Assessment of the risk that Porcine Reproductive and Respiratory Syndrome Virus may enter Australia due to import of fresh Danish bone-in hams

DANISH BACON & MEAT COUNCIL
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Contents

Preface

In January 2001, the Australian authorities released a hazard identification entitled "Generic Import Risk Analysis for Uncooked Pig Meat". According to the report it is envisaged to carry out a risk assessment for each hazard identified. Since The Danish Bacon & Meat Council (DBMC) is interested in exporting fresh pork to Australia, DBMC decided to undertake a risk assessment of the risk that Porcine Reproductive and Respiratory Syndrome Virus may enter Australia due to import of fresh Danish pork bone-in. In February 2001, a task group was appointed to carry out the risk assessment, which was finalised in June 2003.

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1. Summary

Australia is concerned that Porcine Reproductive and Respiratory Syndrome (PRRS) Virus might enter Australia due to import of fresh pork from countries like Denmark, where PRRS is endemic. At present, import of pork from Denmark into Australia is permitted, only if the pork is deboned and destined for processing at an approved Australian processing facility. Here, the pork is heat-treated until it reaches a core temperature of 56°C for a minimum of 60 minutes or an equivalent combination of time and temperature.

The Danish Bacon & Meat Council wishes to export bone-in hams with subsequent heat treatment in Australia if a risk assessment shows that the risk is below the acceptable risk level. Therefore, DBMC undertook a risk assessment to estimate the risk of introducing PRRS Virus into Australia due to import of this commodity.

The assessment is qualitative and carried out according to present international standards for risk assessment. It contains information on the prevalence of PRRS in Danish herds as well as in pork. Furthermore, the processing methods applied for bone-in hams are used to document that AQIS' demands for heat treatment have been reached in both meat and bone marrow of pork bone-in.

It is concluded that the probability that PRRS would enter Australia due to import of *fresh Danish bone-in hams, heat-treated upon arrival to Australia,* is negligible because:

- The prevalence of PRRS virus in Danish pork at slaughter is very low despite PRRS being endemic in Denmark, and freezing reduces the prevalence further by 75%,
- If present, virus is in low titers,
- Any virus is inactivated when pork is processed at 56°C for 60 minutes or an equivalent combination of temperature and time
- Our pilot plant experiments have demonstrated that the required temperature in the bone is obtained to the same degree as in the muscle
- A HACCP-based quality assurance programme at the processing plants guarantees that the required time/temperature combination has been reached
- In Australia, the use of swill is restricted by law
- It is questionable how likely PRRS virus is to be transmitted through pork naturally infected with PRRS virus

The consequences of introducing PRRS are by no means devastating since there is no risk for humans, and the swine production will only experience temporary production losses due to an increased number of abortions and decreased fertility during introduction of the virus. Finally, a country with PRRS can continue export of pig meat since only a limited number of countries have demands regarding PRRS.

Risk is a combination of the probability and the consequences of the adverse effect. Since the probability is negligible, and the consequences are limited to production losses over a short time period, the risk associated with import of *Danish bone-in hams heat treated upon arrival to Australia* seems to be below the acceptable risk level.

2. Background

Since 1980 Denmark has requested full access to the Australian market for fresh pork against the background that no OIE list A disease has been present in Denmark for several years. However, PRRS is endemic in Denmark, whereas it is non-occurring in Australia, and Australia is concerned that PRRS might be introduced because of import of fresh pork. Therefore, the Australian authorities refuse the Danish request.

Despite that PRRS virus is on OIE´s list of group B diseases, there are no international guidelines or veterinary conditions limiting the trade in pork from countries with PRRS virus (**http://www.oie.int**). Therefore, Australia is obliged - due to the SPS agreement - to base any veterinary requirements for Danish pork intended for export on an import risk assessment (**http://www.wto.org**).

In 1993, Australia started conducting an Import Risk Analysis on Danish Pig Meat (Anon., 1994a), and in 1994 AQIS evaluated the Danish Veterinary Services (Anon., 1994b). This provided the setting for Australia to open its market for import of fresh pork from Denmark under certain conditions (Anon., 1996). Accordingly, pork could be imported from Denmark, only if de-boned and destined for processing at an approved Australian processing facility. The processing facility should guarantee that the meat would be heat-treated to a core temperature of 56°C for minimum 60 minutes or another equivalent combination of time and temperature (Anon., 1997). In 1999, the Danish Veterinary and Food Administration approved the veterinary certificate specifying the conditions for import of Danish pork (Anon., 1999). Until 2002, approximately 50,000 tonnes of pork at a value of approx. 135 million EURO have been exported from Denmark to Australia.

In August 1999, a Danish request for exporting pork bone-in from Denmark to Australia was rejected against the background that the Australian authorities wanted to carry out further PRRS risk assessments in relation to import of bone-in-cuts of pork. Subsequently, the Australian authorities released a hazard identification entitled "Generic Import Risk Analysis for Uncooked Pig Meat" in January 2001 (Anon., 2001). The report dealt with several hazards and envisaged to carry out a proper risk assessment for each hazard identified.

As the Australian hazard identification focuses on PRRS as 'the' hazard in relation to export of pork from Denmark, The Danish Bacon & Meat Council decided to undertake a risk assessment specifically on the risk of introducing PRRS to Australia due to import of fresh Danish bone-in hams, heat-treated in Australia. As the hazard identification has already been made (Anon., 2001) we only address this shortly and focus on the risk assessment itself.

The assessment is qualitative and – whenever possible - carried out according to international standards (Anon., 1998). Available information from the literature as well as from the manufacturers is presented. If information was missing or of poor quality, assumptions have been made and these are listed in the report. A pathway was set up describing the series of events necessary for exposing Australian swine for PRRS virus originating from Danish pork. For each event the probability of the event occurring was assessed by use of an ordinal scale with 5 levels: negligible (≤0.1%), very low (>0.1-1.0%), low (>1-10%), medium (>10-50%), and high (>50%) The probabilities were derived from the detailed description of each event.

