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Risk assessment regarding the import of Yorkshire sows and semen from the Netherlands

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Contents

1. Summary

On behalf of Norsvin, the Norwegian Veterinary Institute has conducted a qualitative import risk assessment based on OIE guidelines. The aim of the risk assessment is to estimate the risks associated with PRRSv (Porcine Reproduction and Respiratory Syndrome Virus), SIv (Swine Influenza Virus), TGEv (Transmissible Gastroenteritis Virus), PRCv (Porcine Respiratory Coronavirus), *Salmonella* and MRSA ST398 (Livestock-associated methicillin-resistant *Staphylococcus aureus*) regarding:

- The one-off import of 15-20 pregnant Yorkshire sows from one specific SPF breeding facility in the Netherlands. The sows are placed in Norwegian isolation ('Import Isolation Facility 1') where they farrow. The offspring are weaned at approximately 5 days old and moved to new isolation ('Import Isolation Facility 2'). The imported sows are then euthanized. The offspring remain at Import Isolation Facility 2 until they are 5-8 months old. Approximately 60-70 juvenile sows are moved to an existing Norwegian breeding facility for future production of Yorkshire boars. Import Isolation Facility 2 then acts as boar isolation for at least 6 weeks, until approximately 15-20 juvenile boars are moved to Norsvin's artificial breeding center. The offspring that are not used for breeding are slaughtered. Testing for all relevant hazards, equivalent to at least general regulatory samples, is conducted in the export facility, Import Isolation Facility 1, and Import Isolation Facility 2.
- The import of 35-40 doses of fresh semen every 3 weeks from one SPF artificial breeding center in the Netherlands to the same breeding facility in Norway for the production of Yorkshire boars. Before juvenile boars are taken into Norsvin's artificial breeding center, they are first placed in isolation for 6 weeks in separate pre-isolation ('Boar Isolation Facility 1'), then in regular boar isolation ('Boar Isolation Facility 2'). In both boar isolation facilities, the juvenile boars are tested for PRRSv. The assessment is based on a time perspective of approximately 10 years regarding such imports.

All six agents were considered hazards when importing livestock. Only PRRSv, TGEv, *Salmonella*, and MRSA ST398 were considered hazards when importing semen. While PRRSv is known to be transmissible via semen, the situation is unknown regarding TGEv, *Salmonella* and MRSA ST398, and these are included as a precaution due to a theoretical possibility of contamination of semen. SIv and PRCv are not considered to be transmissible via semen, and they are therefore not defined as hazards when importing semen.

PEDv (Porcine Epidemic Diarrhea Virus) is not included in the assignment, but should be considered. The risk assessments made for TGEv will be useful in such a context.

Based on the assumptions made (including a 10-year perspective), the overall risk assessment of **importing semen** is as follows:

- PRRSv: The probability that imported semen contains PRRSv is considered very low. The probability that any PRRSv in the semen is also spread to Norwegian pigs outside the import facility and Boar Isolation Facility 1 is considered negligible.
- TGEv: The probability that imported semen contains TGEv is considered very low. The probability that any TGEv in the semen is also spread to Norwegian pigs outside the import facility and boar isolation facilities is considered very low to negligible. The probability of TGEv spreading can be reduced to negligible by adequate testing.
  The consequences of the Norwegian pig population outside the import facility and the boar isolation facilities being exposed to TGEv imported with Yorkshire semen are considered severe.
- *Salmonella*: The probability that imported semen contains *Salmonella* is considered very low to low. The probability that any *Salmonella* in the semen is also spread to Norwegian pigs outside the import facility and the boar isolation facilities is considered very low. The assessment is associated with a lot of uncertainty due to lack of knowledge about the infection status of the boar center, the resistance of any strains to antibiotics used, and the possibility of transmission of infection via semen. The probability can be reduced by testing boars in Boar Isolation Facility 1.
  The consequences of the Norwegian pig population being exposed to *Salmonella* due to imports of semen are considered moderately significant.
- MRSA ST398: The probability of imported semen containing MRSA ST398 is considered low to moderate. The probability that any MRSA ST398 in the semen is also spread to Norwegian pigs outside the import facility and boar isolation facilities is considered low. The assessment is associated with a lot of uncertainty due to lack of knowledge about the infection status of the boar center, the resistance of any strains to antibiotics used, and the possibility of transmission of infection via

semen. The probability can be reduced by testing boars in Boar Isolation Facility 1.
The consequences of the Norwegian pig population being exposed to MRSA ST398 due to imports of semen are considered to be of little significance.

Based on the assumptions made (including a one-off event and thorough testing), the overall risk assessment **of importing livestock** is as follows:

- PRRSv, SIv, PRCv, TGEv, and MRSA ST398: The probability of importing these agents into the import facility or Norsvin's artificial breeding center via the import of pregnant sows is considered negligible.
- *Salmonella:* The probability of importing *Salmonella* into the import facility or Norsvin's artificial breeding center via the import of pregnant sows is considered very small to negligible. It can be reduced to negligible if the offspring is tested serologically in addition to compulsory culture samples. The consequences of the Norwegian pig population being exposed to *Salmonella* due to imports of live sows are considered moderately significant.

Since there are possibilities for the introduction of agents, and/or animals with positive serology, it is important that adequate contingency plans are in place before importing. It is important to have good hygienic routines in the isolation facilities and in the import facility in order to prevent the spread of infection via personnel, animal transport, etc. Both conditions are assumed in our assessment.

2. Abbreviations and terminology

ADv	Aujeszky's disease virus
AI	Artificial Insemination
AQIS	Australian Quarantine and Inspection Service
MRSA ST398	Livestock-associated methicillin-resistant *Staphylococcus aureus*
NSP	National Surveillance Programs
PCV	Porcine circovirus
PEDv	Porcine epidemic diarrhea virus
PMWSv	Post-weaning multi-systemic wasting syndrome virus
PRCv	Porcine respiratory coronavirus
PRRSv	Porcine reproductive and respiratory syndrome virus
SIv	Swine influenza virus
TCID50	Median tissue culture infectious dose: amount of virus resulting in infection of 50% of inoculated cells
TGEv	Transmissible gastroenteritis virus

The terminology used for **probabilities** is as follows:

Very high:	An event will occur with great certainty (it is most likely to occur)
High:	An event can be expected to occur (it is likely it will occur)
Moderate:	There is a slightly greater chance that the event will not occur
Low:	There is little chance of the event occurring (it probably won't happen)
Very low:	There is very little chance of the event occurring (it will most certainly not occur)
Negligible:	It is highly unlikely that the event will occur (in practice, we can disregard that it will occur)
Unknown:	No scientific evidence to estimate the probability

The terminology used for **consequences** is as follows:

Very severe: The establishment of the disease in Norwegian pig farming can be expected to have a major economic impact on the entire industry, and can last for a long period of time. Alternatively or additionally, it can cause major environmental problems or pose a severe threat to humans.

Severe: The establishment of the disease in Norwegian pig farming can be expected to have major health consequences (severe illness in many animals). This may last over a lengthy period of time, and the disease may be difficult to eradicate. The establishment can be expected to have severe economic consequences for the entire industry. Alternatively or additionally, it can harm the environment or pose a threat to humans.

Moderately significant: The establishment of the disease in Norwegian pig farming can be expected to have less severe health consequences. The economic consequences can be severe for individual producers or groupings, but not for the Norwegian pig industry as a whole. It will be possible to control or eradicate the disease, but at a significant price. The establishment can harm the environment, but without it having major consequences.

Little significance: The establishment of the disease in Norwegian pig farming can be expected to have little health consequences, or could easily be controlled or eradicated. The economic consequences may harm individual producers or groupings, but have an insignificant effect on the Norwegian pig industry. Any effects on the environment will be small, or of short duration.

Insignificant: The establishment of the disease in Norwegian pig farming can be expected to have no health consequences, or of short duration and easy to control or eradicate. The economic consequences will be moderate for individual producers and have no effect on groupings or the Norwegian pig industry. No harmful effects on the environment.

3. Introduction

3.1. Objective

The objective of the risk assessment is to estimate the risks associated with:

- A one-off import of 15-20 pregnant Yorkshire sows from one specific SPF breeding facility in the Netherlands. The sows are placed in Norwegian isolation where they farrow. The offspring are weaned at approximately 5 days of age and moved to new isolation facilities. The imported sows are then euthanized. The offspring remain in the new isolation facilities until 5-7 months of age and are tested at least twice in this isolation. The sows are moved to one existing Norwegian breeding facility for future production of Yorkshire boars. When they reach an age of 6-7 months and after additional testing for PRRSv, ADv and Brucellose, the boars will be taken directly to Norsvin's artificial breeding center. The import of 35-40 doses of fresh semen every 3 weeks from one SPF artificial breeding center in the Netherlands to the same breeding facility in Norway for the production of Yorkshire boars, which via two boar isolation facilities will enter Norsvin's semen production. The assessment is based on a time perspective of approximately 10 years with such imports.

The assessment addresses the following six agents:

- PRRSv: Highly infectious viral disease with impaired non-specific immune system and varying symptoms. Never detected in Norway, endemic in the Netherlands since 1990. The infection quickly spread to large parts of the pig population in many countries in the early 1990s. The import of PRRS virus to Norway will have major economic and animal welfare consequences for Norwegian pig production. PRRS virus is part of the National Surveillance Program for specific viral infections in pigs in Norway.
- SIv: Swine-adapted influenza virus (other than pandemic H1N1 2009 virus). Highly infectious viral disease with respiratory symptoms. Never detected in Norway, endemic in the Netherlands. Imports of new, swine-adapted influenza viruses will have a major economic and animal welfare impact on pig production. Influenza viruses are included in the National Surveillance Program for specific viral infections in pigs in Norway.
- TGEv: Highly infectious viral disease with severe intestinal inflammation, especially in piglets. Never detected in Norway, was previously common in the Netherlands. TGE (and the related PED) has not been diagnosed in the Netherlands for over 20 years, but there is no regular surveillance of these diseases in the Netherlands. PRCv provides cross-immunity to TGEv and can therefore hide the presence of this virus. the import of TGEv will have a major economic and animal welfare impact on pig production. TGEv is included in the National Surveillance Program for specific viral infections in pigs in Norway.

- PRCv: Highly infectious viral disease that causes moderate or no symptoms from the respiratory tract. Closely related to and cross-reacts in many serological tests with TGE. Never detected in Norway, endemic in the Netherlands. The import of PRCv will have small/moderate economic and animal welfare consequences. PRCv is indirectly included in the National Surveillance Program for specific viral infections in pigs in Norway.
- *Salmonella*: Bacteria that cause intestinal infections in animals and humans. Almost 60% of Dutch breeding facilities and 8% of slaughter pigs tested positive for *Salmonella* in the EFSA baseline study in 2008. No Norwegian breeding facilities have tested positive for *Salmonella* in recent years. Very low prevalence of *Salmonella* in slaughter pigs in Norway (0-0.15% of slaughter pigs) compared to most other countries. The import of *Salmonella* will have little immediate consequence for the health of pigs, but *Salmonella* is an important zoonosis, and increased prevalence in Norwegian pig facilities can have major economic consequences for the facilities affected. Norway has a National Surveillance Program for the prevalence of *Salmonella* in livestock and livestock products.
- MRSA ST398: A special livestock-associated clone of MRSA that has experienced widespread prevalence in the European pig population over the past 5-6 years. In the EFSA 2008 baseline study, 12.8% of breeding facilities in the Netherlands tested positive for MRSA ST398. In Norway, MRSA ST398 has not been detected in samples taken from pigs at facilities, but in 2011, MRSA ST398 was detected in samples taken from pigs after slaughter at one specific slaughterhouse. It later turned out that the barn at this slaughterhouse was contaminated with MRSA ST398. The import of MRSA ST398 will not have direct health consequences for Norwegian pigs, but it could eventually lead to an increased prevalence of MRSA ST398 in humans and thereby increased pressure on Norwegian healthcare institutions. MRSA in pigs is included in NORMvet's surveillance program for 2012.

3.2. Progress

The Norwegian Veterinary Institute received a request from Norsvin to carry out the risk assessment in October 2011, with the wish of having the assessment ready on 1 December 2011. An initial meeting was held on 20 October, where specifications, methods and data requirements were presented. Peer Ola Hofmo has been the contact person for Norsvin. Geertjan Van Groenland has been the contact person for Topigs. Anne Jørgensen from the Norwegian Pig Health Service attended an initial meeting.

A preliminary draft was sent to Norsvin on 1 December, and discussed on 2 December.

Comments and changes were included in the updated draft which was sent for a brief consultation to Per Wallgren at the Swedish Veterinary Agency, Svenska Djurhälsovården c/o Sten-Olof Dimander, ETT Finland (equivalent to the Norwegian KOORIMP) c/o Pirjo Kortesniemi, and KOORIMP c/o Nina Svendsby. A summary of input is provided at the end of the report.

The report was originally written in Norwegian, and translated into English in 2024.

3.3. Validity

As a general rule, an import risk assessment and any health standard should be updated in the event of important changes to:

- health status in the Netherlands or Norway
- health status in the export facility or import facility
- insight into the diseases
- test methods and test regimens
- quantities imported into Norway
- the way imports take place
- other prerequisites

4. Materials and methods

The analysis is based on OIE's guidelines for risk analysis regarding imports (OIE 2011).

A qualitative risk assessment has been carried out, i.e. a relatively rough assessment of the risk, where probabilities are expressed in the form of 'little', 'major', 'negligible', etc. and consequences as 'moderate', 'severe', etc.

A qualitative risk assessment helps to provide a basic understanding of the problem (knowledge of the diseases, routes of infection, regulations, etc.) and in many cases is sufficient to reach a conclusion that is good enough to take the necessary measures. An important advantage of a qualitative risk assessment is that it is relatively quick, and moderately resource-intensive.

If it is impossible to establish clear guidelines for managing existing risks based on the conclusion of a qualitative risk assessment, there may be reason to deepen the analysis. In many cases, a quantitative risk assessment is a useful addition. However, such an approach is more resource-intensive, and in some cases impossible due to lack of source data. The quantitative assessment will in all cases build on elements described in the qualitative assessment, which can then be considered the first phase of the work.

4.1. Hazard identification

An agent is defined as a hazard if it can potentially be introduced from export countries (in this case the Netherlands) into Norway via import of pregnant sows or semen and lead to health, economic or environmental consequences for animals or people in Norway. In the context of WTO/SPS/OIE, these consequences must be greater than in the case of trading within the same country/region, either because the agent is not present or there is a milder variant, or it is actively combated in the importing country/region (OIE 2011).

4.2. Risk assessment

Hazards are further assessed in four stages:

Probability of the infectious agent being introduced (Release assessment)

Probability of the Norwegian pig population being exposed to infection (Exposure assessment)

Consequence of the Norwegian pig population being exposed (Consequence assessment)

Overall risk assessment (Risk estimation)

A number of elements must take place at the same time for the agent to be introduced. If one stage leads to the exclusion of the risk of the specified infectious agent upon import, it is not mentioned in the following stage.

The scenario-tree is shown in Figure 1.

