.8 The \* \_\_\_\_\_ will ensure that all equipment associated with the processing of imported pig meat will be regularly maintained and calibrated in accordance with procedures described in Appendix 4.

### **3 PRODUCT STORAGE and IDENTIFICATION**

- 3.1 The \_\_\_\_\_ will ensure that imported pig meat product is clearly identified and stored separately from processed pig meat product, domestic or product for export, Appendix 2
- 3.2 Imported pig meat must be identified at all stages from receipt to successful completion of heat treatment, and must enable traceability back to its original container number.
- 3.3 The \* \_\_\_\_\_ will treat all domestic pig meat that comes into contact with imported product as imported and will process it in accordance to the imported pig meat requirements.

### **4 WASTE MANAGEMENT**

- 4.1 The \* \_\_\_\_\_ will document procedures detailing how waste from the processing of imported pig meat product, spoiled product and associated packaging will be identified and disposed of, Appendix 3.
- 4.2 Waste associated with imported pig meat product will only be disposed of in accordance with the procedure(s) approved by AQIS.

### **5 TRANSPORT**

- 5.3 The \* \_\_\_\_\_ will ensure that imported pig meat moved by or on behalf of the Company between premises shall at all times be palletised, shrinkwrapped, identified as subject to quarantine, and an AQIS regional contact number clearly marked on the Goods.
- 5.4 The \* \_\_\_\_\_ shall notify AQIS if imported pig meat does not arrive in either the container it was exported in (seals intact), arrives in quantities other than those stipulated in the associated movement direction, or under the conditions stipulated in 5.1.
- 5.5 The \* \_\_\_\_\_ will obtain a quarantine movement direction 24 hours prior to transporting pig meat.

## **6 DOCUMENTATION AND RECORD KEEPING**

- 6.1 The \* \_\_\_\_\_ will ensure that all documents (including any amended documents) relating to the importation, storage, quarantine movement, heat treatment, release and quality assurance of imported pig meat product are maintained for a minimum of 12 months after heat treatment.

NOTE: Where original documents are not available for commercial reasons, a photocopy of the document will be kept. Records will be provided to AQIS on request at audit.

- 6.2 Records shall be specifically identifying:

- ❖ Stock control – amount received, amounts processed, stock on hand, and import permit number.
- ❖ Waste disposal – (As identified by Company, Appendix 3)

## **7 HEAT TREATMENT**

- 7.1 All imported pig meat shall be cooked to minimum core temperatures and times as specified in Item 7.2

core temperature of 56° for 60 minutes  
core temperature of 57°C for 55 minutes  
core temperature of 58°C for 50 minutes  
core temperature of 59°C for 45 minutes  
core temperature of 60°C for 40 minutes  
core temperature of 61°C for 35 minutes  
core temperature of 62°C for 30 minutes  
core temperature of 63°C for 25 minutes  
core temperature of 64°C for 22 minutes  
core temperature of 65°C for 20 minutes  
core temperature of 66°C for 17 minutes  
core temperature of 67°C for 15 minutes  
core temperature of 68°C for 13 minutes  
core temperature of 69°C for 12 minutes  
core temperature of 70°C for 11 minutes