3. Hazard identification

3.1 The virus

PRRS is a small, enveloped, single strained RNA virus from the arterivirus group, classified within the Togavirida family. In 1991, the virus was isolated in both the Netherlands and in the USA. The use of modified live vaccines, based on American strains of PRRS virus, in Europe, has resulted in American strains occurring in Europe.

3.1.1 Virus distribution in tissues

The target cells of PRRS replication are matured monocytes/macrophages. Infected cells are primarily found in the lung, thymus, tonsils, lymph nodes, and serum (Mengeling et al., 1995). The carrier state for PRRS virus is characterised by predilection and maintenance of the virus in tissues other than meat, that is the tonsils and lungs (Farez and Morley, 1997).

3.1.2 World distribution

PRRS occurs in domestic, feral and wild porcines only. At present, PRRS is endemic in North America, most European countries, Russia, the Philippines, Korea, Taiwan, and Japan. Countries that are believed to be free of PRRS include Australia, New Zealand, Norway, Finland, and Sweden.

3.2 The disease

The majority of the herds will either be endemicly infected or non-infected, leaving a small fraction to be acutely infected. Incubation time is usually 2-5 days. Typically, the herd will experience an acute disease episode lasting 2-4 months (acute phase) followed by a gradual return to normal production (endemic phase) (Christianson and Joo, 1994; Meredith, 1995). The infection usually persists for years in herds (Albina et al., 1994) unless specific measures are taken to eliminate the infection. A recent simulation study showed that the average time to extinction in a herd with 115 breeding sows would be 6 years, and 80 years in a herd of twice the size (Nodelijk et al., 2000). The disease symptoms vary from none to severe (see below) upon the infection of previously un-infected herds (Christianson and Joo, 1994).

3.2.1 Naive adult pigs

The symptoms in boars and non-pregnant sows are mild and transient (fever, inappetence) although some strains of the virus have been associated with increased mortality in sows (Lager et al., 1998). The infection may cause abortion in late-term pregnant sows, prolonged farrowings, the birth of stillborn and weak-born piglets and agalactia (Christianson and Joo, 1994).

Pigs initially exposed to PRRS virus will generally have antibodies detectable by indirect fluorescent antibody (IFA) or ELISA within ten days of post infection (Wensvoort, 1994). The disease is highly infectious with an estimated basic reproduction ratio of 3 (Nodelijk et al., 2000). Within a susceptible herd, an average of 85% of exposed adults will sero-convert during the acute phase (Swenson et al., 1994). After recovery, the vast majority of pigs appear to be immune to further expression of the disease. The duration of the viraemia in experimentally infected 6-week old pigs varied from 2-35 days (Farez and Morley, 1997), and it is estimated that peak viraemia occurs after 11 days (Anon., 2000). However, experimental studies have indicated that clinically healthy animals might infect susceptible animals for prolonged periods, up to 99 days post infection (Albina et al., 1994; Dee et al., 1994). Stress or immune suppression may play a part in inducing viraemia in pigs with neutralising antibodies and without clinical signs (Albina et al., 1994). These authors reported the seroconversion of pigs placed in contact with non-viraemic, non-clinical, seropositive piglets that had been given exogenous corticosteroids and submitted to transport stress.

3.2.2 Piglets

During the acute phase of an outbreak, piglets might be weak-born and viraemic. Increased pre-weaning and post-weaning mortality are common results. The clinical signs include respiratory symptoms in young pigs and increased susceptibility to secondary infections (Christianson and Joo, 1994). However, mild symptoms might also be seen, e.g. in a recent Dutch experiment, the only symptoms of disease were lethargy, mild respiratory distress, fever, and inappetence for a short period of time - and only among a part of the animal (only 3 out of 81 needed antibiotic treatment) (Anon., 2000). Likewise, the diagnosis of PRRS is difficult as sub-clinical infections are common in all age groups. According to Murray (2001) it is probable that most finishing herds in infected areas are infected without clinical signs, and PRRS may only be detected when respiratory diseases are being investigated among weaners.

Piglets born from sows that became infected in late gestation might have antibodies to PRRS virus at birth. Piglets might also obtain maternal antibodies in colostrum or sero-convert following a challenge by PRRS virus in the farrowing room or nursery (Albina et al., 1994). Titres of maternal antibodies progressively decrease and might be absent at weaning although titres subsequently rise where PRRS is endemic in the growing and fattening herds (Dee and Joo, 1994; Stevenson et al., 1994). In this situation, 80-100% of the piglets will be positive on IFA by 8-9 weeks of age, although the sero-prevalence in finishing pigs (5-6 months) may vary from 25-50% (Dee and Joo, 1994).

3.2.3 Endemic situation

During the endemic phase, clinical signs may disappear in all stages of the production. In some herds reproductive failure of first parity sows may occur, and endemic infection in the nursery sections may result in increased death losses (Dee and Joo, 1994). In Danish herds, weaners in the nurseries usually become sero-negative due to the decline of maternally derived antibodies. Virus circulation seems to persist among growers when they are introduced into growers and finishers units (Nymark et al., 1998). By the end of the finishing period, 83% of the animals in 1,603 infected herds were seropositive (Mortensen et al., 2001).

In conclusion, infection will occur 2-4 months before slaughter following the introduction of 25-30 kg pigs in grower-finisher units. Viraemic pigs at slaughter could possibly occur as a consequence of a new introduction of the virus in a previously non-infected herd or as sporadic cases in endemically infected herds. The probability of a swine being viraemic exactly at slaughter is considered to be low, whereas in a newly infected herd the probability is considered to be medium to high.