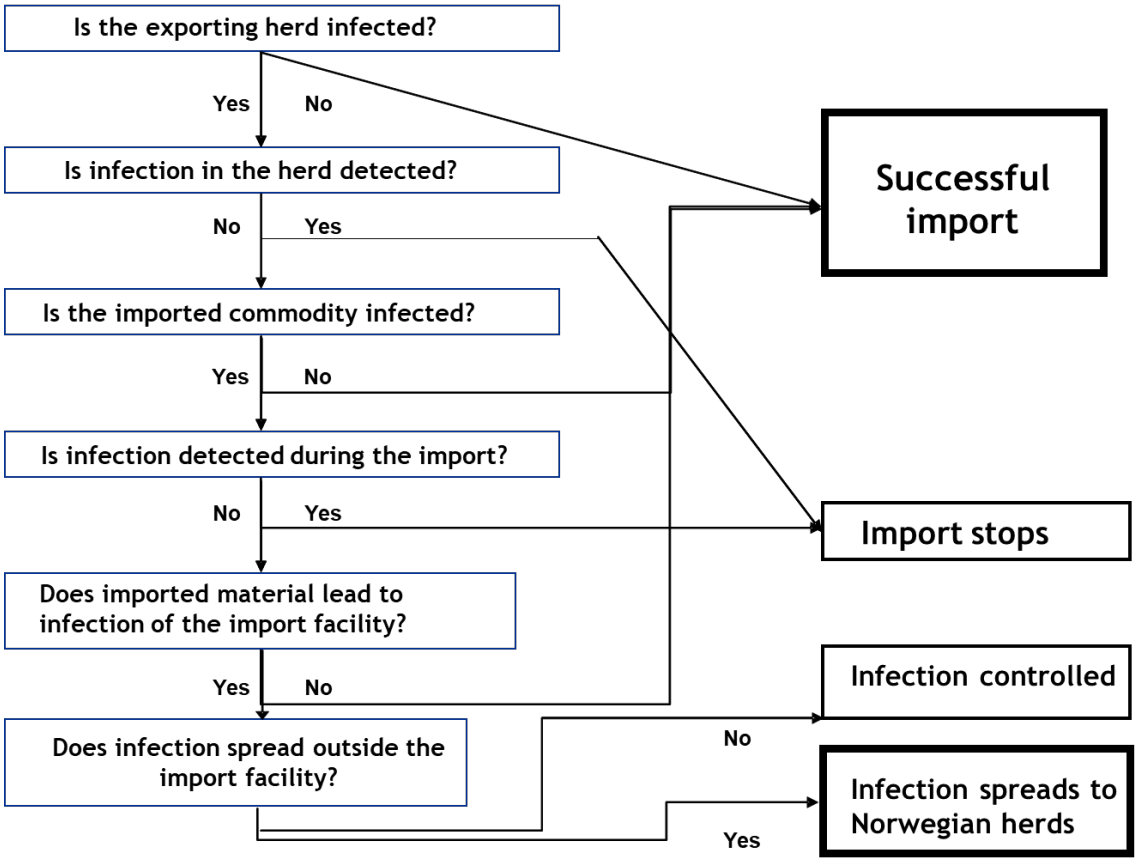

Figure 1. Scenario-tree when importing Yorkshire gene material to Norway

A successful import will occur each time the export facility is free of infection, or the export facility is infected but the sample being imported is not infected, or the sample is infected but does not lead to infection of the import facility (the amount of infectious agent imported is not sufficient for the disease to establish itself via relevant routes of infection).

Imports of semen will be stopped if infection with PRRSv is detected at the artificial breeding center in the Netherlands or in the Norwegian import facility.

The import of sows will be stopped if infection with a relevant agent is detected in the export facility or in the sample of sows.

However, in the relevant import, exceptions are made for serological reactions regarding SIv and PRCv in sows in export isolation and in Import Isolation Facility 1. The reason for this is that it is expected that one or more of the sows will be serologically positive for SIv and/or PRCv without them necessarily being carriers of infection. The intention is to compensate for this by adding an additional isolation facility in Norway with testing of the offspring (see Section 4.3.7). If infection is detected in at least one animal, adequate measures must be taken to prevent further infection.

It will be possible to eradicate/eliminate/combat the infection before it spreads to the Norwegian pig population provided it is discovered before it has spread to other facilities.

Infection of the Norwegian pig population will occur every time all stages lead to an adverse event. This means that infection of the Norwegian pig population as a result of importing Yorkshire genetic material requires that a number of events occur at the same time.

4.3. Assumptions

The assessments have been made on the basis of available information as of the current date, and with a systematic precautionary attitude in relation to lack of knowledge.

It is assumed that the provisions of FOR 2006-02-14 No. 199: Instructions for the Norwegian Food Safety Authority, the District Offices, regarding the isolation and examination of animals, and the livestock industry's additional requirements for importing live pigs and importing boar semen, and rules for quarantine facilities when importing boar semen are complied with unless otherwise stated by the client (Cf. Sections 9.1, 9.2 and 9.3).

The assessment is based on the following assumptions:

4.3.1 Semen import procedure – flow chart, quantities and time aspect

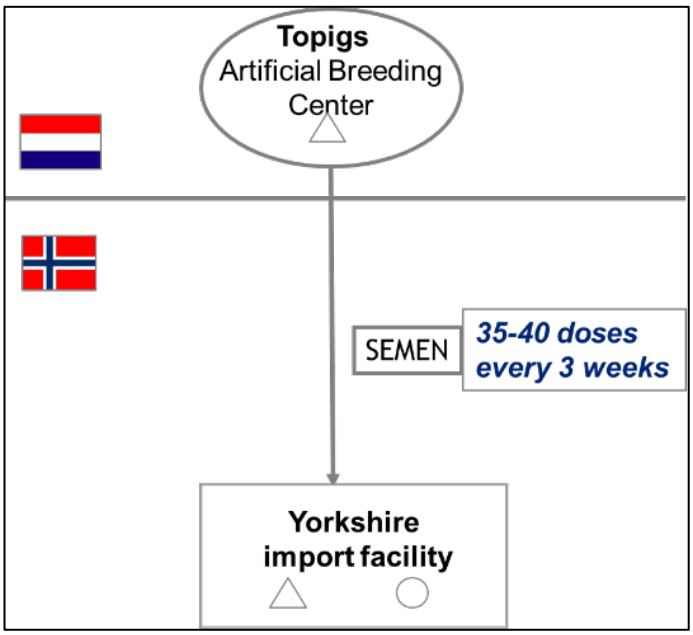

Figure 2. Import of semen (sows symbolized by a circle, boars by a triangle).

The semen must be imported from one of Topigs' SPF artificial breeding centers that have special status regarding documented freedom from PRRS. A detailed description follows.

Every 3 weeks, 35-40 doses of fresh Yorkshire semen will be imported and used in one specific import facility. The time between collection and use of semen is 1-4 days. 15-20 sows are inseminated with imported semen. The assessment is based on a time perspective of 10 years.

4.3.2 *Livestock import procedure - flow chart, quantities and time aspect*

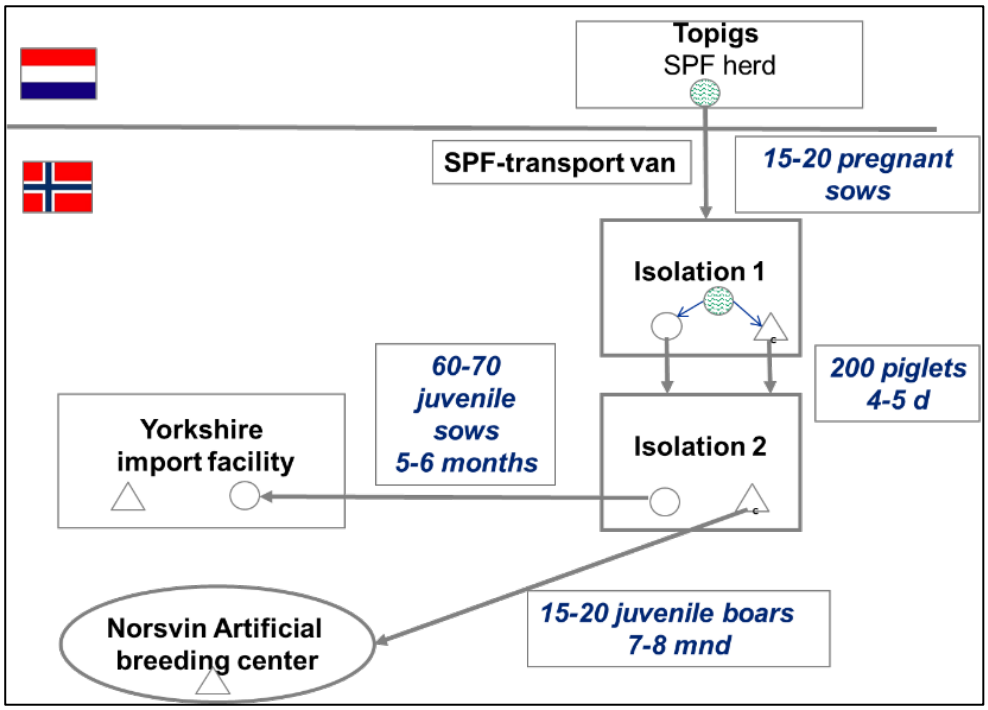

Figure 3. Flow chart for import of livestock (sows symbolized by a circle, boars by a triangle)

Export facility: One of Topigs' SPF breeding stock facilities. A detailed description follows.

Export animals: 15-20 pregnant sows. The sows are 'isolated' and tested according to government and industry guidelines. A detailed description follows.

Transport vehicle: Must be disinfected before and after use, special air filters.

Import Isolation Facility 1: The sows are transported from the export facility to Import Isolation Facility 1 approximately 3 weeks before the expected farrowing, and then slaughtered when the piglets are approximately 5 days old. The sows remain in Import Isolation Facility 1 for approximately one month in total. They are tested after 2-4 weeks.

Import Isolation Facility 2: The offspring are transferred to Import Isolation Facility 2 when they are approximately 5 days old.

The juvenile sows are kept in Import Isolation Facility 2 until they are to be covered at approximately 5-6 months old.

The juvenile boars remain in the import isolation facility for at least 6 weeks after the sows have left it, and are then transferred to Norsvin's artificial breeding center.

Juveniles considered unsuitable for breeding are sent to slaughter.

Relatively high mortality in piglets is expected due to early weaning.

Approximately 150 juveniles are expected to remain in Import Isolation Facility 2 for approximately 5 months.

Approximately 75-90 animals are expected to be further used in breeding.

At 12 weeks, a representative sample of the animals is tested in Isolation Facility 2, and all animals to be further used in breeding are tested at 5 months, and transfer occurs when there are negative test results.

4.3.3 *Use of animals from the Yorkshire import facility – flow chart, quantities and time aspect*

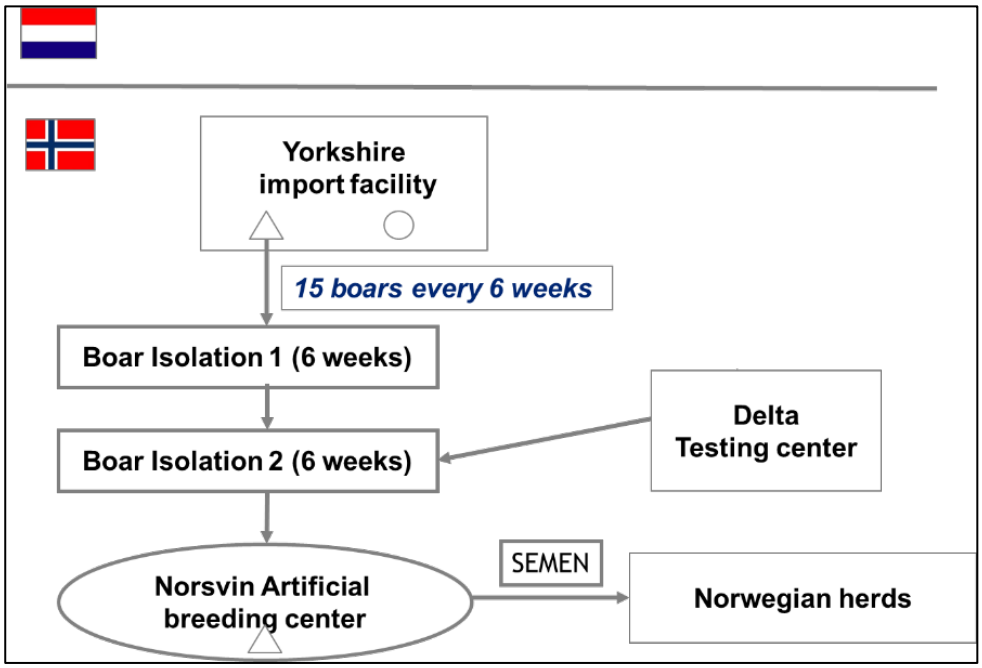

Figure 4. Flow chart for the use of boars from the import facility

Boars are removed from the import facility and transferred to Boar Isolation Facility 1 when they are 6-7 months old. Transfer of approximately 15 boars occurs every 6 weeks.

Boar Isolation Facility 1 (separate pre-isolation for Yorkshire boars): The boars are housed for 6 weeks and tested after 3-4 weeks.

Boar Isolation Facility 2 (ordinary isolation for breeding boars): The boars are housed for 6 weeks. Here, they are mixed with boars from Norsvin's Delta testing center. All are tested after 3-4 weeks.

Therefore, it takes 12 weeks from when the juvenile boars leave the import facility (which receives semen), until they are introduced to Norsvin's artificial breeding center.

4.3.4 *Health status of the Dutch pig population*

The Netherlands is officially free from foot and mouth disease, classical and African swine fever, vesicular stomatitis, Techen disease, swine vesicular disease, Aujeszky's disease, brucellosis and trichinellosis in pigs. All of these are notifiable diseases.

Leptospirosis; antibodies against L. Bratislava occur in some facilities, but it has not been documented that L. Bratislava has caused disease problems in pigs in the Netherlands. The situation regarding Leptospirosis thus seems to be analogous to the situation in pigs in Norway.

TGE has not been diagnosed in over 20 years, but the Netherlands has no active surveillance of the prevalence of these infectious agents. This report assumes that TGEv is highly likely to occur in the Dutch pig population.

PRCv, PRRSv, SIv (H1N1, H3N2 and H1N2, Porcine-adapted variants), MRSA ST398 and *Salmonella* are all endemic in the Netherlands.

4.3.5 *Topigs' artificial breeding center*

Semen will be imported from a specific Topigs' SPF artificial breeding center.

General requirements for Topigs' artificial breeding centers

There are good procedures in place for biosecurity and health documentation at Topigs' artificial breeding centers.

The unit and country/region in which the center is located must be free from infectious diseases in accordance with OIE standards, including freedom from AD.

The facilities from which the boars are recruited are documented as being free from atrophic rhinitis and scabies.