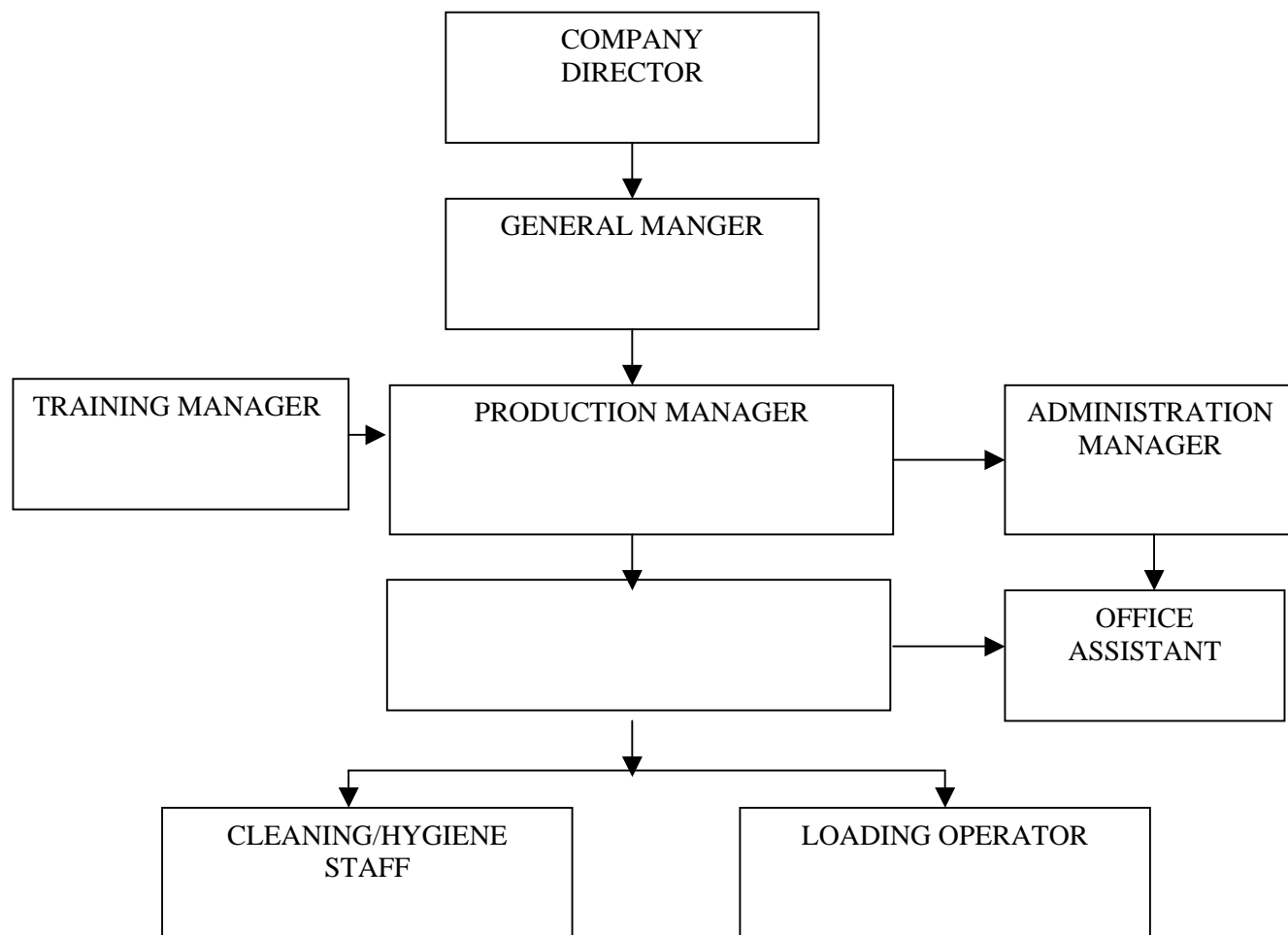
- 7.2 Cooking sheets shall be completed and kept for the Goods (both whole cuts and trimmings). The cooking sheets shall be clearly identified as being for use when cooking imported pig meat, and must include the cooking date, type of product, cooking temperature and time, and a product identification code.
- 7.3 The cooking process shall be monitored to ensure that the core times and temperatures required by Item 7.2 are met with every batch. The cooking process shall be monitored by electronic monitoring/ recording equipment.
- 7.4 After each imported pig meat run, all equipment will be washed with hot soapy water.

## **8 TRAINING**

- 8.1 All staff handling imported pig meat shall be trained to a level necessary to understand and comply with the PMS.
- 8.2 The Company shall maintain a training program which shall include the following types of training for staff involved in the processing of imported pig meat:
  - 8.2.1 Prompt induction training to ensure understanding and compliance with this Manual of Operations;
  - 8.2.2 Prompt induction training for new staff.
  - 8.2.3 Key personnel as identified in the PMS are conversant with the PMS, Quarantine awareness and conditions associated with imported pig meat

APPENDIX 1

COMPANY ORGANISATION CHART



*NOTE: Company orgainisation chart should identify all positions named in the text of the process management system and name persons responsible for that positions duties.*

*NOTE: Persons may hold more than one position, but in all cases a trained backup person should be named.*