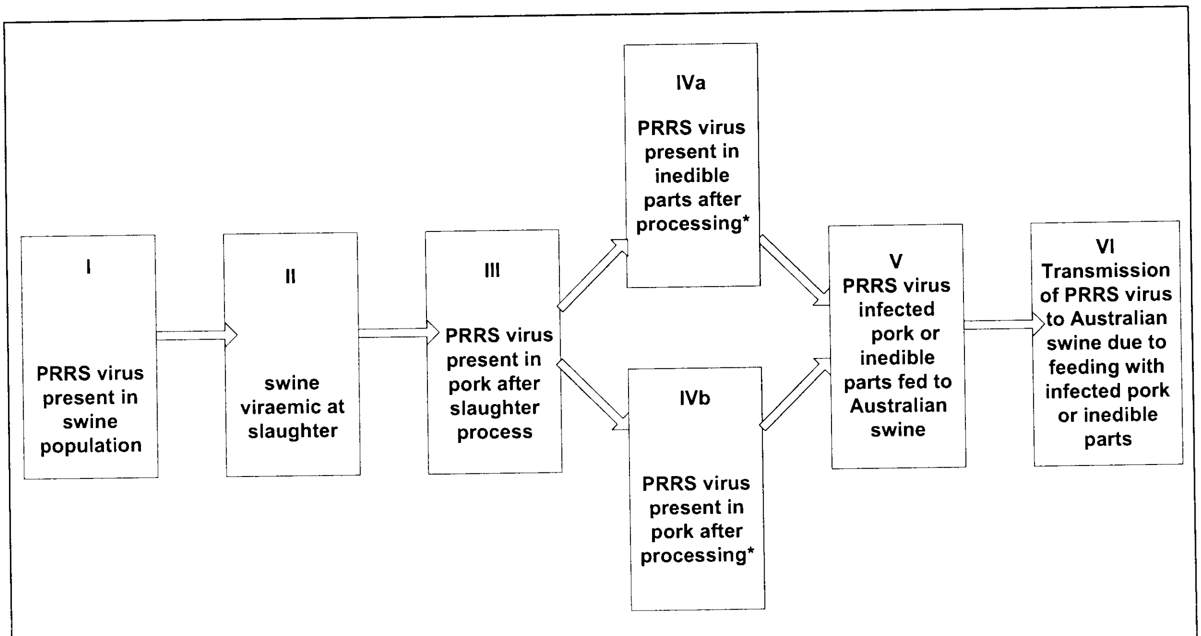
3.2.4 Transmission

In general, PRRS virus is transmitted within a susceptible herd or population at a high rate. However, the rate appears to vary with the viral strain and with the structure and density of the pig producing enterprises in the region (Halbur et al., 1992). The primary vector in the transmission is the infected pig (Dee et al., 1994). Transmission by direct contact has been demonstrated both experimentally (Collins et al., 1992, Christianson et al., 1992) and in field observations, where the spread of PRRS virus by movement of infected stock into susceptible herds has produced epidemic diseases (Dee, 1991). Aerosol transmission of PRRS virus has been reported, particular in conditions of high humidity, low wind speed, and low ambient temperature (Edwards et al., 1992; Mortensen and Madsen, 1992; Dee and Joo, 1994; Lager and Mengeling, 2000). PRRS virus may be spread by semen from infected boars (Meredith, 1992; Yaeger et al., 1993; Swenson et al., 1994; Christopher-Hennings et al., 1995). Experimental transmission of PRRS virus by certain waterfowl species has been reported (Zimmerman et al., 1997); the magnitude of this effect has not been substantiated however. According to Hooper et al. (1994) rats and mice are not a reservoir for the virus. Vomites may play a part (Yoon et al., 1993; Dee and Joo, 1994; Dee et al., 1994).

The above-mentioned ways of transmission are not relevant for the present risk assessment, which deals with export of fresh Danish bone-in hams. Therefore, we have only dealt with *infected pork* as a way of transmission (Section 3.2.2).

4. Risk Assessment

The series of events necessary for fresh Danish bone-in hams to expose Australian swine to PRRS virus is described in Figure 1. Firstly, PRRS virus must be present in the Danish swine population, secondly in swine at slaughter. Thirdly, virus must be present in the pork after the entire slaughter process. Fourthly, virus must survive in pork, i.e. in heat treated bone-in hams or in bits and pieces not undergoing processing. Virus could also survive in inedible parts, i.e. refuse, waste, packing material and effluents. Fifthly, pork or inedible parts containing PRRS virus should be fed to Australian swine. Finally, Australian swine should develop infection to PRRS due to the feeding of pork or inedible parts containing PRRS virus.
The risk assessment consists of 3 parts: 1) Release assessment (steps I-III), 2) Exposure assessment (steps IV-VI), and 3) Consequence assessment, here combined with Risk estimation. In the risk assessment, the probability of the specific event occurring is assessed qualitatively.



* Processing includes heat treatment and takes place in Australia

Figure 1 Pathway describing the series of events needed for PRRS virus to pass from an infected swine population via export of infected pork to the Australian swine population.

4.1 Release assessment

4.1.1 Prevalence in Danish swine herds

The pig industry in Denmark maintains a voluntary programme that monitors the PRRS status of about 4,100 participating herds, 3,700 in the SPF-system (SPF=Specific Pathogen Free) and 400 non-SPF. The aim of the programme is to reduce dissemination of the virus among herds. Breeding and multiplying herds (genetic herds) are required to maintain their status by monthly blood samples. Production herds participating in the programme are required to maintain their status by yearly blood samples (Mortensen et al., 2001). The SPF & PRRS-programme covers approximately 60% of the national sow population and about 45% of the finishing herds. 60% of the national finishing pig population originate from participating sow herds. Most of these finishing herds are following the same regulations as the SPF system, but without control-obligations. There are approximately 2,000 herds declared free of PRRS in Denmark. (Jensen, H. K., personal communication, 2003). The annual incidence is estimated to 8% (we expect that 8% of the *non-infected* herds become infected each year) Mortensen et al. (2001). Both the American and European type of PRRS virus is prevalent in Denmark.

In conclusion, there is a high probability that an individual Danish pig gets infected with PRRS virus during its life span. Usually, this will occur 2-4 months before slaughter following the introduction of 25-30 kg pigs in grower-finisher units.