The facilities from which the boars originate and/or the boars themselves are documented free from:

- PRRSv tested using Idexx-ELISA (Indirect ELISA) and optionally verified using Hipra-ELISA (Indirect ELISA) or IPMA test.
- *Mycoplasma hyopneumoniae* (Idexx-ELISA optionally verified using Dako-ELISA).
- *Actinobacillus pleuropneumoniae* (1-9-11, 2, and 5a-5b), all-type anti-toxin ELISA (APX-II or APX-IV) optionally verified using LPS ELISA.

Requirements for nucleus breeding facilities and boars before they enter Topigs' SPF quarantines

The facilities must have a 'free from' status, and the boars must be tested and achieve a negative result for:

Brucella suis (Rose Bengal test)

Classic swine fever virus (ELISA)

AD (gB ELISA)

PRRSv (see previous section)

Mycoplasma hyopneumoniae (see previous section)

Actinobacillus pleuropneumoniae (see previous section)

Testing in quarantine

After 28 days in quarantine and within 15 days prior to transfer to the artificial breeding center, all boars must test negative for antibodies to: Brucella suis, ADv, PRRSv, *Mycoplasma hyopneumoniae*, and *Actinobacillus pleuropneumoniae* (for tests, see previous sections).

Testing at the artificial breeding center

A representative sample of the boars is tested every 14 days (approximately 5% of the boars randomly at the center). Tests are conducted for the same infectious agents as specified for quarantine testing plus classical swine fever test. All newly arrived boars are tested in the period 2-8 weeks after arriving at the center. All boars are then tested at least once a year.

PRRSv unsuspected certification

Two centers (Lienden and Heerde) are certified as PRRSv unsuspected. The threshold for antigen-antibody reaction is reduced from standard SP<0.4 to SP <0.1. At antibody level > 0.1, follow-up examinations are performed using alternative tests.

Control and documentation

External and internal infection prevention procedures are reviewed at least twice a year and all health status information is stored on computer.

Control of boars during semen collection

Semen is only collected from healthy boars. In connection with each semen collection, the body temperature of each boar is measured. If the body temperature is above 39°C and remains so for half an hour, the semen is destroyed. The boar is removed from production and observed for at least one week. All boars that die or are euthanized at the center undergo a post-mortem examination.

Use of semen in SPF facilities

The semen must not be used in SPF facilities until at least 24 hours after dilution. This ensures the efficacy of added antibiotics against bacteria, and reduces any viral contamination. Semen plasma has some inhibitory effect against viruses along with the presence of lymphocytes and macrophages.

When semen is delivered from artificial breeding centers that do not have SPF status to SPF facilities in the Netherlands, the semen is tested according to regular procedures using PCR for the presence of PRRSv (Hipra PCR test for PRRS, detects 0.2 TCID50/ml of undiluted semen).

Diluent is added to the semen which contains 1g of neomycin sulfate and 40mg (950,000 IU) of benzylpenicillin sodium per liter of diluent.

4.3.6 Topigs' export facility

15-20 sows will be imported from a defined Topigs SPF facility.

The facility has a documented health status that is high and stable. It is assumed that the facility has good procedures in place regarding infection prevention measures, and that these are at least on par with what is required in Norwegian breeding stock facilities.

Submitted test results indicate that the facility is free from PRRSv and MRSA ST398.

There is strong evidence that the facility is free from *Salmonella* because only one animal has tested positive using serology (idexx Elisa) in 2010, there were no positive samples in 2011. Serological testing for *Salmonella* has high sensitivity but relatively low specificity.

In addition, the facility has been tested and found free from classical swine fever, AD, SVD, Brucellosis, *Mycoplasma hyopneumoniae, Actinobacillus pleuropneumoniae, Pasteurella Multocida Toxin, Brachyspira hyodysenteriae,* and scabies.

The facility's status regarding SIv, TGEv, PRCv and PEDv is unclear, mainly due to lack of testing. There have been positive reactions for SIv in 2010 and 2011, mainly H1N1, but it is not differentiated in relation to H1N1pdm09.

4.3.7 Isolation in the Netherlands and transport to Norway

The animals (15-20 pregnant sows) to be imported into Norway will be kept in an export facility until they are transported to Norway with one of Topigs' SPF transport vehicles approximately 3 weeks before the expected farrowing. During this period, they are tested for all agents included in the risk assessment, as well as other agents imposed by government regulations and the livestock industry's additional requirements for the import of live pigs (see sections 9.2 and 9.3). Before departure to Norway, the pigs are treated for parasites.

Transport will be cancelled if any results return positive, with the exception of SIv and PRCv. The reason for the latter is that there is a high probability that the sows have antibodies against these infectious agents. The intention is to compensate for this uncertainty in the program by creating two import isolation facilities in Norway, see Section 4.3.8 and Figure 3.

4.3.8 Import isolation facilities in Norway

Information on localization and detailed description of facilities, routines for infection hygiene and the operation of import isolation facilities 1 and 2 are not available at the current date. It is assumed that the requirements stipulated in the isolation regulations are followed when establishing these isolations.

Import Isolation Facility 1

The sows are placed directly into Import Isolation Facility 1.

The newborn piglets are weaned at 4-5 days old and transferred to Import Isolation Facility 2.

The sows are slaughtered immediately after the piglets are weaned.

Sampling in Import Isolation Facility 1: Blood samples will be taken from all imported animals 2-4 weeks after arrival.

The samples are tested for all viruses included in the risk assessment, and other agents as determined in the government regulations and the livestock industry's additional requirements when importing live pigs (see 9.2 and 9.3). Exceptions are SIv and PRCv if the sows had positive tests in export quarantine in the Netherlands.

Samples for *Salmonella* will be taken from all sows at weeks 1 and 3. Tests for MRSA must also be conducted in Import Isolation Facility 1. Environmental samples are also considered for both agents.

Any sows that die before slaughter must undergo a post-mortem examination by a competent laboratory (Norwegian Veterinary Institute).

Import Isolation Facility 2

A representative sample of the offspring is tested after 12 weeks. The size of the sample is calculated based on the expected prevalence and sensitivity of the tests.

At 5 months of age, all offspring to be used in breeding are tested (75-90 animals). At this point, it is assumed that the rest of the offspring is sent to slaughter.

The testing involves all agents included in the risk assessment, and those required by government regulations and the livestock industry's additional requirements when importing live pigs (see sections 9.2 and 9.3).

After the sows have left the isolation facility, the boars are kept there for at least 6 weeks before being transferred to Norsvin's artificial breeding center. During that period, they are tested for PRRSv in accordance with regulations for breeding stock boars.

No animals are moved to the import facility or the artificial breeding center unless all test negative in all tests. If a serological test is used for *Salmonella*, an expert assessment is made in the event of positive results, due to low specificity.

Any sows that die before slaughter must undergo a post-mortem examination.

4.3.9 Yorkshire import facility

The import facility is located in Skollenborg in Buskerud and has modern buildings. The nearest pig farm/facility is approximately 5 km away.

It was established as a Yorkshire multiplier herd with animals from a Norwegian Yorkshire facility in 2005. The piglets are kept in farrowing pens until they are 10 weeks old. They are then moved to the recruitment department where they are mixed with older recruitment animals. The facility is subject to and meets the industry's requirements stipulated in the Health and Hygiene Regulations for Breeding Herds. It has an entrance with a hygiene lock where visitors change into the facility's clothing and footwear and wash hands when transitioning from the 'unclean' outer zone to the 'clean' inner zone. There are showers on the way in and out of the facility. The facility has systematic rodent control and birds are unable to enter areas where livestock are kept.

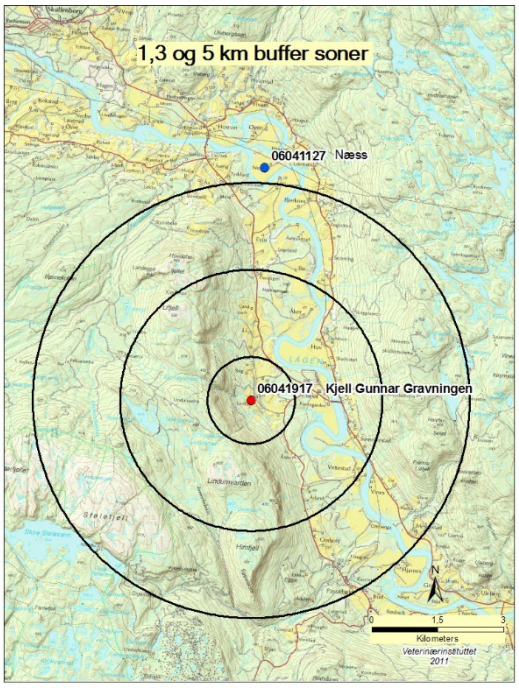

Figure 5. Pig farms/facilities in the area around the import facility

There is a separate unloading room for pigs, and the animal transport is always empty, washed and disinfected when it comes to pick up animals. Only semen is taken into the facility, no animals. When animals leave the facility, they either go to Norsvin's boar isolation facility (6-7 month old boars) or directly to slaughter when they have an approximate live weight of 120 kg. If Topig's semen from the Netherlands eventually gets introduced, the boars will first go to an additional isolation facility (Boar Isolation Facility 1) where they can be screened for specific disease agents.

The facility operates according to a 3-week batch production with approximately 12 sows per batch and produces approximately 200 liters per year. This means that 35-40 doses of semen must be imported every 3 weeks. For each batch, 4 weeks after insemination, samples must be taken from at least 50% of the inseminated sows (at least 7 animals for each batch). The samples should represent all donor boars and should be examined for antibodies to PRRSv.

There is no necropsy requirement for animals that die at the import facility before slaughter.

<u>Routines for hygiene locks and management of imported semen.</u>

The semen arrives packed in a thermo box. An 'unclean person' with disposable gloves takes the semen doses out of the package and makes the necessary labeling on each dose using a permanent marker pen. The outer packaging is destroyed in a responsible manner.

The semen doses are then placed for a minimum of 4 minutes in a disinfecting bath (e.g. Virkon S) that maintains 17 °C and is then transferred to the 'clean zone' at the facility. The doses must not be used until cleared from Topigs and no earlier than 24 hours after collection.

4.3.10 Boar Isolation Facility 1, pre-isolation facility for Yorkshire boars

Approximately 15 selected boars that are to enter an artificial breeding center are moved from the import facility to a pre-isolation facility, Boar Isolation Facility 1. They are kept there for 6 weeks before being moved on to Norsvin's ordinary isolation facility for breeding stock boars.

All are tested after 4 weeks for PRRS, AD, Brucellosis and Classical Swine Fever.

The stay at Boar Isolation Facility 1 gives a 6-week longer observation period both for health status at Topigs' artificial breeding center and for health status at the import facility before the boars are mixed with other boars.

Negative results must be achieved before they are moved to Boar Isolation Facility 2.

6-week batch production: The boars are moved out on Friday, the isolation facility is left empty over the weekend where it is washed and disinfected, before a new batch is introduced on Monday.

4.3.11 Boar Isolation Facility 2, ordinary isolation facility for breeding stock boars

This is Norsvin's ordinary isolation facility for boars entering the artificial breeding center. The boars are housed for 6 weeks and blood samples are taken from all boars after 4 weeks in the isolation facility. Samples are tested for PRRS, AD, and Brucellose. 6-week batch production: The boars are moved out on Friday, the isolation facility is left empty over the weekend where it is washed and disinfected, before a new batch is introduced on Monday.

4.3.12 Summary of required tests

	PRRSv	SIv	TGEv	PRCv	Salmonella	MRSA ST398
IMPORT OF SEMEN						
Topigs' artificial breeding center (1)	x					
Import facility (2)	x					
Boar Isolation Facility 1	x					
Boar Isolation Facility 2	x					
IMPORT OF SOWS						
Topigs' export facility	x	x			serology	x
Sows for export	x	x	x	x	2 feces	x
Import Isolation Facility 1	x	x	x	x	2 feces	x
Import Isolation Facility 2 (sample, 12 weeks)	x	x	x	x	feces	x
Import Isolation Facility 2 (breeding stock, 5 months)	x	x	x	x	feces	x
Import Isolation Facility 2 (juvenile boars, 7 months)	x					

(1) Representative sample, every 2 weeks

(2) >50% inseminated sows

5. Hazard identification

In the context of international risk assessment, a hazard is defined as an agent that may lead to an adverse outcome, in this case importing an agent/disease. In the context of OIE, it is also required that the agent exists in the exporting country, that it can be imported with the relevant import material, and the importing country either does not have the agent, or has an active control plan, or has milder variants (OIE 2011).

5.1. PRRSv

PRRSv is a hazard when importing live pigs or semen from the Netherlands to Norway, because:

PRRSv occurs endemically in the Netherlands and the virus can be spread both via live animals and semen. For the latter route of infection, there are both epidemiological and experimental evidence. PRRSv has never been detected in Norway, despite active surveillance since 1995.

Topigs' artificial breeding center and SPF facility for the export of pigs to Norway are tested regularly for PRRSv, and both have tested negative over several years.

The introduction of PRRSv will have major health and economic consequences for Norwegian pig production. PRRS is a list-B disease and its eradication will likely take place through stamping out.

5.2. SIv

The influenza virus (except pandemic H1N1 2009 virus) is a hazard when importing live pigs, but not semen from the Netherlands to Norway because:

Swine-adapted varieties of influenza virus occur endemically in the Netherlands and viruses can be spread with live animals. The Norwegian pig population is free from swine-adapted varieties of influenza virus.

The probability of influenza virus occurring in semen is considered negligible. There are no reports that influenza virus has been transmitted to sows through semen. Based on the affinity of the virus to special receptors in the respiratory tract and to lymphoid tissues in the respiratory tract, and the absence of viremia, AQIS (2000) concludes that the probability of influenza virus spreading with semen from infected boars in connection with artificial insemination is negligible, and that there is no need for special safety measures against influenza viruses in connection with imports of semen.

Topigs' artificial breeding center is not tested for SIv. The SPF facility for exporting pigs to Norway tested negative for SIv until 2010. It has subsequently been serologically positive for antibodies to SIv (mainly H1N1). It has not been clarified whether this is H1N1pdm09.

Infection with influenza virus has low mortality but high morbidity and is a potential zoonosis.

If the swine-adapted influenza virus is introduced into the Norwegian pig population, the risk of further spread and establishment in the population is high. SI is a list-B disease.

5.3. TGEv

TGEv is a hazard when importing live pigs and semen from the Netherlands to Norway because:

The Netherlands has not been documented as being free from TGEv, even though TGE has not been diagnosed in the Netherlands for more than 20 years.

At infected facilities, semen may be contaminated with TGEv (fecal contamination), but there is no evidence that TGEv has been spread by artificial insemination. The probability of TGEv being transmitted via semen is considered very low/negligible.

Neither the artificial breeding center nor the SPF facility have been tested for TGEv.

If TGE is transmitted to and becomes established in the Norwegian pig population, costs may be high in piglet production. TGE is a list-B disease and its eradication will likely take place through stamping out.

5.4. PRCv

PRCv is a hazard when importing live pigs, but not semen, from the Netherlands to Norway because:

Norway is documented free from PRCv, and the virus occurs endemically in most facilities in the Netherlands, probably also in the export facility.