**PRODUCT STORAGE AND IDENTIFICATION**

*NOTE: Company to describe how product will be identified, where it will be stored, and by what means it will be separated from other product to maintain its integrity.*

### APPENDIX 3

#### WASTE MANAGEMENT

*NOTE: The Company will describe how waste disposal is to be controlled and managed for the three types of waste products. (Liquid waste, meat scraps or spoiled meat, packaging)*

*Specific details will be provided in relation to*

- ❖ Management of wastewater, wash down and water associated with thawing, washing or processing of pig meat product,*
- ❖ collection and storage of waste product and associated packaging, and*
- ❖ the collection and disposal of waste.*

*In relation to the collection and disposal of waste the Company will identify the either Contractor or means by which waste is to be disposed of.*

**MAINTENANCE AND CALIBRATION**

*NOTE: The Company will describe and document how they maintain and calibrate all equipment associated with the processing of imported pig meat.*

*Specific details will be provided in relation to*

- *the frequency of internal calibrations at a minimum of once every two weeks.*  
*NOTE: A NATA accredited mercury-in-glass reference thermometer must be used to calibrate hand held thermometers.*
- *the external institution used for calibrating the reference thermometer and cooking equipment. Records of external maintenance must be kept.*

## Guidelines for the Approval of Countries

11 June 1999

### **ANIMAL QUARANTINE POLICY MEMORANDUM 1999/41**

Chief Veterinary Officers, all States and the NT	CSIRO Division of Animal Health
Animal Programs Section, AQIS Operations	National Farmers' Federation
Office of the Australian CVO	Quarantine and Animal Health Task Force, NFF
Animal and Plant Health Branch, NOAPH	Australian Animal Health Council
Veterinary Counsellors, Washington, Brussels & Seoul	Australian Veterinary Association
Agricultural Counsellor, Tokyo	Australian Livestock Exporters' Council
Australian Dairy Industry Council	National Meat Association of Australia
Meat and Livestock Association	Australian Registered Cattle Breeders' Association
Australian Alpaca Association	Australian Poultry Industries' Association
Australian Dairy Industry Council	Australian Registered Cattle Breeders' Association
Australian Egg Industry Association	Deer Industry Association of Australia
Australian Horse Council	National Poultry Association
Australian Ostrich Association	Pork Council of Australia
Australian Trout and Salmon Farmers Association	Fisheries and Aquaculture Branch, AFFA
Tasmanian Salmonid Growers Association Ltd	Fisheries Research & Development Corporation
Australian Seafood Importers Association	Fishing Industry Advisory Committee
Australian Fisheries Management Authority	Australian Recreational & Sport Fishing Confederation
Division of Marine Research, CSIRO	Aquaculture CRC Limited
Australian Seafood Industry Council	Australian Prawn Farmer's Association
Australian Institute of Marine Science	Australian Aquaculture Forum
ACIAR Fisheries Coordinator	Food and Beverage Importers Council
PIJAC	WA Fishing Industry Council
Tuna Boat Owners Association	Health and Environment Committee
Standing Committee on Fisheries & Aquaculture	Aquatic Animal Disease Experts
Aquaculture Committee	Scientific and Research Organisations
Wildlife Australia, Environment Australia	Fishing, Industry and Community Organisations
Wildlife Protection Section, Environment Australia	 
Chief Veterinary Officer, MAF RA, NZ	EU Delegation, Canberra

### **GUIDELINES FOR THE APPROVAL OF COUNTRIES TO EXPORT ANIMALS (INCLUDING FISH) AND THEIR PRODUCTS TO AUSTRALIA.**

#### 1. INTRODUCTION

Where generic conditions for the importation of animals or animal products are developed as a result of a generic risk analysis, it will generally be appropriate to specify as part of the conditions that permits will only be issued for importations from countries that have been specifically approved by AQIS. Approval would normally be based on an assessment of the ability of the certifying authority of the country to provide informed and reliable certification that Australia's quarantine requirements have been met. The 'approved country' approach provides a mechanism for rapid introduction of new controls on importations from a particular country in the event of a change in the animal health status of that country or where AQIS detects breaches of quarantine requirements, such as fraudulent certification.