4.1.2 Transport of Danish swine to slaughter

Pigs are slaughtered at approximately 6 months of age, when they weigh around 100 kg. In general, pigs are delivered for slaughter in special trucks, and the transport is as short and comfortable as possible. Typically, pigs are only transported for two hours due to short distances from farms to slaughterhouses. Thereafter, pigs are stabled for approximately two hours before slaughter. Occasionally, pigs are stabled overnight (personal communication, Gade, 2001).

In conclusion, the stress level among the transported pigs is relatively low, and transport time and lairage are short in general. Hence, there is a low probability that a pig, which was previously infected with PRRS virus, would develop PRRS during transport and lairage.

4.1.3 Slaughter of Danish swine

The slaughter process includes: Stunning -> Bleeding-> Scalding -> Flaming -> Rinsing -> Evisceration -> Meat inspection -> Chilling. The carcasses weigh around 76 kg after dressing. The carcasses are chilled as quickly as possible after slaughter in order to optimize the yield and quality of the meat. During the first part of the chilling process, the carcasses are in the chilling tunnel, where the temperature is freezing (-18 to -25°C) and the air velocity is high (2-3 m/s). After approximately 60 minutes, the carcasses are shell frozen and put in storerooms at a temperature at 5°C until the core temperature of the carcasses has reached a maximum of 7°C. The carcasses are stored and chilled for at least 24 hours (24-72 hours with a mean period of 48 hours) before cutting (Kyrme, personal communication, 2003). After cutting, the meat is packed and frozen to -18 to -25°C within 1-2 days. Most of the carcasses are cut at the slaughterhouses in 3 or 4 primal cuts (fore-end, pork leg, pork belly and pork loin) (Danish Bacon and Meat Council, 2001).

4.1.4 PH in pork after slaughter

The ultimate pH, measured 24 hours post mortem, was on average 5.6 in ham (sd=0.1)

(Maribo et al. A and B, 1998; Aaslyng and Gade, 2001).

In conclusion, the pH of bone-in hams is 5.6 on average, measured 24 hours post mortem. Hence, if PRRS virus is present in the pork at slaughter, it will be reduced, but not fully eliminated since the pH is not low enough during the maturing period, which can be as short as 24 hours.

4.1.5 PRRS virus in pork from experimentally infected pigs
Several researchers have examined the role of pig meat in the transmission of PRRS virus. In a study conducted by Bloemraad et al. (1994), 4 pigs were infected experimentally. The pigs were slaughtered 5 days (2 pigs) and 10 days (2 pigs) post infection, respectively. Carcasses were stored at 4°C and samples of muscle and bone marrow were collected from the carcasses 0, 24, or 48 hours after slaughter. PRRS virus was recovered sporadically from muscle samples 0 and 24 hours after slaughter, but not 48 hours after slaughter. No virus was recovered from the bone marrow samples. Likewise, Duan et al. (1997) did not find PRRS virus in the bone marrow of any of 16 experimentally infected pigs, which were euthenased at day 3, 14, 21, 28, 35, 42, or 82 post infection. Mengeling et al. (1995) exposed 21 pigs to one of three PRRS virus strains, with one pig exposed to each virus strain euthenased on days 3, 7, 14, 22, 35, 49, and 70 post infection. PRRS virus was isolated from the ham muscle from one pig only (several muscle groups were sampled), which was euthenased seven days post infection. Frey et al. (1995a) demonstrated PRRS virus (both European and American strains) in pooled samples of ham muscle and bone marrow in pigs slaughtered six days post infection. Hence, it is not known whether PRRS virus was actually present in the bone marrow. The pooled muscle bone marrow samples retained infectivity for several weeks when stored at 4°C and at least for one month when stored at -20°C. Magar et al. (1995) found that PRRS virus was isolated in muscle samples from 2 out of 2 pigs seven days post infection, but not 14 days post-infection. Bloemraad et al. (1994), Mengeling et al. (1995), and Magar et al. (1995) all suggested that low levels of PRRS virus detected in muscles were due to residual infected blood, not because the muscle cells were actively infected with the virus.

4.1.6 PRRS virus in pork from naturally infected pigs
Several groups have investigated the presence of PRRS virus in commercially slaughtered pork. Frey et al. (1995b) examined 1,049 sample pools taken from 178 lots of fresh pork (40,000 lbs per lot) for PRRS virus, finding 6 of the sample pools positive for virus (prevalence 6/1049=0.6%). In the positive samples virus levels were low. In another study, Magar et al. (1995) collected muscle samples from 44 abattoir pigs derived from seropositive herds. No virus was isolated and no viral antigens were detected by immunogold silver staining. This same research group subsequently expanded the study to 73 lots of frozen packaged pig meat, each sampled by six pools of meat samples. All samples were negative both by virus isolation and reverse transcription – polymerase chain reaction (RT-PCR) (Larochelle and Magar, 1997). Likewise, a Danish study examined the presence of PRRS virus in pork from 22 herds, where PRRS virus was active up to six months previously. A total of 234 pools of muscle samples were collected at slaughter from approximately ten pigs per herd. All samples were negative by virus isolation. For that reason, the authors concluded that pork does not retain detectable amounts of PRRS virus in endemicly infected herds (Olsen, personal communication, 1998). However, it cannot be ruled out that this might occur occasionally. If 234 pools were sampled from a population consisting of 10,000 pigs, this would correspond to a 95% confidence interval for the prevalence from 0.0-1.3% in the population – which includes the prevalence of 0.6% obtained by Frey et al. (1995b).

There are probably several reasons explaining the difference in prevalence found in experimental and observational studies:

1. High doses of virus are used in experimental set-ups, whereas in real life the virus levels are probably lower because the animals are infected weeks to months before slaughter.
2. Usually pigs in a viraemic phase are febrile. Febrile pigs cannot be slaughtered according to Danish (and EU) meat inspection rules. The producer, the transport driver and the meat inspector (veterinarian at the abattoir) are each responsible for only slaughtering healthy pigs.
3. During the maturing of the pig meat, any virus being present will gradually be reduced, so that no virus (or close to no) is present after 48 hours. In the example, a Dutch study showed that while PRRS virus could be found in 12 out of 24 muscle samples analysed directly after slaughter, PRRS virus could only be found in 3 out of the same 24 samples after freezing. Hence, a 75% decrease in the prevalence (Anon., 2000).