At infected facilities, there is a probability that semen can become contaminated with PRCv (aerogenic or fecal contamination), but there is no evidence that PRCv has been spread via artificial insemination. The probability of PRCv being transmitted via semen is considered negligible.

Neither the artificial breeding center nor the SPF facility have been tested for PRCv.

PRCv does not cause any, or only moderate, clinical symptoms, but the virus spreads very quickly in the population, and experiences from other countries indicate that, upon introduction in the Norwegian population, there is a high risk of the virus establishing itself in the population. PRCV is a list-C disease. It is unclear which official measures will be implemented in the event of positive findings.

5.5. Salmonella

Salmonella is a hazard when importing live pigs and possibly semen from the Netherlands because:

A large proportion of the pigs in the Netherlands are infected with *Salmonella*. Through the National Surveillance Program for *Salmonella,* there are many years of documentation showing that the prevalence of *Salmonella* in Norwegian pigs is very low (0-0.15%).

The probability of *Salmonella* being transmitted via semen is unknown but cannot be ruled out. At infected facilities, semen can theoretically be contaminated with *Salmonella*. Growth in diluted semen at 20° C for 1-4 days cannot be ruled out through antibiotic resistance. There are no known publications that have studied the presence and growth of *Salmonella* in boar semen, or looked at whether *Salmonella* can be spread to new facilities via artificial insemination.

No testing for *Salmonella* takes place at the artificial breeding center. With the exception of one sample, the SPF facility for exporting sows has tested serologically negative for *Salmonella* (<1:40).

Salmonella represents a moderate/small health risk for Norwegian pigs, but *Salmonella* is a zoonosis, and increased prevalence in the Norwegian pig population represents increased risk of infection for humans. *Salmonella* is a list-B disease and facilities that test positive will be placed under quarantine in accordance with FOR 1995-01-31 No. 107: Regulation on the surveillance and control of the presence of *Salmonella* in live cattle and pigs.

5.6. MRSA ST398

MRSA ST398 is a hazard when importing live pigs and possibly semen from the Netherlands because:

A large proportion of the pigs in the Netherlands are infected with MRSA ST398. The bacterium has not been detected in pigs in Norway when sampling at facilities.

The probability of MRSA being transmitted via semen is unknown but cannot be ruled out. At infected facilities, semen may theoretically be contaminated with MRSA ST398. Growth in diluted semen at 20° C for 1-4 days cannot be ruled out through antibiotic resistance. There are no known publications that have studied the presence and growth of MRSA ST398 in boar semen, or looked at whether the bacterium can be spread to new facilities via artificial insemination.

No testing for MRSA ST398 takes place at the artificial breeding center. Repeated sampling at the SPF facility for exporting sows tested negative for MRSA ST398.

MRSA ST398 poses no health risk to Norwegian pigs, but introduction of the bacterium into the Norwegian pig population may result in increased risk of infection at human healthcare facilities.

MRSA is not on the list of reportable infectious agents in animals. It is not likely that official restrictions will be imposed in the event of MRSA being detected in pigs.

5.7. Summary of relevant hazards

Table 1. Hazard identification regarding the import of live sows and fresh semen from the Netherlands as of 1.1.2012

Agent	Present in the Netherlands	Can be transmitted via		Hazard	
		Sows	Semen	Sows	Semen
PRRSv	Yes	Yes	Yes	Yes	Yes
SIv	Yes	Yes	No	Yes	No
PRCv	Yes	Yes	No	Yes	No
TGEv	Unknown*	Yes	Unknown	Yes**	Yes**
Salmonella	Yes	Yes	Unknown	Yes	Yes**
MRSA ST398	Yes	Yes	Unknown	Yes	Yes**

* probably occurs
** lack of knowledge, precautionary principle

6. Risk assessment of importing semen

The following infectious agents are further assessed for semen: PRRS, TGEv, *Salmonella* and MRSA.

In Section 6.1, only the probability that imported semen contains the infectious agents is assessed. In Section 6.2, the probability of infection spreading to Norwegian pigs is assessed.

6.1. Introduction of infectious agent via semen

An agent will be introduced with imported semen if all of the following events occur at the same time:

- The agent is present at the artificial breeding center
- The agent goes undetected at the artificial breeding center
- The agent is present in the semen imported into Norway and survives transport
- The agent goes undetected in the semen

In the following, the probability of each stage occurring is assessed, provided that the preceding stage has taken place and assessed in a 10-year perspective.

6.1.1 Probability of an agent being present in Topigs' artificial breeding center

The artificial breeding center was established relatively recently and has a high degree of biosecurity for a number of agents, including PRRSv. All three agents are frequently found in the Netherlands.

PRRSv: Very low, due to good documentation since start-up (2009), special status as 'unsuspected', requirements when recruiting boars. The artificial breeding center has remained free from PRRS for approximately 2 years.

TGEv: Unknown. Not tested. No requirements when recruiting boars.

Salmonella: Unknown. Not tested. No requirements when recruiting boars.

MRSA: Unknown. Not tested. No requirements when recruiting boars.

6.1.2 Probability that an agent goes undetected at the artificial breeding center, provided it is present

Undetected agents may be due to inadequate testing, low sensitivity of tests, or introduction of infection after testing.

PRRS: Very low, because the artificial breeding center is thoroughly tested and the test used has high sensitivity (97-99%), prevalence of PRRS is high in infected facilities. The artificial breeding center is tested regularly. The only alternative is if PRRSv is introduced shortly before semen collection (within a time interval corresponding to incubation time + test interval).

TGEv: Very high due to few clinical signs in adult animals and no testing.

Salmonella: Very high due to few clinical signs and no testing.

MRSA: Very high due to few clinical signs and no testing.

6.1.3 Probability of an agent being present in the semen imported into Norway and surviving transport (provided the agent is present and goes undetected at the artificial breeding center)

35-40 doses of semen are imported, from 4-5 different boars every 3 weeks. There are 320 boars at the artificial breeding center. This means that each import of semen comes from 1-2% of the boars at the artificial breeding center.

PRRS: Moderate to high, because PRRS spreads rapidly to many boars, and because semen is often infected in the viremic phase. The amount of infective virus in semen decreases with time after collection.

TGEv: Very low. TGE is excreted in an active infection phase of up to a few weeks, through the feces. Semen can be contaminated, but the amount of virus is thought to be low and will decrease over time after collection. Contamination is counteracted by good hygienic routines during semen collection, only clinically healthy, adult boars in semen production, short-term excretion, relatively low survival in an artificial breeding center environment.

Salmonella: Very low to low. Frequent occurrence of *Salmonella* in the Dutch pig population is counteracted by good hygienic routines during semen collection, only clinically healthy, adult boars in semen production, relatively low animal density, low and intermittent excretion of *Salmonella*, addition of Neomycin and Penicillin to the diluent.

MRSA: Low to moderate. Frequent occurrence of MRSA in the Dutch pig population and high prevalence in an infected facility is counteracted by good hygienic conditions during collection and the addition of Neomycin and Penicillin to the diluent.

6.1.4 Probability of an agent going undetected before semen is introduced to the import facility (provided that an agent is present and undetected in the semen)

PRRSv: Very high. No testing. Can be reduced to very low if semen is tested using PCR.

TGEv: Very high. No testing.

Salmonella and MRSA: Very high. No testing. Can be reduced to very low by cultivation from semen (before addition of antibiotics).

6.1.5 Summary per agent

Table 2. Probability that imported semen contains PRRSv.
the probability for each stage applies provided that the previous stage is positive (e.g. Probability of imported semen being infected is considered moderate to high given that the export facility is infected and the infection goes undetected).

PRRSv in semen	Probability	Comments
1. Export artificial breeding center is infected	Very low	High biosecurity, recruitment of boars only from PRRSv negative facilities
2. Infection goes undetected (given that the artificial breeding center is infected)	Very low	Frequent testing, sensitive method, high prevalence of infected pigs. Probability can be further reduced by testing donor boars immediately before and 2-3 weeks after semen collection
3. Imported semen is infected (given undetected infection at the artificial breeding center)	Moderate/High	In the event of a new infection at the artificial breeding center, many boars may be viremic for a period of time.
4. Infection in semen is not detected upon import (provided semen is infected)	Very high	No testing. Probability can be reduced to very low if semen is tested using PCR
Conclusion: AGENT IMPORTED	VERY LOW	

Table 3. Probability that imported semen contains TGEv
Probability for each stage applies provided that the previous stage is positive

TGEv in semen	Probability	Comments
1. Export artificial breeding center is infected	Unknown	No testing
2. Infection goes undetected (given that the artificial breeding center is infected)	Very high	No testing, rare clinical signs in adult animals
3. Imported semen is infected (given undetected infection at the artificial breeding center)	Very low	Short-term excretion, adult boars, hygiene during semen collection, semen not collected from boars that have fever or

		diarrhea, viruses are inactivated in the semen over time
4. Infection in semen is not detected upon import (provided semen is infected)	Very high	No testing. Probability can be reduced to very low if semen is tested using PCR
Conclusion: AGENT IMPORTED	VERY LOW	

Table 4. Probability that imported semen contains *Salmonella*
Probability for each stage applies provided that the previous stage is positive.

Salmonella in semen	Probability	Comments
1. Export artificial breeding center is infected	Moderate?	High biosecurity but high risk of infection in the Netherlands. Average in a 10-year perspective
2. Infection goes undetected (given that the artificial breeding center is infected)	Very high	No testing or clinical signs. Probability can be reduced to low through testing
3. Imported semen is infected (given undetected infection at the artificial breeding center)	Very low/low	Intermittent excretion, adult boars, semen not collected from boars that have fever or diarrhea, hygiene during semen collection, addition of antibiotics to semen – resistant strains only
4. Infection in semen is not detected upon import (provided semen is infected)	Very high	No testing. Can be reduced to very low by cultivation from each ejaculate.
Conclusion: AGENT IMPORTED	VERY LOW/LOW	

Table 5. Probability of introduction of MRSA to import facility via semen.
Probability for each stage applies provided that the previous stage is positive.

MRSA in semen	Probability	Comments
1. Export artificial breeding center is infected	Unknown	High biosecurity but high risk of infection in the Netherlands
2. Infection goes undetected (given that the artificial breeding center is infected)	Very high	No testing or clinical signs. Probability can be reduced to low through testing
3. Imported semen is infected (given undetected infection at the artificial breeding center)	Low/Moderate	Found on skin and in the environment. Addition of antibiotics to semen – resistant strains only
4. Infection is not detected on import (given that semen is infected)	Very high	No testing. Can be reduced to very low by cultivation from each ejaculate.
Conclusion: AGENT IMPORTED	LOW/MODERATE	

6.2. Norwegian pig population exposed to agent

If imported semen contains agents, the Norwegian pig population (in addition to the import facility) can be exposed to agents either through boars going to Norsvin's artificial breeding center, or through transfer to the environment, personnel, etc. In each case, several events must occur:

A. Exposure via boars
1. The agent is transmitted to animals at the import facility, AND
2. The agent is transmitted to boars born at the import facility, AND
3. The agent is not detected before boars are transferred to the artificial breeding center.

B. Exposure via environment, etc.
1. The agent is transmitted to animal transport, people, equipment, air, etc. AND
2. The agent comes into contact with Norwegian pigs.

For each route of infection (via boars or via environment, etc.), we assess the probability of each stage occurring, provided that the previous stage has occurred.

6.2.1 Exposure via boars

1. Probability of agents being transmitted to pigs at the import facility.
   An agent may be present in semen and contaminated packaging. The probability of transfer to the import facility will therefore depend on
   a. Possibility of transfer to inseminated sows in connection with insemination
   b. Hygiene lock routines when the package of semen enters the facility, and the possibility of infecting animals at the facility.

   PRRSv: Assessed as high. Can be found both in the semen and as contamination. Known to infect *in utero*. Probability of transmission via semen to recipient sows is thought to be high, but depends on infection dose. The probability of infection via packaging is considered very low/negligible.

   TGEv: Considered very low. Probability of transmission *in utero* from semen is unknown, but cannot be ruled out in the absence of evidence. The uterus has a good non-specific immune system during estrus, and is not the target organ for TGEv. Probably very low doses. No evidence that TGEv has been transmitted via semen.

   Salmonella and MRSA: Assessed as low. Probability of transmission *in utero* from semen is unknown, but cannot be ruled out in the absence of evidence. The uterus has a good non-specific immune system during estrus, and is not the target organ for *Salmonella*. Probably low doses, but growth in semen at 20° C for 1-4 days cannot be ruled out in the event of antibiotic resistance. Hygiene lock routines when the package of semen enters the facility can reduce the probability of agent transmission from contaminated packaging.

2. Probability of agents being transmitted to boars born at the import facility, given that pigs at the import facility are infected.

   The probability of at least one boar being infected is considered very high for all four agents.

3. Probability that an agent is not detected before the boars are transferred to the artificial breeding center, provided they are infected.

   PRRSv: testing takes place on many levels:
   - Inseminated sows: planned testing of at least 50% of inseminated sows, so that all donor boars are represented. Since the probability of transmission of PRRS via semen is uneven between sows, some may be infected even if others are negative. Horizontal transmission will lead to seroconversion in more animals than those infected *in utero*. Using Elisa, antibodies can be detected after 9-13 days. Such testing is therefore insufficient to guarantee that the semen was free from infection, even if all donor boars are represented.
   - Boar Isolation Facility 1: Boars are transferred to Boar Isolation Facility 1 every 6 weeks. Samples are taken from all boars after 3-4 weeks. Tested for PRRSv.
   - Boar Isolation Facility 2: The boars are also tested for PRRSv in Boar Isolation Facility 2 before being transferred to the artificial breeding center.

- Topigs' artificial breeding center: During the 12-week isolation period (each isolation period lasts 6 weeks), Topigs' artificial breeding center in the Netherlands has been tested 6 times for PRRSv in addition to clinical observation. There will be the possibility of expanding testing at the import facility and of the boars in Boar Isolation Facility 1 if the export facility were to become positive before the juvenile boars leave Boar Isolation Facility 1. Topigs must immediately inform Norsvin in the event of positive findings.

Therefore, the probability of undetected PRRSv is considered negligible when the juvenile boars are transferred to the artificial breeding center.

TGEv: TGE is likely to cause symptoms in piglets in the event of infection at the import facility. In the given assumptions, there is currently no planned routine testing, neither at Topigs' artificial breeding center, of inseminated sows, nor at the boar isolation facilities.
The probability that the agent goes undetected is considered low. It can be reduced to negligible by testing all juvenile boars in Boar Isolation Facility 1.

Salmonella and MRSA: Usually without symptoms in pigs. The import facility is tested once a year through the National Surveillance Program for *Salmonella*. No testing for MRSA is planned. The probability of undetected infection is very high.
The probability of undetected infection can be significantly reduced by testing all boars in Isolation Facility 1 for MRSA and *Salmonella* after 3-4 weeks in the isolation facility. The probability of undetected infection can be further reduced by testing environmental samples in addition to individual animals.

6.2.2 Exposure via environment, transport vehicles, personnel, etc.

1. Probability of an agent being transmitted from the import facility or boar isolation facilities to transport vehicles, people, equipment, air, etc.