AQIS takes into account the following criteria when considering the approval of countries to export animals/products to Australia:

- . the effectiveness of veterinary services and other relevant certifying authorities,
- . the animal health status of the country,
- . legislative controls over animal health, including quarantine policies and practices,
- . the standard of reporting to the Office International des Epizooties (OIE) of major contagious disease outbreaks,
- . effectiveness of veterinary laboratory services, including compliance with relevant international standards,
- . effectiveness of systems for control over certification/documentation of products intended for export to Australia.

The import conditions will identify the key risk management issues that should be considered in the approval of countries.

This paper provides a framework, based on guidelines as specified in section 1.4.3 of the OIE International Health Code for the assessment of a country for approval to export to Australia. Although some countries may be able to provide quantitative data, in most cases AQIS's assessment will be based on qualitative information.

Where import requirements include pre-export processing as part of the risk management measures, AQIS may restrict the issue of permits to product prepared in plants that have been formally approved by the exporting country authority and/or AQIS. Guidelines for the approval of plants for the processing of animal products for export to Australia are also included in this paper.

These guidelines refer to terrestrial, aquatic and avian species and their products.

## 2. CRITERIA FOR THE APPROVAL OF EXPORTING COUNTRIES

AQIS considers that exporting countries are responsible for the sanitary standard of goods exported to Australia. Where product is sourced in one country and exported from another, AQIS holds the exporting country responsible for the health certification that accompanies those goods. In this context, it is the exporting country and its official certifying authority that must be approved.

In some exporting countries, AQIS may assess several competent authorities, including the relevant authority for animal health, fish health and human health. These authorities may operate at a Federal, State or provincial level.

### 2.1 Countries with an established export trade in animals/products to Australia.

This section deals with countries that regularly export to Australia items such as live animals, genetic material and animal products in commercial volume. It does not include countries that export items such as laboratory specimens, artefacts and samples for evaluation, ie non-commercial exports or countries that export products that are exempt from quarantine control.

AQIS would normally approve without formal assessment those countries that have a history of exporting animals/products in compliance with Australia's sanitary requirements. All approvals remain under review and can be suspended on an emergency basis at any time. Such action may be taken, for example, if AQIS were to detect serious non-compliance, such as the provision of false certification by a regulatory authority.

AQIS monitors the performance of approved countries in reporting OIE listed diseases, and notifying Australia of changes in disease status, including any incursions of disease that might affect bilateral trade in animals/products. On the basis of formal bilateral agreement, exporting countries may undertake to directly notify Australia of changes in status for diseases other than those listed by the OIE.

AQIS will monitor the performance of approved countries via routine collection of intelligence on disease, including from scientific literature and internet postings, through the conduct of visits and inspections and by liaison with other veterinary authorities (including chief veterinary officers of Australian states/territories). If AQIS becomes aware that unreported serious disease is present in the country of export, approval may be suspended pending clarification of the situation.

## **2.2 Countries with no established export trade in animals/ products to Australia**

AQIS's formal assessment of a country for approval to export to Australia, may include:

- . examination of information supplied by the country,
- . consideration of the results of an assessment by Australia's major trading partners to the country as an exporter of like commodities (such assessment will take into account the extent to which the regulatory requirements of trading partners are consistent with those of Australia)
- . formal evaluation of the country's veterinary services and/or certifying authority (this may involve country visits by AQIS or AQIS authorised officers).

### **a) An effective veterinary/fish health service**

An approved country should have national veterinary and fish health authorities, which are responsible for animal health, quarantine, export certification and international reporting of the country's animal disease status.

- . Where non-government veterinarians provide export services, they should be Official Veterinarians as defined in the OIE Code. The national veterinary authority must be responsible for the overall system of control of the export-related activities of private veterinarians, including arrangements for training, auditing and compliance.
- . The performance of the certifying authority should be subject to independent audit and a satisfactory level of competency must be maintained.

### **b) Animal health status of the country of origin/export**

The country should be free from or have effective zoning of diseases as appropriate to AQIS's quarantine requirements. This should be supported by legislative controls such as mandatory notification of disease outbreaks and official control programs.

### **c) Quarantine measures**

AQIS will consider the disease status of neighbouring countries and the effectiveness of border measures and buffer zones in preventing disease incursions in assessing countries for approval to export to Australia.