In conclusion, PRRS virus has been isolated from muscles of experimentally infected pigs, primarily in the early stages of infection where the pigs usually are febrile. Contrary, PRRS virus has been isolated from slaughterhouse pork seldomly, and if virus was present, it has been in low levels, which decrease further during maturing and freezing (prevalence dropped by 75%). Therefore, the probability that a commercial pork carcass contains PRRS virus is assessed to be very low, around 0.6%.

4.2 Exposure assessment

4.2.1 Oral transmission of PRRS virus due to infected pork

Transmission under experimental conditions following administration of doses of 10^7 $TCID_{50}$ virus has been reported previously (cited from Farez and Morley, 1997). The oral transmission of PRRS virus by feeding infected pork to pigs has been investigated recently (Anon., 2000). A preliminary study included 24 eight weeks old pigs infected by intranasal inoculation with either a European or an American strain of PRRS virus. The pigs were slaughtered 11 days post-inoculation, and the semimembranosus muscle was assayed to determine PRRS viral titres. PRRS virus was detected in the muscle of 12 pigs (50%) after slaughter ($10^{3.3}$-$10^{4.3}$$TCID_{50}/g$). The muscle was frozen until it was used in the feeding experiment, and muscle titres were determined before feeding. In most samples, titres decreased during freezing (below $10^{1.8}$-$10^{3.8}$$TCID_{50}/g$) and virus could only be found in 3/24 pigs, hence a 75% reduction in prevalence. 500 g of raw muscle from each experimentally infected pig were fed over a 2-day period (250 g/day) to each of two receiver pigs (48 pigs). Sera were collected for virus isolation and antibody detection for 3 weeks post feeding. Horizontal transmission occurred since sentinel pigs in contact with receiver pigs became infected, probably a result of group housing. Oral transmission was demonstrated. However, some reservations remain as PRRS virus could be isolated from all receiver pigs even though PRRS virus was not detectable in muscle samples. This could be because the detection level was not low enough, but it could also indicate horizontal transmission.

In general, the oral pig infective dose 50% (PID_{50}) for PRRS virus is expected to be considerably higher for feeding of infected pork than for instilling virus in culture media on the tongue of a pig, feeding the virus suspended in a liquid medium such as milk or forcefeeding homogenized infected tissue (Farez and Morley, 1997). Additionally, as the predilection sites are other than pork, it might be expected that virus titres are low in pork with PRRS virus making it questionably whether transmission might occur under natural conditions. According to Farez and Morley (1997), uncooked waste of pork or pork products have been incriminated in the transmission of classical swine fever, African swine fever, swine vesicular disease, and foot and mouth disease, but never of PRRS.

In conclusion, oral transmission of PRRS virus due to infected pork is possible under experimental conditions. However, it is not known how likely this is to occur under natural conditions where the virus titers in infected pork are lower than under experimental conditions. It is assessed that the probability of the event under natural conditions is very low.

4.2.2 Description of bone-in hams

Danish exporters have a special interest in exporting Danish bone-in hams for further processing in Australia.

The specific type of bone-in ham, intended for export, is described as pork leg round cut (standard cut) without tailbone, flank fat and flank meat. It contains the aitch bone (os ischium), leg bone (femur) hind shank bone (fibula and tibia) and hock bones (tarsus). A ham weighs 10 kg on average. The product contains approximately 10% bone (1 kg bone) (DANISH CROWN, Randers, Denmark).

The Danish bone-in hams will be sent frozen (- 18°C during transport), wrapped in plastic and packed in cartons, weighing approximately from 20-30 kg. The cartons will be marked with the following information: package no., produced at (name, address), authorization number, type of product, description of goods, production date(s) / lot no, species of animal, net weight and health mark (DANISH CROWN, Randers, Denmark).

It is estimated that Denmark can export 5,000 tonnes bone-in hams to Australia annually at a value of 8 million EURO (Funch, personal communication 2001).

4.2.3 Heat treatment of the raw bone-in hams

Australia requires that the core temperature should be 56°C for 60 minutes or an equivalent combination of time and temperature in order to inactivate PRRS virus.

The ham is heat-treated to the required temperature by monitoring the core temperature of the ham. It has been questioned whether the heating required for inactivating any PRRS virus will be reached in the bone. Therefore, we set up an experimental study with the aim of demonstrating whether there were any differences between the temperature in the bone and the meat during the heating process. The experiment was conducted twice; at first, four hams were measured during pre-trial, secondly ten hams were measured during the study itself. The results showed that in fact the temperature in the bone was higher than in the meat during the entire heating process for each of the six hams. The reason is that the bone is placed laterally in the ham, not centrally, and hence more exposed to the heat (Frøstrup et al., 2002).

In conclusion, when heat-treating bone-in hams, the temperature in the bone is higher than in the meat during the heating process. Hence, there is no excess risk associated with bone-in hams compared with hams without bone, provided the cooking procedure has been carried *out adequately.*

4.2.4 Quality assurance programme

The Quality Assurance Programme at the meat producing plants handling Danish pork should secure that PRRS virus is inactivated. The programme should describe both the processing (heat treatment) of pork (de-boned as well as bone-in) as well as the handling of bits and cuts and the inedible parts from the production.

The Australian meat-processing factory P & M Quality Smallgoods (1995) has a detailed Quality Assurance Manual, based on HACCP principles, for the processing of uncooked pig meat (deboned) imported from Canada and Denmark. The manual describes the total process flow of Danish pork, e.g receipt of uncooked meat, identification of the product during processing, heat treatment of pork (including heat treatment of edible trimmings), sterilisation of equipment, heat treatment of refuse, disposal and treatment of waste, packaging material and effluents. The manual is based on AQIS's quality and quarantine requirements with regard to the handling and processing of uncooked pig meat from Denmark and Canada. The manual is approved by AQIS.