   The import facility has already received semen from abroad (Sweden and Finland), so it is assumed that good biosecurity routines are in place. Isolation facilities have special hygiene routines that will reduce the probability of infection spreading to the environment.

2. Probability of agents coming into contact with Norwegian pig population

   The import facility is isolated (> 5 km from the nearest pig facility) and does not sell livestock to other facilities in Norway.

   Animals for slaughter are sent directly to slaughterhouses. Ordinary routines for slaughter hygiene, including washing and disinfection of transport vehicles, are assumed to protect against the spread of PRRSv, TGEv, *Salmonella* and MRSA. For example, slaughter on Fridays allows transport vehicles to stand empty during the weekend after washing and disinfection, and before transporting animals from other facilities.

   Tests for PRRSv are conducted frequently. Therefore, any infection will be quickly detected and measures implemented, which also prevent further infection via the environment, transport vehicles etc.

   Therefore, the probability of infection spreading to other pig facilities is assumed to be very low to negligible for PRRSv and very low for TGEv, *Salmonella* and MRSA.

6.2.3 Summary per agent

Table 6. Probability of the Norwegian pig population being exposed to PRRSv if imported semen is infected

Exposure assessment, PRRSv in semen	Probability	Comments
A. Infection via boars		
1. Agent is transmitted to pigs at the import facility (by insemination)	High	Insemination known route of transmission, dose dependent
2. Agent is transmitted to boars (given that the facility is infected)	Very high	Highly infectious disease
3. Agent not detected before boars enter the artificial breeding center (given that the boars are infected)	Negligible	Continued testing at Topigs' artificial breeding center while the juvenile boars are in isolation (12 weeks), testing of sows at the import facility and testing of boars in isolation facilities 1 and 2
Conclusion: ARTIFICIAL BREEDING CENTER BEING EXPOSED TO INFECTION VIA BOARS	NEGLIGIBLE	
B. Infection via environment/persons/animal transport		
1. Agent is transmitted to the environment/surroundings (comes from the import facility given that it is infected)	Very high	Airborne infection, virus in feces
2. Agent in contact with pigs at other facilities (given that it gets out of the facility)	Very low/Negligible	Isolation, personnel hygiene lock and distance. Pigs to boar isolation facility only and directly to slaughter. PRRS will be detected quickly due to testing.
Conclusion: OTHER PIG FACILITIES BEING EXPOSED TO INFECTION VIA ENVIRONMENT	VERY LOW/ NEGLIGIBLE	

Table 7. Probability of the Norwegian pig population being exposed to TGEv if imported semen is infected

Exposure assessment, TGEv in semen	Probability	Comments
A. Infection via boars		
1. Agent is transmitted to sows at the import facility (by insemination)	Very low	Transmission not documented, low dose, precautionary principle
2. Agent is transmitted to boars (given that the facility is infected)	Very high	Highly infectious disease
3. Agent not detected before boars enter the artificial breeding center (given that the boars are infected)	Low	Clinical signs common in piglets. Can be reduced to negligible through testing
Conclusion: ARTIFICIAL BREEDING CENTER BEING EXPOSED TO INFECTION VIA BOARS	VERY LOW/ NEGLIGIBLE	Can be reduced to negligible through testing
B. Infection via environment/persons/animal transport		
1. Agent is transmitted to the environment/surroundings (comes from the import facility given that it is infected)	High	Virus in feces
2. Agent in contact with pigs at other facilities (given that it gets out of the facility)	Very low	Isolation, biosecurity and distance
Conclusion: OTHER PIG FACILITIES BEING EXPOSED TO INFECTION VIA ENVIRONMENT	VERY LOW	

Table 8. Probability of the Norwegian pig population (artificial breeding center) being exposed to *Salmonella* if imported semen is infected

Exposure assessment, *Salmonella* in semen	Probability	Comments
A. Infection via boars		
1. Agent is transmitted to the import facility via insemination (given that the semen is infected)	Low	Lack of knowledge, precautionary principle, 10-year perspective. There is no evidence that *Salmonella* has spread between facilities via semen.
2. Agent is transmitted to boars (given that the import facility is infected)	Very high	Bacteria survive for long periods of time in the environment
3. Agent is not detected before boars are moved to the artificial breeding center (given that the boars are infected)	Very high	Annual testing at the import facility only, symptom-free. The probability can be reduced to low/very low by testing all boars in addition to environmental samples in Boar Isolation Facility 1
Conclusion: ARTIFICIAL BREEDING CENTER BEING EXPOSED TO INFECTION VIA BOARS	LOW	Changes to very low/negligible if boars and environmental samples are tested in Boar Isolation Facility 1
B. Infection via environment/persons/animal transport		
1. Agent is transmitted to the environment/surroundings (gets out of the import facility given that it is infected)	High	Transmitted to feces, personnel, etc. *Salmonella* is resistant in the environment
2. Agent comes into contact with pigs at other facilities (given that bacteria get out of the import facility)	Very low	Isolation, biosecurity and distance
Conclusion: OTHER PIG FACILITIES BEING EXPOSED TO INFECTION VIA THE ENVIRONMENT	VERY LOW	

Table 9. Probability of the Norwegian pig population being exposed to MRSA ST398 if imported semen is infected

Exposure assessment MRSA ST398 in semen	Probability	Comments
A. Infection via boars		
1. Agent is transmitted to import facility (given that the imported semen is infected)	Low	Lack of knowledge, precautionary principle. There is no evidence that MRSA ST398 has spread between facilities via semen.
2. Agent is transmitted to boars (given that the import facility is infected)	Very high	High prevalence, bacteria survive for long periods of time in the environment
3. Agent is not detected before boars enter the artificial breeding center (given that the import facility is infected and the infection has not been detected)	Very high	No testing at the import facility, symptom-free. Changes to low/very low if all boars and environmental samples are tested in Boar Isolation Facility 1
Conclusion: ARTIFICIAL BREEDING CENTER BEING EXPOSED TO INFECTION VIA BOARS	LOW	Changes to very low/negligible if boars and environmental samples are tested in Boar Isolation Facility 1
B. Infection via environment		
1. Agent is transmitted to the environment/surroundings (given that the import facility is infected)	High	MRSA is resistant in the environment
2. Agent in contact with pigs at other facilities (given that the import facility is infected and the infection is not detected)	Very low	Isolation, biosecurity and distance
Conclusion: OTHER PIG FACILITIES BEING EXPOSED TO INFECTION VIA THE ENVIRONMENT	VERY LOW	

6.3. Consequences of the Norwegian pig population being exposed to agents

6.3.1 PRRSv

If PRRSv enters the Norwegian pig population, it will have major health and economic consequences. From abroad, a 5-20% decrease in production has been reported in newly infected facilities. For Norsvin, the introduction of PRRSv will have a negative effect on exports. PRRS is a notifiable and B-listed disease and upon first detection in Norway an assessment will be made to combat infection with slaughter of positive herds. Sweden succeeded with such a strategy in 2007. The infection can be spread via livestock, air (3km), animal transport, semen, people and equipment. PRRSv has no consequences for human health.

The consequences of Norwegian pigs outside the import facilities and the boar isolation facilities being exposed to PRRSv imported via Yorkshire semen are therefore considered very severe.

6.3.2 TGEv

If TGEv enters the Norwegian pig population, it will have a great economic and animal welfare impact on pig production. TGEv is part of the National Surveillance Program for specific viral infections in pigs in Norway.

The consequences of Norwegian pigs outside the import facilities and the boar isolation facilities being exposed to TGEv imported via Yorkshire semen are therefore considered very severe.

6.3.3 Salmonella

There is a very low occurrence of *Salmonella* in Norwegian pigs.

With the exception of a few special swine pathogenic variants, *Salmonella* infection rarely leads to disease in Norwegian pigs.

There can be major economic consequences for individual producers affected by imposed control measures. An increased occurrence of *Salmonella* in pigs represents an increased risk of infection in humans via pork.

The probability of Norwegian pig production being exposed to *Salmonella* through contact with persons (workers, farmers) who themselves come from, or who have been on holiday in countries where *Salmonella* is far more common both in humans and animals, is considered significantly greater than through the described import of boar semen from the Netherlands. This is considered to apply even if *Salmonella* is introduced to the artificial breeding center, because semen is not a known route of infection for *Salmonella*.

The consequences of the Norwegian pig population being exposed to *Salmonella* due to imports of semen are therefore assessed as moderately significant.

6.3.4 MRSA ST398

MRSA ST398 has not been detected in Norwegian pigs tested at facilities.

MRSA ST398 does not cause disease in Norwegian pigs. An increased prevalence of MRSA in pigs represents an increased risk of infection at Norwegian healthcare facilities.

Possible prevalence of MRSA in imported semen is considered to represent a very low additional risk when importing into Norway compared to import via people with contact abroad. This is considered to apply even if MRSA is introduced to the artificial breeding center, because semen is not a known route of infection for MRSA.

The consequences of the Norwegian pig population being exposed to MRSA ST398 due to the import of semen are therefore considered of little significance.

6.4. Overall risk assessment

This section compiles all assessments made regarding the import of agents, the spread of agents, and the consequences of infection spreading when this is relevant (not negligible probability). In addition, the effect of proposed additional measures is specified.

Based on the assumptions made, and the sub-assessment presented above, the following assessments have been made:

6.4.1 Risk of importing PRRSv to the Norwegian pig population via semen

The probability that imported semen contains PRRSv is considered very low. This is due to high biosecurity (only boars from PRRSv-free facilities, and boars that test negative) and frequent testing at the export artificial breeding center.

However, if semen were to contain PRRSv, the probability of Norwegian pigs becoming exposed to it (other than the import facility and boars in isolation) is assessed as:

- negligible via boars (due to testing of sows, continued surveillance of the Dutch artificial breeding center while the boars are in Norwegian isolation facilities, and testing of boars in isolation facilities 1 and 2 before transfer to the artificial breeding center), and
- very low via environment, animal transport vehicles, employees etc. due to high biosecurity. Due to ongoing testing at Topigs' artificial breeding center, the import facility and of boars in isolation, any infection with PPRSv will be quickly detected so that additional measures can be implemented.

The probability that semen contains undetected PRRSv AND that it simultaneously spreads to Norwegian pigs outside the import facility and Boar Isolation Facility 1 is considered negligible.

6.4.2 Risk of importing TGEv via semen

The probability of imported semen containing TGEv is considered very low. This is due to high biosecurity with a low probability of semen contamination (excreted in feces), short-term excretion, clinically healthy adult animals, inactivation in semen.

However, if semen were to contain TGEv, the probability of Norwegian pigs becoming exposed to it (other than the import facility and boars in isolation) is assessed as:

- very low to negligible via boars, because semen is not considered a route of infection for TGEv; and because infection at the import facility would most likely be detected due to clinical signs in piglets. Can be further reduced through testing in Boar Isolation Facility 1.
- very low via the environment, animal transport vehicles, employees etc. due to high biosecurity.

The probability that semen contains undetected TGEv AND that it simultaneously spreads to Norwegian pigs outside the import facility and Boar Isolation Facility 1 is considered low to negligible
The probability can be reduced to negligible through testing of juvenile boars in Boar Isolation Facility 1.

6.4.3 Risk of importing Salmonella *via semen*

The probability that imported semen contains *Salmonella* is considered very low to low. This is due to intermittent excretion, low prevalence, low probability of contamination of semen with feces, and the use of antibiotics in the semen.

However, if semen were to contain *Salmonella*, the probability of animals outside the import facility and the boar isolation facilities being exposed to infection via boars is considered low (due to a moderate probability of transmission to the import facility) and very low via the environment, animal transport vehicles, employees, etc., due to high biosecurity. The probability of infection spreading can be reduced to very low/negligible through the testing of all boars in Boar Isolation Facility 1.

The probability that semen contains undetected *Salmonella* AND that it simultaneously spreads to Norwegian pigs outside the import facility and boar isolation facilities is considered very low. It can be reduced by testing boars in Boar Isolation Facility 1.

Consequences of the Norwegian pig population being exposed to *Salmonella* due to the import of semen are considered moderately significant.

6.4.4 Risk of importing MRSA ST398 via semen.

The probability of imported semen containing MRSA ST398 is considered low to moderate. This is due to the moderate probability of contamination (somewhat higher than for Salmonella and TGEv), and the use of antibiotics in the semen.

However, if semen were to contain MRSA ST398, the probability of animals outside the import facility being exposed to infection via boars is considered low (due to a moderate probability of transmission to the import facility) and very low via the environment, animal transport vehicles, employees, etc., due to high biosecurity.

The probability that semen contains undetected MRSA ST398 AND that it spreads to Norwegian pigs outside the import facility and boar isolation facilities is considered low.

It can be reduced by testing boars in Boar Isolation Facility 1.

The consequences of the Norwegian pig population being exposed to MRSA ST398 due to imports of semen are considered to be of little significance.

7. Risk assessment of importing sows

The following infectious agents are assessed for the import of sows:

- PRRSv
- SIv
- TGEv
- PRCv
- *Salmonella*
- MRSA ST398

7.1. Introduction of relevant infectious agents to Norway, beyond import isolation facilities

An infectious agent will be introduced to the import facility (via juvenile sows) or to Norsvin's artificial breeding center (via juvenile boars) if all of the following events occur at the same time:

- The agent is present at the export facility
- The agent remains undetected at the export facility until the offspring of imported sows are introduced to the import facility
- The agent is present in the 15-20 sows imported into Norway
- The agent survives transport to Norway
- The agent is not detected in the sows before the offspring are introduced to the import facility
- The agent is transmitted to the offspring
- The agent is not detected in the offspring before they are introduced to the import facility (sows) or to Norsvin's artificial breeding center (boars)

7.1.1 Probability that the export facility is infected at the time of export.

General information about the export facility: SPF facility with good infection hygiene.

Documented infection status:

PRRSv: Free from, well documented (78-488 samples annually since 2007)

SIv: unclear – was negative in 2009 (120 samples), somewhat positive in 2010-11, uncertain whether it is pandemic H1N1 or porcine-adapted variants (17 positive for H1N1 out of 40 samples in 2011, 2 of the positive for H3N2)

TGEv: Not tested in the period 2007-2011

PRCv: Not tested in the period 2007-2011 but presumed positive

Salmonella: Tested in 2010 (Serology 1 positive (OD>40) out of 42 samples and 2011 (36 samples, no positive)

MRSA ST398: There are good procedures in place for biosecurity and health documentation at Topigs' artificial breeding centers. All negative. Unknown sample material.

Probability of infection being introduced:

All agents except TGEv are known to be endemic in the Netherlands. The status of TGEv is unclear due to lack of testing.

Estimated probability that an agent is present at the export facility at the time of export:

PRRSv: Very low

SIv: Very high

TGEv: Unknown

PRCv: Very high

Salmonella: Low/very Low

MRSA ST398: Low/very Low

7.1.2 Probability that an agent will remain undetected at the export facility up until the offspring of imported sows are introduced to the import facility (given that the export facility is infected)

After the imported sows have left the export facility, they are kept in Import Isolation Facility 1 approximately 3 weeks before farrowing. Thereafter, the offspring are transferred to Import Isolation Facility 2, where they stay for a minimum of 5 months. Therefore, approximately 6 months pass from the time the sows leave the export facility until the offspring are transferred to the import facility. During this period, any detection of infectious agents at the export facility may result in additional measures in Norwegian isolation facilities.

