



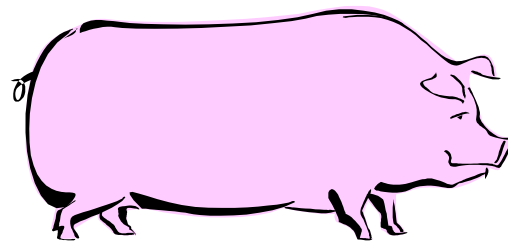
Australian Government

Department of Agriculture, Fisheries and Forestry

Generic Import Risk Analysis (IRA) for Pig Meat

Draft Import Risk Analysis Report

Annexes



August 2003

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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 4-13⁰ 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 dendrytes.

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

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1) SUMMARY

This document addresses the AFFA Issues Paper for the Import Risk Analysis of Pigmeat (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 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. Current events internationally are highlighting the importance of swill feeding and livestock movement as risk management issues. Transmission of disease from pigmeat 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 pigmeat entering Australia, and the volume of pigmeat 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 Pigmeat, released by Agriculture, Fisheries and Forestry Australia (AFFA) on January 8th, 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 pigmeat 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 pigmeat, and a Risk Analysis Panel was established.

b) Pigmeat as a commodity

For the purposes of the IRA, pigmeat 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 carcase 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

<u>Affecting humans</u>	<u>Affecting animals</u>
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
	TGE
	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

<u>Affecting humans</u>	<u>Affecting animals</u>
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 1st.

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 TCID₅₀/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 meat².

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

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

3. 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.

4. 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.
5. 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.

6. 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, 31st 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, 8th 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, 6th 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, 8th 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 3rd 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.

1

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 12th 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 Piguheat**

7 January 2003

Australian Pork Limited

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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 2nd criterion by reference to Evans' postulates, and in the 3rd 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,¹ 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

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

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.

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 50th 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 8th 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 19th 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

² 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.

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.

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 mathematic 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).³

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)

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

³ 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.

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.⁴

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.

Comment on consequence assessment & risk estimation

⁴ 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.

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 95th 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 50th 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	I Gussed at the Extreme Category
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	

(3) Product of Likelihood and Consequences

- based on multiplying Maximum (upper bound) of ranges and then translated back to categories

Likelihood	<u>High</u>	E. low	Very low	Low	Moderate	High	Extreme	Extreme
	<u>Moderate</u>	Negligible	E. low	Very low	Low	Moderate	Moderate	High
	<u>Low</u>	Negligible	E. low	Very low	Low	Low	Low	Moderate
	<u>Very low</u>	Negligible	E. low	Very low	Very low	Very low	Very low	Low
	<u>Extremely low</u>	Negligible	E. low	E. low	E. low	E. low	E. low	Very low
	<u>Negligible</u>	Negligible	Negligible	Negligible	Negligible	Negligible	Negligible	E. low
		<u>Negligible</u>	<u>Extremely low</u>	<u>Very low</u>	<u>Low</u>	<u>Moderate</u>	<u>High</u>	<u>Extreme</u>

Consequences

Notes

Extremely low category is removed from consequences

Upper bound for High category is 1 for Likelihood

Upper bound for High category is NOT 1 but say .9 (guess) for Consequences

Shading indicates same result as Table 8 & 9

This indicates that Table 8 and 9 are not simply the product of Likelihood & Consequences

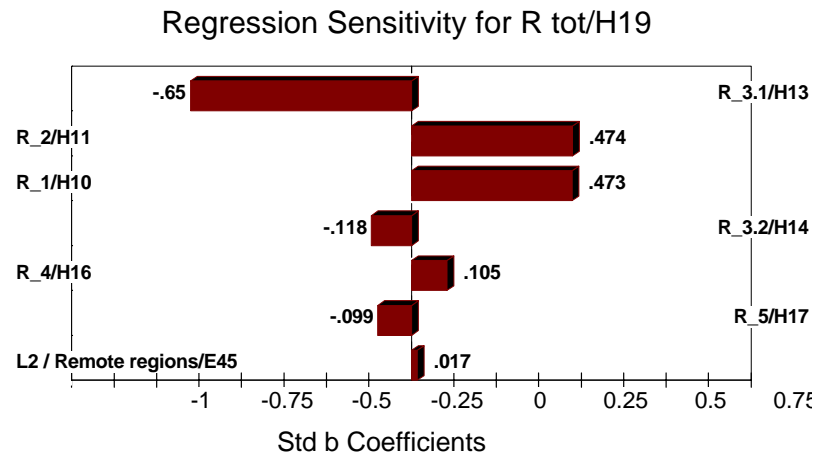


Figure 1. Sensitivity of risk estimate to input variables.
Tornado Graph

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).

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.

Disease/disease agent	Hosts susceptible to infection	Possible clinical effects in native wildlife if infection occurred
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.
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.	

Disease/disease agent	Hosts susceptible to infection	Possible clinical effects in native wildlife if infection occurred
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.