P & M Quality Smallgoods imports over 70 % of the total amount of pork from Denmark and Canada to Australia. The company is also interested in importing Danish pork bone-in for further processing. The company is aware that import of Danish pork bone-in implies amendments to their manual concerning cooking programmes for pork bone-in and disposals including pork bone. The company is interested in participating in "field tests" in connection with general import approval of Danish pork bone-in by AQIS.

In conclusion, it is assessed that the probability is negligible that a pork cut or inedible parts contain PRRS virus when leaving the processing plant.

4.2.5 Swill-feed

Animal Health Australia reports that all states in Australia have imposed legislation restricting the use of swill feed, and the farmers will be punished if they feed swill to pigs. As part of a national publicity programme, a special video has been prepared on the penalties for feeding swill to pigs (http://www.aahc.com.au/status/ahiareport/1994/aahr9407.htm). Presumably, compliance is high, but we have no information on the subject.

In conclusion, it is assessed that the probability is low that pork or other inedible parts will be fed to Australian swine.

4.3 Consequence assessment

There is no risk associated with PRRS for humans or any other species than porcines. If PRRS virus should be introduced extensively into the Australian pig population, the same series of event are expected as in other countries where PRRS virus is now endemic.

<u>Direct consequences</u>

Production and economical losses as a result of infection with PRRS were examined in 28 sow herds and 15 finisher herds. In Danish Farrow – to – finisher herds the losses, as a result of acute PRRS symptoms, have been calculated to amount to 119 Euro per year sow. The costs include losses as a result of a decrease in production of weaners and finishers. For pure sow herds the losses was 47 Euro per year sow and for pure finisher herds 4 Euro per finisher

(Anon., 1994 c). As gross margin over time is constant, the average losses described from 1994 are acceptable estimates for losses today (Udesen, personal communication, 2003).

The clinical expression of PRRS varies greatly, and the losses sustained in the herds also differ. This is mainly due to the infection load of other production diseases in the herds. Herds that are declared free of specific production diseases and follow management programmes to ensure low infection load, experience fewer production losses than conventional herds (Anon., 1994 c).

It has been established that to ensure a low infection load during an outbreak of PRRS implementation of management programmes has a positive effect on the production rate during the endemic phase. The positive effect of these management programmes has been found to outweigh the negative effect of PRRS during the endemic phase (Christensen, personal communication, 2003).

Mortensen et al. (2001) have estimated that 8% of non-infected herds become infected each year.

Indirect consequences

According to OIE no special measures (including eradication) are required in relation to introduction of PRRS virus into a country (http://www.oie.int). So far, none of the countries affected by PRRS has chosen to eradicate the disease after introduction. The costs of controlling the disease (eradication, compensation, surveillance and control costs) vary depending on the measures against PRRS.

In the Danish National Pig Breeding Programme, under the National Committee for Pig Production, there is a demand for testing for PRRS in the nucleus and multiplying herds. The tests are done on a monthly basis (10 samples). The owners of these herds have a so-called Health Advisory Contract with their veterinary practitioner. The contract comprises minimum 12 visits per year, and the blood samplings are done in connection with these visits. The costs of the samplings amount to EURO 3.80 per test, and the analysis EURO 7 per test (Rønn, personal communication 2003).

Since the mid 90ies, the Danish pig industry has implemented a voluntary programme that monitors the PRRS status of the participating herds (Mortensen et al., 2001).

The cost connected with declaration on PRRS free status is due to sampling and analysis of 20 blood tests yearly (122 EORO per year). The clinical examination for presence of PRRS in the herd is normally done under the health advisory contract with the veterinary practitioner. Approximately 80% of all swine producers have signed a health advisory contract.

Piglets/weaners free from PRRS are sold at an additional price of 4-6 %. The high price is an incentive to keep the herd free from PRRS (Jensen, personal communication 2003).

In case PRRS virus is introduced into Australia and becomes endemic, restrictions in export to other countries are expected to be the same as for other countries with PRRS. Denmark exports pork to many countries. Access to markets are not denied with reference to PRRS, but there are special demands regarding PRRS in connection with export to Argentina, Cyprus, New Zealand, Russia, Ukraine, Belarus, Lithuania, and Australia. The financial impact of the restrictions on exports to the specified markets depends on the kind of products exported, the volume and the price of the products (Danish Bacon and Meat Council, 2003).

The most important export restrictions due to PRRS are imposed on exports to Australia and New Zealand which both are high price markets (Danish Bacon and Meat Council, 2003).

Based on Danish experience in fulfilling export conditions to countries with specific demands for PRRS (bilateral agreements with Russia and Argentina), there are also different costs in connection with the administration of pigs under slaughter restrictions for PRRS. These costs are mainly due to transport of pigs to special abattoirs in order to fulfil the export conditions. The costs for slaughtering pigs under PRRS restrictions are estimated to be 9 EURO for each pig (DANISH CROWN, Randers 2002).

In 2001, Australia exported approximately 13% of their total pork production. Singapore and Japan constitute Australia's biggest markets in volume and value. These markets account for 71 % of the total pork export (76 % of the export value). Trade in pig meat to countries imposing restrictions on PRRS (New Zealand, Russia) accounts for 7% of the total pork export (5 % in value) (WWW.apl.au.com).

Denmark exports breeding pigs to many countries. There are no requirements for freedom from PRRS in the country of origin, but demands for freedom from PRRS in the herd of origin and in the animal. (Bramsen, personal communication, 2003).

It is presumed that there will be the same demands for import of live pigs from Australia.

In conclusion, there are no international demands for eradication of PRRS virus after introduction. The introduction and spread of PRRS virus will only affect export of meat to few markets. This will be in the context of special demands for attestations for PRRS in connection with export. Export of live animals will not be affected if a declaration and monitor system of PRRS is set up to meet the special demands of each importing country. There will be no import ban.