According to general import rules, all export animals must be kept in isolation for 30 days in the exporting country and tested for all hazards discussed in this report. In this specific case, this will take place in the facility of origin, which is assumed to have adequate infection hygiene in order to operate as an isolation facility. The possibility of contamination of the sows after testing is present.

Based on the testing regime at the export facility, it is likely that the facility will be tested several times in the 6-7 months that run from the time the sows have left the export facility until the juvenile sows are to be moved from Isolation Facility 2 to the import facility.

PRRSv: The probability of not detecting newly introduced PRRSv is very low through routine testing during this period.

SIv: Has been detected.

PRCv: Very high probability of not detecting due to lack of testing, but presumed present.

TGEv: The probability of not detecting agent is very high. TGE probably wouldn't cause symptoms because the animals are presumed immune due to PRCv, no routine testing. The probability can be reduced to very little if testing is carried out at the facility.

Salmonella: The probability of not detecting agent is considered moderate because serological testing of relatively few animals takes place.

MRSA ST398: The probability of not detecting agent is considered moderate due to little routine testing, but good sensitivity at facility level.

7.1.3 Probability of an agent being present in the 15-20 sows imported into Norway

The export facility consists of 380 sows and 2800 pen places for juvenile pigs. The 15-20 animals to be imported are a small proportion of this herd, and none of the diseases referred to have a 100% prevalence. However, we assume that some of the animals selected for export will be infected if the facility is infected. *Salmonella* may be an exception due to low prevalence.

7.1.4 Probability of an agent surviving transport to Norway

If agents are present in the livestock when leaving the facility, they will be present when they arrive at the import isolation facility. Washing the sows with disinfectant upon arrival (Virkon S) will not remove MRSA or *Salmonella* from the animals because the agent is also present on mucous membranes and intestinal contents (*Salmonella*).

7.1.5 Probability that an agent is not detected in the imported sows before the offspring is introduced into the import facility (sows) or the artificial breeding center station (boars)

All sows must be tested for all hazards at the export isolation facility, twice for *Salmonella* (culture), and once for the others. The results must be available before transport to Norway.

In addition, all sows must be tested after 2-4 weeks at Import Isolation Facility 1 for the viral diseases. For *Salmonella*, they must be tested at Week 1 (shortly after transport) and Week 3, both times through cultures from fecal samples. For MRSA, one sample per animal (nose swab) must be taken during the stay. Consider testing for MRSA while taking samples for *Salmonella*.

There is a very small possibility that the sows may be contaminated after testing at the export isolation facility, either from the export facility or during transport to Norway.

It is assumed that there will be positive findings for antibodies against PRCv and SIv

SIv and PRRSv testing have high sensitivity (97-99%), and the probability of not detecting infection during the specified testing is considered very low/negligible.

TGEv and PRCv testing also have high sensitivity (93%, with 95% CI 77-99%), and the probability of not detecting the infection with the specified test regimen is considered very low/negligible.

Test sensitivity for *Salmonella* in bacteriology is low at the individual level. All sows must be tested twice at Export Isolation Facility and twice at the Import Isolation Facility. The probability of not detecting infection in the population of imported sows is considered very low. Consider analyzing environmental samples in addition to individual samples.

MRSA ST398 test sensitivity is moderate/high at the individual level. All sows must be tested once at the Export Isolation Facility and once at Import Isolation Facility 1. The probability of not detecting infection is considered very low. Consider analyzing environmental samples in addition to individual samples.

7.1.6 Probability of an agent being transmitted to offspring

Vertical transmission *in utero* is known for PRRSv, not the other agents. For transmission to take place, the sows must be viremic during pregnancy. This will happen if the sows are infected shortly before, or during pregnancy, for example during transport.

Horizontal transmission may occur in Import Isolation Facility 1, if the sows excrete viruses or bacteria during this period of approximately one month. It assumes that they are relatively newly infected with viral infections (approximately 14 days for SIv to one month for PRRSv).

The offspring will be exposed to possible agents for 4-5 days, from birth to weaning. During this period, they are normally considered well protected against viral infections that the mother may have had, due to the transfer of maternal immunity in colostrum. This applies to a lesser extent to *Salmonella* and MRSA. This also applies to a small extent to newly infected sows, which have limited amounts of antibody at the time of birth.

The probability of transmission to the offspring, if the sows are infected (and actively shedding or excreting), is considered high for *Salmonella* and very high for other relevant hazards.

7.1.7 The probability that an agent in the offspring is not detected before the offspring is introduced to the import facility (sows) or the artificial breeding center (boars).

The offspring must be kept at Import Isolation Facility 2 for least 5 months. There, a representative sample of the pigs must be tested at 12 weeks of age, and all pigs to be used in breeding (approximately 75-90) must also be tested before moving to the import facility or artificial breeding center.

Viruses will be tested using serological testing. MRSA ST398 and *Salmonella* will be tested using cultures from individual and, if applicable, environmental samples.

In the event of infection with viruses, the antibody level will reach measurable levels after 2-4 weeks. The level will remain above the limit of detection for at least 6 months. Any maternal antibodies are thought to last for 8-10 weeks.

If offspring are infected with PRRSv, SIv, TGEv or PRCv, prevalence of serologically positive animals is expected to be high. The number of animals that seroconvert will increase over time as the infection spreads.

The sensitivity of the test at the facility level (at least one animal tests positive) depends on the sensitivity of the test at the individual level and the prevalence of infected animals at the facility.

For the viruses in question and MRSA ST398, the prevalence is believed to be high. Since all animals (75-90 offspring) that are to be moved on to the import facility or artificial breeding center are tested, even a moderate sensitivity to MRSA detection at the individual level is compensated by the large number of tests. The probability that none give a positive result if an agent is present is considered negligible.

For *Salmonella*, it is assumed that only a few of the animals will be carriers. In addition, there may also be intermittent excretion in juvenile animals. Therefore, if testing takes place in the form of cultures from feces, there will be a possibility of not detecting infection. This possibility will also be lower in cultures from environmental samples and significantly lower in serological testing for *Salmonella*, but there is also the possibility of false positive reactions.

7.1.8 Summary per agent

Table 10. Probability of introduction of PRRSv to import facility via livestock.
Probability for each stage applies provided that previous stages are positive.

Introduction PRRSv livestock	Probability	Comments
1. Export facility is infected	Very low	High biosecurity, never detected PRRSv
2. Infection at the export facility is undetected (given that the export facility is infected)	Very low	Testing several times a year, sensitive method
3. The sows for export are infected (given undetected infection at the export facility)	Very high	
4. Agent survives transport (given that the sows are infected)	Very high	
5. Infection in the sows is undetected (given that they are infected)	Very low/Negligible	15-20 animals in close contact are tested, high test sensitivity and agent prevalence, all animals are tested twice
6. Agent is transmitted to the offspring (given undetected infection in the sows)	Very high	Vertically and/or horizontally
7. Infection in the offspring is undetected (given that they are infected)	Negligible	75-90 animals in close and long-term contact are tested, high test sensitivity and agent prevalence, all animals are tested twice
CONCLUSION: Agent is imported	NEGLIGIBLE	

Table 11. Probability of introduction of SIv (other than pandemic) to import facility via livestock.
Probability for each stage applies provided that previous stages are positive.

Introduction SIv livestock	Probability	Comments
1. Export facility is infected	Very high	Serologically positive for H1N1 and H3N2, not documented to be pandemic
2. Infection at the export facility is undetected (given that the export facility is infected)	Has been detected	
3. The sows for export are infected (given undetected infection at the export facility)	Very high	
4. Agent survives transport (given that the sows are infected)	Very high	
5. Infection in the sows is undetected (given that they are infected)	Very low/negligible	15-20 animals in close contact are tested, high test sensitivity and agent prevalence, tested twice
6. Agent is transmitted to the offspring (given undetected infection in the sows)	Very high	Horizontal infection
7. Infection in the offspring is undetected (given that they are infected)	Negligible	75-90 animals in close and long-term contact are tested, high test sensitivity and agent prevalence, all animals are tested twice
CONCLUSION: Agent is imported	NEGLIGIBLE	

Table 12. Probability of introduction of TGEv to import facility via livestock.
Probability for each stage applies provided that previous stages are positive.

Introduction TGEv livestock	Probability	Comments
1. Export facility is infected	Unknown	Not tested, status in Netherlands unknown
2. Infection at the export facility is undetected (given that the export facility is infected)	Very high	No testing
3. The sows for export are infected (given undetected infection at the export facility)	Very high	
4. Agent survives transport (given that the sows are infected)	Very high	
5. Infection in the sows is undetected (given that they are infected)	Very low/negligible	15-20 animals in close contact are tested, high test sensitivity and agent prevalence, tested twice
6. Agent is transmitted to the offspring (given undetected infection in the sows)	Very high	Horizontal infection
7. Infection in the offspring is undetected (given that they are infected)	Negligible	75-90 animals in close and long-term contact are tested, high test sensitivity and agent prevalence, all animals are tested twice
CONCLUSION: Agent is imported	NEGLIGIBLE	

Table 13. Probability of introduction of PRCv to import facility via livestock.
Probability for each stage applies provided that previous stages are positive.

Introduction PRCv livestock	Probability	Comments
1. Export facility is infected	Very high	Not tested, high prevalence in the Netherlands
2. Infection at the export facility is undetected (given that the export facility is infected)	Very high	No testing
3. The sows for export are infected (given undetected infection at the export facility)	Very high	
4. Agent survives transport (given that the sows are infected)	Very high	
5. Infection in the sows is undetected (given that they are infected)	Very low/negligible	15-20 animals in close contact are tested, high test sensitivity and agent prevalence, tested twice
6. Agent is transmitted to the offspring (given undetected infection in the sows)	Very high	Horizontal infection
7. Infection in the offspring is undetected (given that they are infected)	Negligible	75-90 animals in close and long-term contact are tested, high test sensitivity and agent prevalence, all animals are tested twice
CONCLUSION: Agent is imported	NEGLIGIBLE	

Table 14. Probability of the introduction of *Salmonella* to import facility via livestock.
Probability for each stage applies provided that previous stages are positive.

Introduction *Salmonella* livestock	Probability	Comments
1. Export facility is infected	Low/Very Low	Only one positive serology, high biosecurity, infection can spread from people
2. Infection at the export facility is undetected (given that the export facility is infected)	Moderate	Little testing, but with serology
3. The sows for export are infected (given undetected infection at the export facility)	High	
4. Agent survives transport (given that the sows are infected)	Very high	
5. Infection in the sows is undetected (given that they are infected)	Very low	15-20 animals in close contact are tested, low test sensitivity (culture) and agent prevalence. Testing (culture) of all animals twice before import and twice at Isolation Facility 1.
6. Agent is transmitted to the offspring (given undetected infection in the sows)	High	Horizontal infection, moderate to low prevalence
7. Infection in the offspring is undetected (given that they are infected)	Low/Very Low	75-90 animals in close and long-term contact are tested, low test sensitivity and agent prevalence, higher probability of detecting infection by supplementing with environmental samples.
CONCLUSION: Agent is imported	VERY LOW/ NEGLIGIBLE	Negligible if offspring are tested serologically

Table 15. Probability of introduction of MRSA ST398 to import facility via livestock.
Probability for each stage applies provided that previous stages are positive.

Introduction MRSA livestock	Probability	Comments
1. Export facility is infected	Low/Very Low	High biosecurity, can spread from people. No positive samples.
2. Infection at the export facility is undetected (given that the export facility is infected)	Moderate	Low testing
3. The sows for export are infected (given undetected infection at the export facility)	Very high	
4. Agent survives transport (given the sows are infected)	Very high	
5. Infection in the sows is undetected (given they are infected)	Very low	15-20 animals in close contact are tested, good test sensitivity and high agent prevalence
6. Agent is transmitted to the offspring (given undetected infection in the sows)	Very high	Horizontal infection, also via the environment
7. Infection in the offspring is undetected (given that they are infected)	Negligible	75-90 animals in close and long-term contact are tested, good test sensitivity and high prevalence of agents, consider supplementing with environmental samples
CONCLUSION: Agent is imported	NEGLIGIBLE	

7.2. Exposure of Norwegian pig population to agent

A negligible probability of importing all agents except *Salmonella* has been found, unless serology is used when importing.

Therefore, only *Salmonella* is assessed here.

If *Salmonella* is introduced to the import facility via juvenile sows, it may be further spread either via environment, personnel, transport vehicles, etc., or via boars to the artificial breeding center. Reference is made to previous analysis after import of infected semen, where this has been discussed (Section 6.2). The only difference is that infected sows will be able to infect other animals more effectively than when infection is introduced via semen.

If *Salmonella* is introduced to Norsvin's artificial breeding center via juvenile boars, the probability of it spreading to other boars at the center is very high.

Table 16. Probability of Norwegian pig population (artificial breeding center) being exposed to *Salmonella* when importing livestock (given that juvenile sows are infected)

Exposure assessment, *Salmonella* in livestock	Probability	Comments
A. Infection via boars		
1. Agent is transmitted to import facility from juvenile sows (given that they are infected)	Very high	
2. Agent is transmitted to boars (given that the facility is infected)	Very high	Bacteria survive for a long period of time in the environment
3. Agent is not detected before the boars are moved to the artificial breeding center (given that the boars are infected)	Very high	Annual testing at the import facility only, symptom-free. The probability can be reduced to low/very low by testing all boars in Isolation Facility 1
Conclusion: ARTIFICIAL BREEDING CENTER BEING EXPOSED TO INFECTION VIA BOARS	VERY HIGH	See comment above
B. Infection via environment/persons/animal transport		
1. Agent gets out of the facility (given that the import facility is infected)	High	Transmitted to fertilizers, personnel, etc. *Salmonella* is resistant in the environment
2. Agent comes into contact with pigs at other facilities (given that the bacteria gets out of the import facility)	Very low	Isolation, biosecurity and distance
Conclusion: OTHER PIG FACILITIES BEING EXPOSED TO INFECTION VIA THE ENVIRONMENT	VERY LOW	

7.3. Consequences of Norwegian pig population being exposed to an agent

This is applicable here for *Salmonella* only and reference is made to Section 6.3.

7.4. Overall risk assessment

Based on the assumptions made, and the sub-assessment presented above, the following assessments have been made:

The probability of importing PRRSv, SIv, PRCv, TGEv and MRSA into the import facility via import of pregnant sows is assessed as negligible.

The probability of importing *Salmonella* into the import facility or Norsvin's artificial breeding center via the import of pregnant sows is assessed as negligible if the offspring are serologically tested in addition to compulsory culture samples. Otherwise, the probability is assessed as very small to negligible.

The consequences of the Norwegian pig population being exposed to *Salmonella* due to imports of live sows are considered moderately significant.