### **d) Animal health controls**

An approved country should be able to demonstrate mechanisms for official notification and control or eradication of diseases identified in the import risk analysis as important in relation to the animal species/product in question. Animal health controls should include arrangements for animal health surveillance, regulatory controls for specified diseases and a formal system of response to animal disease events. AQIS will take into account the country's policies with respect to outbreaks of diseases of concern.

Border controls should be effective in preventing the entry and establishment of significant exotic disease agents relevant to the animal species/product in question.

There should be legislative provisions covering movement controls and inspection procedures in relation to the prevention, control and eradication of disease.

e) Performance in reporting disease

AQIS will take into account the performance of approved countries in reporting OIE listed diseases and significant new or emerging diseases and of notification to Australia of incursions of disease relevant to the bilateral trade in animals/products. If AQIS becomes aware that serious disease is present, unreported, in the country of export, the country's approved status may be suspended, pending clarification, or withdrawn.

f) Access to laboratories that can conduct recognised diagnostic tests to an international standard of competence.

It is accepted that not all countries are able to perform all the necessary tests to definitively diagnose all diseases. Countries should, however, have access to laboratories that meet the OIE Standard for the diagnosis of diseases that AQIS identifies (in an import risk analysis) as being of concern. They should also have competence in the collection, preservation and transport of specimens to these laboratories.

g) Appropriate arrangements for certification/documentation.

Countries should be able to demonstrate:

- . legislative controls over the process of export of animals and animal products, to provide for enforcement of Australia's import requirements. This includes supervision by the official veterinary (or other competent) authority of the export certification process;
- . legislative arrangements that provide for the approval/registration of export premises and provide powers to deny or withdraw registration for premises or certification for commodities as the case may be;
- . arrangements to ensure that certifying officers performing official duties have no conflict of interest;
- . a system of control that provides for reliable correlation of the results of inspections with the documentation provided for export consignments and
- . a system of audit and review of official and private certifying procedures.

### 3. CRITERIA FOR APPROVAL OF EXPORTING FACILITIES

Where there is an appropriate Australian standard (for example, relating to inspection requirements) the exporting country would be expected to follow a standard that would provide an equivalent outcome to that provided by the Australian standard.

Where the certifying and/or veterinary services in the exporting country have previously been assessed and approved, AQIS will normally base approval of processing plants on advice from the certifying authority that the plant meets AQIS's requirements.

In cases where the certifying authority in the exporting country has not previously been assessed, AQIS may conduct an on-site assessment of a plant.

The processing plant will normally be required to demonstrate, as appropriate:

- . suitable separation of raw and processed product;
- . reliable compliance with minimum processing requirements for the product;
- . auditable records of information required by AQIS, for example on the source of raw materials and ingredients, processing records and test results;
- . controls to prevent post-processing contamination; and
- . standards of hygienic construction and operation that provide equivalent public health safeguards to those provided by relevant Australian standards.

## CONSULTATION

The Chief Veterinary Officer of State/Territory Departments of Agriculture in Australia, the Commonwealth Chief Veterinary Officer and his counterparts in New Zealand, Canada and the United States of America have been consulted in the preparation of this Memorandum. Comment should be provided to the contact officer whose details appear below by 9 July 1999.

### Confidentiality

Respondents are advised that, subject to the *Freedom of Information Act 1982* and the *Privacy Act 1982*, all submissions received in response to Animal Quarantine Policy Memoranda will be publicly available and may be listed or referred to in any papers or reports prepared on the subject matter of the Memoranda.

The Commonwealth reserves the right to reveal the identity of a respondent unless a request for anonymity accompanies the submission. Where a request for anonymity does not accompany the submission the respondent will be taken to have consented to the disclosure of his or her identity for the purposes of Information Privacy Principle 11 of the Privacy Act.

The contents of the submission will not be treated as confidential unless they are marked 'confidential' and they are capable of being classified as such in accordance with the Freedom of Information Act.