Comments to Australia's assessment of the financial consequences:
Australia has assessed the expected financial impact of PRRS virus entering Australia (Garner et al., 2001). The assessment forms part of a report, which also deals with Nipah virus (serious zoonosis and classical swine fever (OIE List A disease). The report demonstrates that the consequences associated with the introduction of PRRS virus will be dramatic, not only for Australian pig production but also for Australia as such.

We do understand the uniqueness of Australia's disease-free status with respect to PRRS virus. However, it is interesting to learn about the experiences of the countries in which PRRS is endemic. These countries did not observe the devastating consequences described in the Australian report. In the following we will briefly explain where we have other viewpoints than those stated in the Australian report.

We do not believe that the financial impact on Australia as such will be detrimental because the pig industry in Australia is small compared to international standards (Garner et al. (2001) state that Australia has around 304,000 sows). In comparison, a small country like Denmark (43,000 km^2) has 1,344,000 sows (Eurostat, 2002).

As stated above under "Indirect consequences", only few countries have special demands regarding PRRS virus, and in most cases export of breeding pigs and pig meat is allowed if certain conditions are followed (certification of the fact that the pig meat originates from a herd without clinical symptoms of PRRS). The Australian report states that some consumers would be likely to stop buying pig meat. This might be the case for Nipah virus, which has a serious zoonotic aspect, and for classical swine fever, where infected pig meat has been incriminated in relation to outbreaks several times (Farez and Morley, 1997). However, a consumer ban on pork is unlikely in relation to PRRS virus since only porcines will be affected by the virus (no zoonotic aspect). Furthermore, it is highly debatable whether the virus can be transmitted by pork under natural conditions (Garner et al. 2001).

For years, Denmark has exported approx. 20,000 tonnes pig meat to Sweden. Despite this, Sweden is still considered free from PRRS. This real-life example demonstrates that the probability that PRRS virus should be transmitted via infected pig meat is negligible under natural conditions.

4.4 Risk estimation

The consequences that PRRS virus might enter Australia are not devastating since primary concerns are production losses. Table 2 lists the events describing how PRRS virus might infect Australian swine on account of import of Danish bone-in hams, heat-treated upon arrival to Australia.

Figure 2

List of events that may lead to PRRS virus infecting Australian swine due to import of Danish bone-in hams, heat treated upon arrival to Australia.

Event in pathway	Description of event	Dealt with in section	Assessment of probability
I	PRRS virus present in Danish swine	3.1.1	High

	population		
II	Swine viraemic at slaughter	2.2.2 2.2.3 3.1.2	Low (endemic infected herds) Medium-high (newly infected herds)
III	PRRS virus present in pork after slaughter process	3.1.4 3.1.5 3.1.6	Very low[a]
Iva	PRRS virus present in inedible parts[b] after processing	3.2.3 3.2.4.	Negligible[a]
Ivb	PRRS virus present in pork[c] after processing	3.2.3 3.2.4	Negligible[a]
V	Pork[c] and inedible parts[a] fed to Australian swine	3.2.5	Low
VI	Transmission of PRRS virus to Australian swine due to feeding with infected pork[c] or inedible parts[a]	2.2 3.2.1	Very low[a]
I-VI	**All events happening**		**Negligible**

a: The probability of the event is conditional on PRRS virus being present in the pork/swine
b: Inedible parts comprise waste, refuse, packing material and effluents
c: Pork comprises bone-in hams as well as pieces and cuts

Before PRRS virus enters Australia because of import of *fresh Danish bone-in hams, heat-treated upon arrival to Australia*, all six events in the pathway must happen. This probability may be described by the combined probability of each of the events I-VI. It is concluded that this probability is negligible. The most important reasons are:

- Even though PRRS is endemic in Denmark, the prevalence of PRRS in Danish pork is very low, and further reduced during freezing
- Virus is present in low titres
- Any virus is eliminated when pork bone-in is processed at 56°C for 60 minutes or a similar combination of time and temperature
- Our pilot plant experiments have demonstrated that the required temperature in the bone is obtained to the same degree as in the muscle
- A HACCP-based quality assurance programme on the processing plants guarantees that the required time/temperature combination is reached
- Swill-feed in Australia is restricted by law
- It is questionable how likely PRRS is to be transmitted through pork naturally infected with PRRS virus

Sine there is no risk for humans, the consequences of having PRRS introduced are by no means devastating, and the swine production will only experience temporary production losses due to an increased number of abortions and decreased fertility.

Risk is a combination of probability and the consequences of the adverse effect. Since the probability is negligible and the consequences are limited to short-term production losses, the risk associated with import of *Danish bone-in hams heat treated upon arrival to Australia* is below the acceptable risk level.