8. Conclusion

PRRSv, SIv, TGEv, PRCv, *Salmonella* and MRSA ST398 were assessed as being hazards when importing livestock. Only PRRSv, TGEv, *Salmonella*, and MRSA ST398 were assessed as hazards when importing semen. While PRRSv is known to be transmissible via semen, the situation is unknown regarding TGEv, *Salmonella* and MRSA ST398, and these are included as a precaution due a theoretical possibility of semen contamination. SIv and PRCv are not considered to be transmissible via semen, and they are therefore not defined as hazards when importing semen.

Based on the assumptions made (including a 10-year perspective), the overall risk assessment of **importing semen** is as follows:

- PRRSv: The probability of imported semen containing PRRSv is considered very low. The probability that any PRRSv in the semen is also spread to Norwegian pigs outside the import facility and Boar Isolation Facility 1 is considered negligible.
- TGEv: The probability that imported semen contains TGEv is considered very low. The probability that any TGEv in the semen is also spread to Norwegian pigs outside the import facility and boar isolation facilities is considered very low to negligible. The probability of TGEv spreading can be reduced to negligible by adequate testing.
  The consequences of the Norwegian pig population outside of the import facility and the boar isolation facilities being exposed to TGEv imported with Yorkshire semen are considered severe.
- *Salmonella*: The probability that imported semen contains *Salmonella* is considered very low to low. The probability that any *Salmonella* in the semen is also spread to Norwegian pigs outside the import facility and the boar isolation facilities is considered very low. The assessment is associated with a lot of uncertainty due to lack of knowledge about the infection status of the boar center, the resistance of any strains to antibiotics used, and the possibility of transmission of infection via semen. The probability can be reduced by testing boars in Boar Isolation Facility 1.
  Consequences of the Norwegian pig population being exposed to *Salmonella* due to the import of semen are considered moderately significant.
- MRSA ST398: The probability that imported semen contains MRSA ST398 is considered low to moderate. The probability that any MRSA ST398 in the semen is also spread to Norwegian pigs outside the import facility and boar isolation facilities is considered low. The assessment is associated with a lot of uncertainty due to lack of knowledge about the infection status of the boar center, the resistance of any strains to antibiotics used, and the possibility of transmission of infection via semen. The probability can be reduced by testing boars in Boar Isolation Facility 1.
  The consequences of the Norwegian pig population being exposed to MRSA ST398 due to imports of semen are considered to be of little significance.

Based on the assumptions made (including a one-off event and thorough testing), the overall risk assessment **of importing livestock** is as follows:

- PRRSv, SIv, PRCv, TGEv, and MRSA ST398: The probability of importing these agents into the import facility or Norsvin's artificial breeding center via the import of pregnant sows is considered negligible.
- *Salmonella:* The probability of importing *Salmonella* into the import facility or Norsvin's artificial breeding center via the import of pregnant sows is considered very small to negligible. It can be reduced to negligible if the offspring is tested serologically in addition to compulsory culture samples.
  The consequences of the Norwegian pig population being exposed to *Salmonella* due to imports of live sows are considered moderately significant.

Since there are possibilities for the introduction of agents, and/or animals with positive serology, it is important that adequate contingency plans are in place before importing. It is important to have good hygienic routines in the isolation facilities and in the import facility in order to prevent the spread of infection via personnel, animal transport, etc. Both conditions are assumed in our assessment.

Table 17. Summary of probabilities of importing agents into the Yorkshire import facility, the spread of agents to Norsvin's artificial breeding center or other facilities in the event of agents being imported, and combined probability of import and spread.

	PRRSv	SIv	TGEv	PRCv	*Salmonella*	MRSA ST398
IMPORT OF SEMEN						
Agent is imported	Very low	-	Very low	-	Very low/Low	Low/Moderate
Agent is spread via: juvenile boars	Negligible	-	Negligible /Very low	-	Low	Low
spread via: people, animal transport, environment...	Negligible /Very low	-	Very low	-	Very low	Very low
Agent is imported and spreads	**Negligible**	**-**	**Negligible /Very low**	**-**	**Very low**	**Low**
IMPORT OF SOWS						
Agent is imported	Negligible	Negligible	Negligible	Negligible	Negligible /Very low	Negligible
Agent spreads via: juvenile boars	-	-	-	-	Very high	-
spreads via: people, animal transport, environment...	-	-	-	-	Very low	-
Agent is imported and spreads	**Negligible**	**Negligible**	**Negligible**	**Negligible**	**Negligible /Very low**	**Negligible**

9. Background documentation

9.1. Livestock industry's additional requirements when importing boar semen

KOORIMP will assess each semen import in relation to the sending country's livestock health situation at the time of collection. The introduction of semen into Norwegian facilities must also be assessed specifically for each import.

Additional requirements PRRS:

Semen should only be imported from centers where all animals are clinically documented free from infection, not vaccinated against and serologically negative for antibodies to PRRS. (This is an official requirement for the use of semen in Norwegian facilities, even if it is not an official requirement for the exporting center).

When importing frozen semen from countries that have PRRS, the boars are required to be examined for antibodies to PRRS with a negative result before semen collection and 3 weeks after semen collection at the earliest.

When importing fresh semen from countries that have PRRS, isolation of all recipient animals is required. The isolation facility must meet official isolation requirements and be at least 3 km away from other pig husbandry/facilities. Before the recipient animals can be released from the isolation facility, they must be examined for antibodies to PRRS with a negative result at least 4 weeks after insemination.

The import of semen from countries free from PRRS may, after special assessment, take place without isolation of recipient animals.

Effective from 24/09 2009.

9.2. Livestock industry's additional requirements when importing live pigs

Moving live animals poses the greatest risk of spreading infection as opposed to semen and embryos. The Norwegian livestock industry will therefore always recommend importing new breeding stock in the form of semen and embryos rather than importing live animals.

If one chooses to import livestock, the importer is required to contact KOORIMP beforehand so that KOORIMP can assess the export facility and its health status requirements. Below is an overview of the minimum requirements for importing live pigs. A full overview of additional requirements will be prepared after the importer has contacted KOORIMP so that the livestock health situation in the sending country and export facility can be assessed.

Export facility:

The facility should have been closed (not receiving live animals) for at least one year.

Vaccination against PRRS, swine influenza or Aujeszky's disease should not take place at the facility.

PMWS: equivalent requirements for sales in Norway.

Brucella suis: The facility must be examined for Brucella suis (serology).

Dust samples must have been taken from the environment where the pigs were kept before they were transferred to the isolation facility.

Export animal requirements:

Animals must be born at the export facility.

During the last 30 days prior to shipment, export animals must be isolated and examined with negative results for:

Salmonella (culture of feces twice with at least a 14-day interval). This is not a requirement when importing from Sweden or Finland, but it is advisable to also carry out testing when importing from these countries.

Swine influenza (serology) (H_1N_1, H_3N_2)

PRRS (porcine reproductive and respiratory syndrome) (serology) (both field and vaccine viruses/European/American)

TGE (transmissible gastroenteritis) (serology)

PED (porcine epidemic diarrhea) (serology)

PRCV (porcine respiratory coronavirus) (serology)

Mycoplasma hyopneumonia (serology)

Actinobacillus pleuropneumonia serotype 5 (serology)

Leptospira Pomona (serology)

Methicillin-resistant *Staphylococcus aureus* (MRSA) (nose swabs)

Treatment:

Treatment against internal and external parasites during the last 7 days before the animals are exported to Norway.

After arrival in Norway:

The imported animals must be isolated for at least two months after arrival in Norway. The isolation facility must meet official isolation requirements.

Sanction pattern in the event of violation of the requirements

An agreement has been written between the organizations behind KOORIMP to assess the necessary measures if the recommendations in connection with imports are not voluntarily followed.

Documentation for meeting KOORIMP's additional import requirements is a requirement in the Quality System in Agriculture (KSL). Failure to meet KOORIMP's additional requirements may result in KSL deductions for milk and meat production. To avoid KSL deductions in relation to slaughter, the meat industry requires *all* meat production from the farm (i.e. from all animal species where KSL requirements have been prepared) to meet the KSL standard.

In connection with insurance payments, livestock owners who do not meet KOORIMP's additional import requirements may receive a reduction in compensation.

In addition, the breeding organizations will refuse to deliver semen to and perform artificial breeding services at the facility, and the slaughterhouses will refuse to sell and distribute live animals to and from the facility.

Effective from: 24/09 2009

9.3. Summary of FOR 2006-02-14 No. 199

Government requirements for isolation facilities when importing live pigs into Norway (FOR 2006-02-14 No. 199: Instructions for the Norwegian Food Safety Authority, District Offices, regarding isolation and examination of animals.)

Isolation period minimum 2 months

The following provisions are particularly important in connection with the risk assessment:

- Isolation facilities must be approved by the Norwegian Food Safety Authority. Pigs must be isolated indoors and the building must be at least 3 km away from animal husbandry involving species susceptible to relevant diseases/agents. There are specific requirements for infection protection for persons, handling fertilizers and avoiding contact with wild animals.
- The Norwegian Food Safety Authority will supervise the washing and disinfection of the means of transport, the animals upon arrival and at least once a week for the first 4 weeks.
- Blood samples: After 4 weeks in isolation, blood samples of all animals must be taken for examination for antibodies to agents that may cause:
    - Compulsory: PRRS, swine influenza, PED, TGE, PRCV,
    - After assessment: Brucellosis, Classical swine fever, African swine fever, Leptospirosis (6 serotypes), AD and SVD.
- Feces samples: For examination for *Salmonella* in weeks 1 and 3, all animals

9.4. General information about infection via semen

This chapter is essentially taken from Maes D et al 2008, Guérin B and Pozzi N 2005, Althouse GC and Rossow K 2011 and AQIS, 1999 and 2000;

With regard to infection control, artificial insemination is a favorable method for introducing new genes into a population. However, there are a number of microbes, both apathogenic and pathogenic, bacteria and viruses that can be found in semen.

Semen may be contaminated due to systemic infection (bacteremia/viremia) or local infection in the urine and genitals of the donor. The semen may also be contaminated (from the foreskin, skin, feces, air, surroundings) in connection with semen collection, processing or use of the semen.

It has been documented that some infections, such as classical swine fever and PRRS, can be transmitted and cause disease in recipient animals in connection with artificial insemination. Whether the presence of an infectious agent in the semen will cause infection and disease in the sows and/or embryo/fetus depends on the amount of agent, its virulence and ability to multiply in the sows' reproductive organs.

Due to the risk of extensive spread of infection through the use of artificial insemination, artificial breeding centers are subject to government regulations: *FOR 2003-07-17 No. 972: Regulations on animal health conditions for the production, import, export and use of boar semen.* There are requirements for infection prevention measures and systematic testing to document that the boars at the artificial breeding center are free from defined infectious agents that can be transmitted via semen, such as PRRS.

General measures to reduce the risk of infection with defined infectious agents via semen

- Only recruit boars from facilities that are documented free from the relevant agents
- Test all boars before they enter boar quarantines
- Test all boars after a minimum of 4 weeks stay in boar quarantines and before moving them to the artificial breeding center
- Regular testing of a representative sample of boars at the artificial breeding center
- Clinical surveillance of the boars, only collect semen from healthy boars with a normal body temperature
- Each ejaculate can be tested for the presence of defined infectious agents, such as PRRSv, using RT-PCR (a highly sensitive method).
- Broad-spectrum antibiotics that inhibit the growth of bacteria are added to all semen.

Pathogens that have been detected in boar semen

Bacteria

- Brucellosis
- Chlamydia
- Leptospirosis (bratislava and muenchen) have been detected in the genital tract of boars and it is believed that infection can be transmitted via semen (Ellis et al. 1985 Ellis et al. 1986)
- Mycoplasma sp (less relevant in pigs)
- Tuberculosis

In the production of semen, the artificial breeding centers are required to add antibiotics that reduce the risk of pathogenic bacteria growth. However, due to possible bacterial resistance, one can never guarantee that a dose of semen will be free from pathogenic bacteria.

Virus

The risk of semen containing a given virus is greatest during the acute phase of an infection. The amount of virus in the semen is also greatest during this phase, but in the case of PRRSv, for example, the semen may contain the virus even if the viremic phase of the infection is over. It is also important to note that the semen may be infected before a boar shows signs of disease. By only collecting semen from clinically healthy, fever-free boars, the risk of transmitting an infectious dose of PRRSv is low.

The following diseases in pigs have been proven to be transmitted via artificial insemination:

- *Classical swine fever*; it is well documented that classical swine fever can be transmitted via semen.
- *African swine fever*; it is believed that this virus can be transmitted via semen, but it has not been documented
- *Japanese encephalitis*
- *PRRS*; it is well documented that PRRSv can be spread via artificial insemination.
- *Aujeszky's Disease;* high doses of AD virus have been detected in semen, and it is probable that infection can be spread via semen, but semen is not considered an important factor in the spread of infection.

Agents that have been detected in semen, but where it has not been proven or possibly not investigated whether semen represents a genuine risk of spreading the disease (AQIS, 1999 and 2000; Larochelle et al. 2000): Maes D et al 2008)

- Foot and mouth disease; detected in semen (low doses), but no documented transmission of infection. The risk of spread of infection via semen is thought to be low.
- Swine vesicular disease; detected in semen (low doses), but no documented transmission of infection.
- Enterovirus encephalomyelitis (Teschen disease)
- Porcine adenovirus
- Pestivirus (bovine viral diarrhea)

- Porcine Parvovirus
- Reovirus
- Rubulavirus (paramyxovirus Mexico)
- PCV2; is often detected in semen, and semen is believed to be an important cause of the spread of infection.

Influenza viruses and TGEv are not isolated from semen and there is no evidence of spread of these infectious agents in connection with artificial insemination. In theory, semen can be contaminated with these viruses via aerosols and fecal contamination (TGEv) in connection with the collection and preparation of semen.

Unlike aerogenic infection, infection via artificial insemination is a specific act that the breeder controls. The health risk primarily occurs in specific relation to the sows that have been inseminated with the semen, and at the time when the sows are inseminated with sperm. Therefore, the risk of uncontrolled spread of infection can be limited by increasing the degree of surveillance and isolation in connection with the insemination, such as isolation of the sows and testing after an optimal period of time in relation to which agents are most feared.

9.5. General information about diagnostic test results

In the absence of unambiguous symptoms of infection, diagnostic tests can be used to detect infection. Such examinations rarely provide 100% certainty.

The certainty of saying whether a group of animals (the 'population') is infected or not, i.e., whether at least one animal is infected, depends on the size of the population, the percentage of animals infected ('prevalence'), the number of animals tested ('sample'), and the ability of the test to differentiate between infected and non-infected animals. If one knows the characteristics of the test and has good evidence to predict the prevalence of a disease in a population, one can calculate the necessary size of the sample in order to achieve some degree of certainty. The most common tables assume that the test is perfect, i.e. it will reliably distinguish an infected animal from an uninfected animal. In practice, this is never the case, and here we show the effect of the test's characteristics.

In import situations, all animals are often tested. In such a situation, the number of infected animals, as well as the characteristics of the test, will determine the certainty we have to say whether the group is infected or not.

The sensitivity of the test is the probability of detecting infection in an infected animal. It indicates the probability of giving a positive result if an animal is infected. High sensitivity tests are good at detecting infected animals, they give few false negative results, and are desirable for preventing the spread of infection or ensuring treatment.