DAVID BANKS

A/g Assistant Director

Animal Quarantine Policy Branch

Contact Officer: Warren Vant

Telephone no: 02 6272 4436

Facsimile no: 02 6272 3399

E-mail: [warren.vant@aqis.gov.au](mailto:warren.vant@aqis.gov.au)

Summary of disease agents identified as hazards in uncooked pig meat if infection occurred and potential effects on native Australian wildlife species

Disease/disease agent	Hosts susceptible to infection	Possible clinical effects in native wildlife if infection occurred
Foot-and-mouth disease virus	Cloven-footed animals; infection but not disease reported in native species including kangaroos, wombats and carnivores.	None. Wildlife species not considered to be of epidemiological significance for FMD.
Vesicular stomatitis virus (*)	Clinically affects horses, cattle and pigs; serological evidence in vertebrates including marsupials, reptiles, fish and birds.	Clinical signs unlikely in native species.
African swine fever virus	Pigs only.	
Classical swine fever virus	Pigs only.	
Rinderpest virus	Primarily cattle and buffaloes; reported in pigs, African wild game; not known to affect native wildlife species.	
Swine vesicular disease virus	Pigs; virus isolated from other species but no reports of clinical disease; not known to affect native wildlife species.	
Aujeszky's disease virus	Pigs; reported in other animals including carnivores and therefore potentially native carnivorous wildlife species could be infected.	In dingoes the disease is likely to be fatal. Overseas only sporadic cases occur in carnivores.
Rabies virus (*)	Non specific; most common in carnivores and insectivorous bats.	Dingoes may develop clinical signs similar to dogs; bats occasionally show clinical signs but unlikely to be infected via this route.
Bovine tuberculosis ( <i>Mycobacterium bovis</i> )	Non specific; all mammals; no evidence of infection in wildlife prior to eradication.	None likely. Did not establish in native animals when present previously in Australia.
Haemorrhagic septicaemia ( <i>Pasteurella multocida</i> )	Primarily cattle and buffaloes; unlikely to affect native wildlife species.	
Japanese encephalitis virus (*)	Non specific; native carnivores, birds and reptiles, macropods and possums may be susceptible to infection.	None. Experimental viraemias occur in macropods and possums.
Surra ( <i>Trypanosoma evansi</i> )	Mammals; camels, horses and dogs most severely affected; wallabies infected experimentally.	Mortalities in dingoes and wallabies might be expected.
Venezuelan, Eastern and Western equine encephalomyelitis viruses (*)	Maintained in wild birds; horses, domestic and wildlife species may be infected; oral infection of scavenging birds has not been demonstrated.	Mortalities in emus might be expected with EEE virus and possibly with WEE virus.

Disease/disease agent	Hosts susceptible to infection	Possible clinical effects in native wildlife if infection occurred
Enterovirus encephalomyelitis / Teschen disease	Pigs only.	
Porcine brucellosis ( <i>Brucella suis</i> )	Primarily pigs; reports in dogs, horses and cattle; unlikely to affect native species, possibly dingoes but not reported where infected feral pigs are present.	Acute infection in dingoes may cause abortions; clinical signs unlikely in other native species.
Porcine reproductive and respiratory syndrome virus	Pigs only.	
Transmissible gastroenteritis virus	Pigs; dogs, cats and foxes shed virus but no clinical signs nor evidence they act as carriers or reservoir hosts; not known to affect native wildlife species.	
Trichinellosis ( <i>Trichinella spiralis</i> )	All mammals; particularly omnivores and carnivores and therefore potentially includes native wildlife species.	Clinical signs would be unlikely in infected dingoes or crocodiles.
Cysticercosis ( <i>Cysticercus cellulosae</i> )	Pigs are intermediate host; humans are definitive host; no native animal species likely to be suitable definitive hosts.	
Nipah virus	<i>Pteropus</i> species of bats; pigs, dogs, cats, horse and humans are susceptible; native fruit bats are unlikely to be infected from pigs.	Some infected dingoes could show severe clinical signs, resulting in death; clinical signs unlikely in native fruit bats.
Porcine epidemic diarrhoea virus	Pigs only.	
Porcine respiratory coronavirus	Pigs only.	
Post-weaning multi-systemic wasting syndrome (porcine circovirus type 2)	Pigs only.	
Rubula virus	Pigs only.	
Salmonellosis ( <i>Salmonella typhimurium</i> DT 104)	Non specific.	Probably mild or subclinical in native animals.
Swine influenza virus (*)	Pigs, humans, poultry, waterfowl.	No clinical signs likely in native waterfowl.

(\*) = Unlikely to be transmitted via the ingestion of meat.