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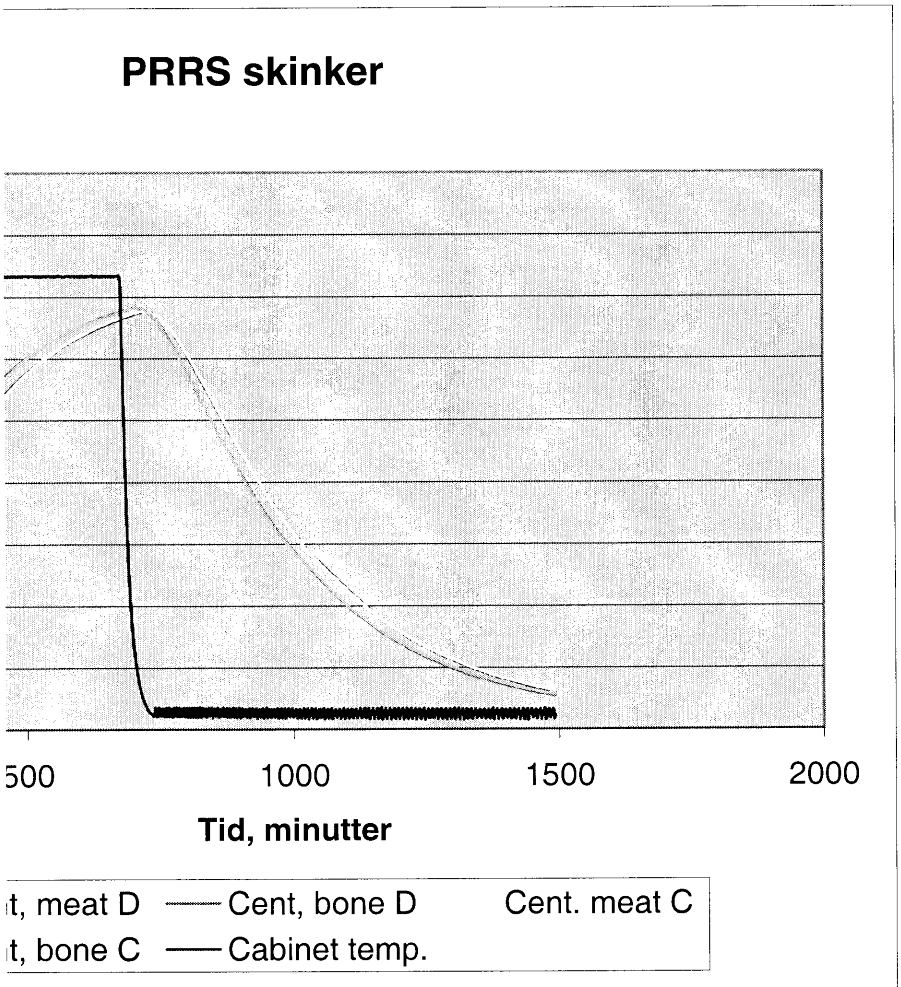
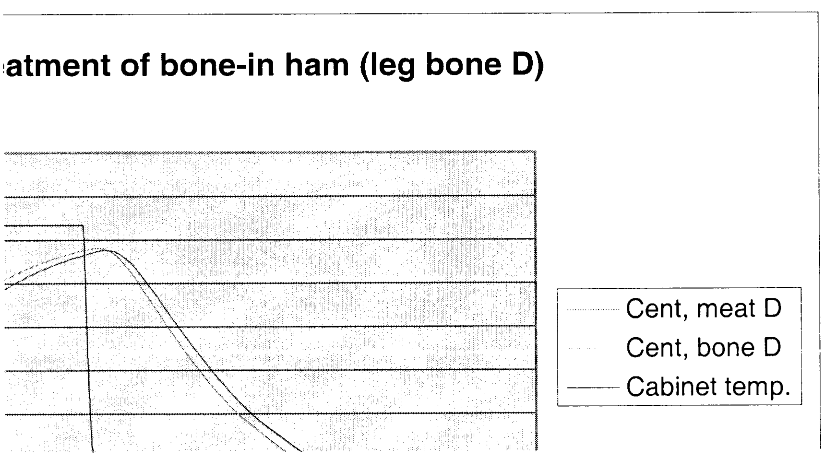
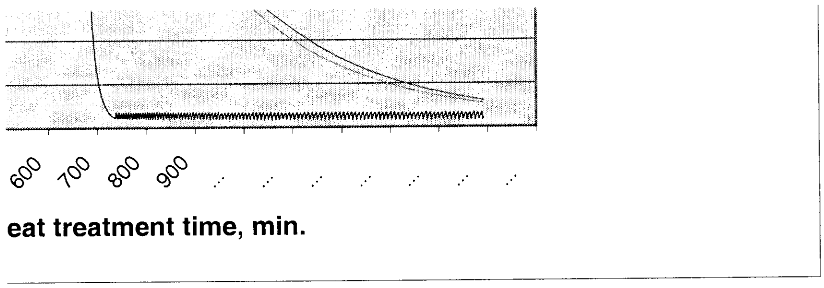
	M00	M01	M02	M03	M04
	NiCr-Ni(K)	NiCr-Ni(K)	NiCr-Ni(K)	NiCr-Ni(K)	NiCr-Ni(K)
°C	°C	°C	°C	°C	
SF 70539		SF70840	SF70842	SF 70664	
12,7	32,6	32,5	32,5	33,8	
-14,6	4,8	5,5	5	1,5	
47,6	68,1	67,6	68,3	78	







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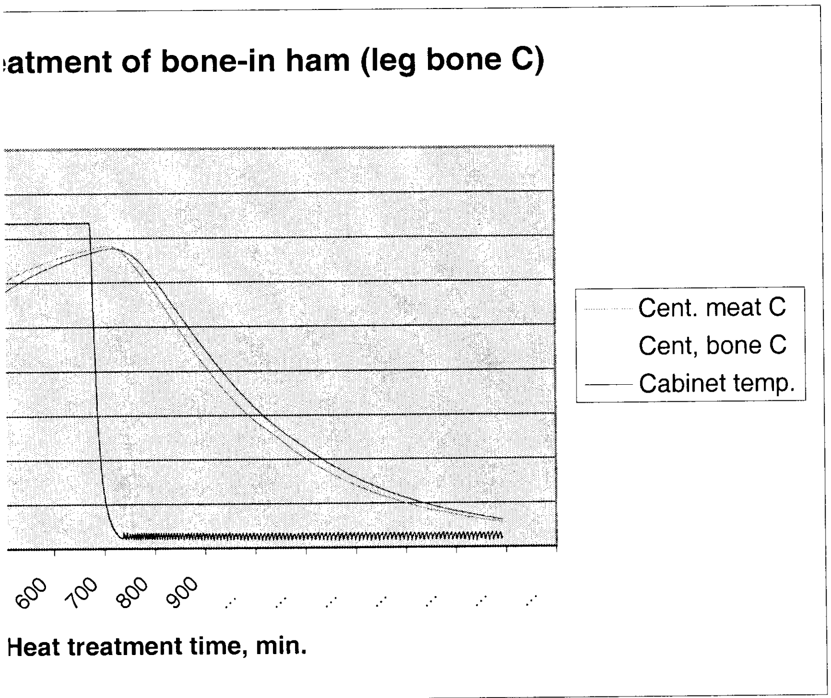
eat treatment time, min.



·atment of bone-in ham (leg bone C)
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Cent, bone C
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700
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