The probability of detecting infection in at least one animal depends on the number of infected animals tested (See Figure 6).

When testing 15-20 imported sows in Import Isolation Facility 1, or 15 boars in Boar Isolation Facility 1, the probability of not detecting infection if it is present in the group is lower than 1% if at least 2 animals are infected and the test has a high sensitivity (at least 90%). However, if the test has a very low sensitivity (30%), one can still have a high probability of detecting infection if a large number of tested animals are infected. The probability of not detecting infection if it is present in the group is then lower than 1% if at least 13 animals are infected. Therefore, infections that easily spread in a group are easier to detect, even when using tests that are weak at the individual level.

When testing 40-70 offspring which have been kept in the same Import Isolation Facility 2 for several months, the probability of detecting infection will be even higher.

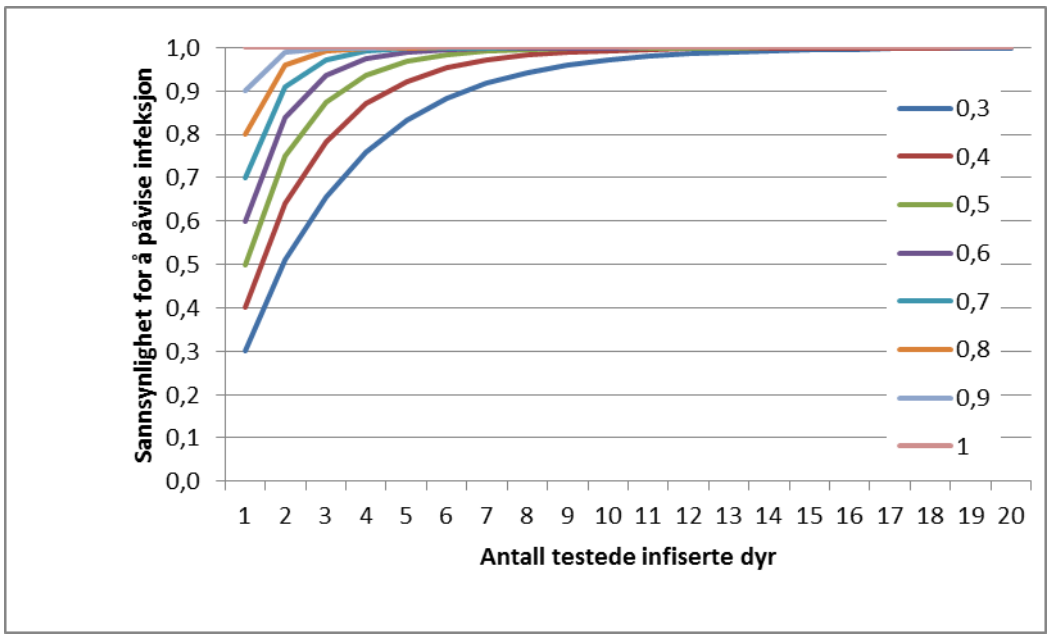

Figure 6. Probability of detecting infection in a group, depending on the number of animals infected (x-axis) and the sensitivity of the test (different curves)

The specificity of the test indicates the ability to give a negative result in animals that are not infected. High-specificity tests give few false positives and help prevent unnecessary infection prevention measures or treatments. The probability of false positive test results occurring increases with the number of animals tested (See Figure 7).

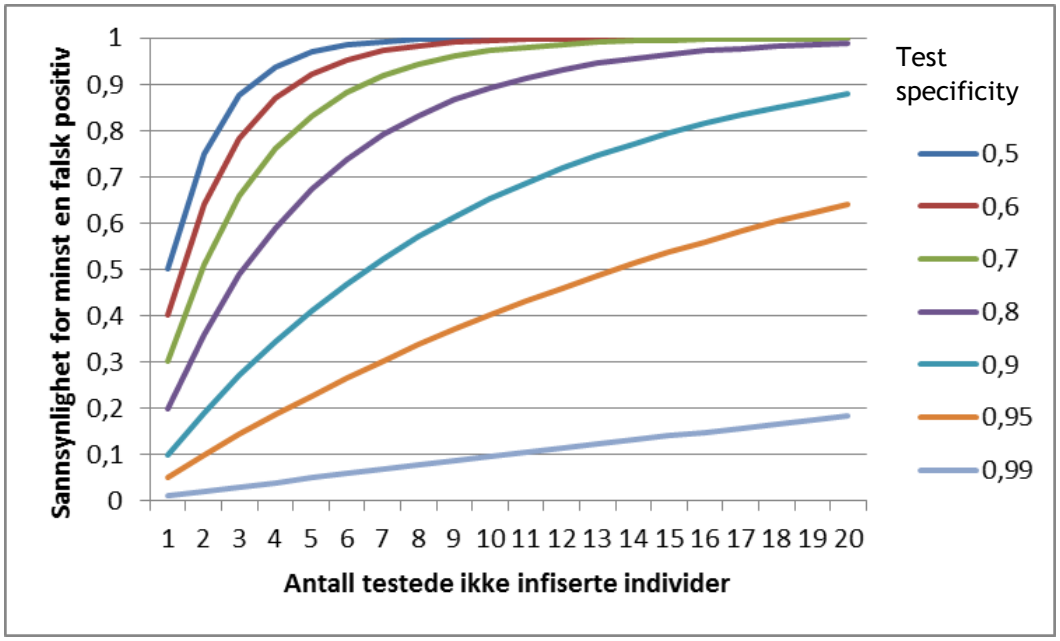

Figure 7. Probability of getting at least one false positive test result in a group, depending on the number of animals that are not infected and tested (x-axis) and the specificity of the test (different curves).

High accuracy requires high sensitivity and high specificity. As a general rule, these characteristics go in opposite directions, and a combination of tests is often necessary.

9.6. Description of specific agents

9.6.1 PRRS v

The general description is based on Zimmermann et al. 2006.

Agent: PRRS is caused by PRRSv, an RNA virus in the *Arteriviridae* family. There are several strains, and two main groups of virus strains, one European and one American. Different strains of viruses have different pathogenicity.

Prevalence: The PRRS disease was first reported in the United States in 1987, and it quickly spread across much of North America. In Europe, the first case was reported in Germany in 1990, and the virus was first isolated in the Netherlands in 1990. The disease then spread to Belgium, England, France and Spain in 1991, and to Denmark in 1992. Sweden had an outbreak of PRRS in 2007, but the infection was quickly eradicated after extensive testing and slaughter (Frøsling et al. 2009). Norway, Sweden and Finland are currently free from PRRSv. The infection is endemic in most other pig producing countries.

Clinical picture: Incubation time is 3-7 days. Infection with PRRSv in a fully susceptible population most often leads to a severe outbreak of disease. However, the infection can also be difficult to diagnose, mild and subclinical forms exist. The latter is especially seen where the infection is endemic.

An outbreak in a newly infected combined facility is often divided into three phases; initial phase dominated by influenza-like symptoms, the intermediate phase involving reproductive problems resulting in return to estrus, abortions, mummified fetuses, stillbirths and weak piglets, as well as lung symptoms in piglets and slaughter pigs, and the final phase in which conditions normalize. A facility outbreak of PRRS can lead to a 5-20% reduction in production, and the infection can persist at the facility for many years. In a Danish study, the prevalence of seropositive sows was 75%, while it was 92% in slaughter pig facilities. In another study, the average prevalence of infected piglet facilities was 25%, and 35% in slaughter pig facilities (Mortensen et al. 1994).

Many boars may be viremic without clinical symptoms being detected, possibly transient fever, reduced appetite, and reduced sex drive (Bouma et al. 2000, Prieto et al. 2005.) Surveillance of PRRSv at artificial breeding centers must therefore be based on specific tests.

Pathogenesis: PRRSv can be isolated from most infected pigs 1-10 days after infection. Viremia rarely lasts more than 20-30 days, depending on the type of virus and the age of the pigs. The virus primarily replicates in monocyte/macrophage cell lines. The virus can be excreted via semen even after the viremic phase is over. The virus can remain in the organs for several months, replicating despite antibodies (Bouma et al. 2000.) In one study, ten out of eleven animals were still carrying the virus 105 days after experimental infection (Horter et al. 2002.) It is unclear whether the presence of PRRSv in semen is due to the virus replicating in cells of boars' genitals, for example spermatocytes, or whether they reach the semen via infected monocytes and macrophages coming from the blood without the virus replicating in sex cells (Prieto et al. 2005). It has been reported that semen from infected boars contains a larger number of immature sperm cells which contain the virus (Sur et al. 1997) The authors believe there is a possibility that the virus replicates in these cells, and that the concentration of the virus may increase in connection with semen storage.

Routes of infection: Infected pigs excrete PRRSv via respiratory air, saliva, nasal discharge, urine, feces, milk and semen. The virus is highly contagious and the infection is spread mainly by direct contact with infected pigs via the mouth and nose. The virus can also be transmitted over long distances via aerosol, especially in humid and cold climates, with an estimated maximum distance of 3-4 km.

The spread of PRRSv via people, animal transport, clothing, footwear and objects is considered to be of significance, especially in cold and humid weather (Dee et al. 2002). In theory, infection can also be spread mechanically via contaminated needles, flies etc., but it is uncertain whether this is of practical significance.

Infection through semen via artificial insemination has been documented both epidemiologically and experimentally. The risk of spreading PRRSv to new facilities from infected boars via semen is considered high. The virus is isolated from semen before antibody response in serum and up to 92 days after infection

(AQIS, 1999). The largest viral amounts in semen are found 7 days after infection (Bouma et al. 2000.) There are large individual variations among boars in the ability to excrete viruses in semen (Christopher-Hennings et al. 2001.)

Laboratory diagnostics: There are several strains, but with common epitopes, which can be used for sensitive tests, e.g. IDEX Elisa. The more specific tests easily give false negatives. It takes 6-21 days for antibodies to be detected. The antibody titer is max after 4-6 weeks and disappears 4-10 months after the infection.

RT-PCR is a highly sensitive and specific test used to detect PRRS virus in semen, and can detect as little as 100 TCID50/semen dose. It is a dose 20 times lower than what has been shown in experimental studies to result in infection in one in 5 sows infected via the genital tract (Benfield et al 2000). RT-PCR is far more sensitive than viral isolation (Van Rijn PA et al. 2004).

Negative RT-nPCR for PRRSv in undiluted semen is a strong indication that the semen dose in question does not contain PRRSv and that it does not contain an infectious amount of virus. The test may be positive due to the presence of gene components from PRRSv even if there is no infectious virus in the semen.

Infectious dose

ID50 is the amount of virus needed for 50% of exposed pigs to be infected. ID_{50} for PRRSv is reported to be approximately $10^{4.5}$ in a study involving insemination (Benfield et al. 2000).

$TCID_{50}$ (Tissue culture ID_{50}) the amount of virus that will cause pathological changes in 50% of cells in a cell culture. In a report, Prieto et al. 1996 found $7x10^2$ $TCID_{50}$/ml in fresh semen. When diluted 15-30 times, it corresponds to $4x10^1$ $TCID_{50}$/ml diluted semen. That is equivalent to $4x10^3$ $TCID_{50}$ PRCV in a dose of diluted semen (100 ml)

Disease prophylaxis: There are several commercial vaccines.

PRRSv - Surveillance in Norway

Norwegian surveillance of PRRSv is combined with surveillance of Aujeszky's disease (AD), which complies with ESA guidelines for maintaining the free status of AD (Lium et al. 2010).

Each year, samples are taken from pigs from the following types of facilities:

All breeding stock and reproduction facilities, and all breeding sow facilities. Samples are also taken from a random sample of sow facilities (approximately 300) and a sample of slaughter pig facilities (60 facilities).

An evaluation of the surveillance results in 1992-1996 was conducted by Larry Paisley (1997 report a,b Norwegian Veterinary Institute, Section for Epidemiology). He concluded that the results in 1996, when 4968 samples from 468 facilities were found negative, suggested that less than 0.02% of Norwegian pigs and less than 0.7% of Norwegian facilities were infected. The same program is repeated every year with negative results, which is a strong documentation that Norway is free from PRRSv. However, the results also showed that if five Norwegian facilities were infected with PRRSv, there would be a 58% risk that none of these would have been tested. However, sampling of all breeding stock facilities guarantees that the disease is not present among these at the time of sampling.

Import restrictions: There is no OIE standard for import conditions specific to PRRSv.

FOR 2006-02-14 No. 199: Instructions for the Norwegian Food Safety Authority, the District Offices, regarding isolation and examination of animals have provisions for testing for PRRSv when importing live pigs and boar semen and the livestock industry's requirements both for importing livestock and for importing boar semen specify which measures should be implemented in connection with imports to Norway (see 10.1 – 10.3).

A risk assessment from AQIS in Australia (AQIS, 2000; AQIS, 2002) which is free from PRRS recommends the following protection when importing semen:

Boars should be born and raised in a country that AQIS approves as being free from PRRS;

or

Boars should come from an artificial breeding center without PRRS vaccination and where all boars in the isolation unit have been tested negative for antibodies to PRRSv. In addition, during stays at the artificial breeding center, the boars must be tested at a maximum of 6-month intervals, must be tested together with at least three in-contact pigs using IDEXX or another test approved by AQIS, in connection with the collections, at least 28 days after the last collection and at the earliest 3 months before the first collection. IDEXX Elisa should be considered positive if the ratio sample/positive control is equal to or greater than 0.3.

In addition, each semen collection should be tested for PRRSv using PCR or bioassay in a lab approved by AQIS.

A quantitative evaluation of the risk of importing 10-25 live pigs from Denmark carried out at the Norwegian Veterinary Institute (Paisley 1997) concludes that a serological test of the import animals in Denmark and one in Norway provide sufficient protection if no infection can occur between the two tests. If such a possibility exists, e.g. due to aerogenic infection during transport, tests carried out at the import facility would provide sufficient security.

PRRSv is B disease and positive results will be managed in accordance with FOR 1990-02-05 No. 144: Regulation on instructions for A, B and C diseases (animal diseases) and FOR 2002-06-27 No. 732: Regulation on measures against contagious animal diseases.

9.6.2 SIv

The general description is based on Olsen et al. 2006.

Agent: Swine influenza virus is a type A influenza, a member of the Orthomyxoviridae family. The most common swine influenza virus serotypes are swine-adapted variants of H_1N_1, H_3N_2 and H_1N_2 (Van Reeth et al. 2008.) In 2009, the pandemic H1N1 2009 virus spread from humans to pigs (Forgie et al. 2011).

Prevalence: Swine-adapted variants of influenza viruses are endemic in most pig-producing countries, including the Netherlands, Denmark and Sweden. Infection with influenza virus (except pandemic H1N1 2009 virus) has never been detected in pigs in Norway, despite active surveillance since 1997 (Lium et al. 2011). Pandemic H1N1 2009 virus was introduced to the Norwegian pig population through infection from humans in the autumn of 2009 (Hofshagen et al. 2009). The 2010 surveillance program showed that pigs at 41% of facilities had antibodies against pandemic H1N1 2009 v.

Clinical picture: Swine influenza virus is a highly contagious, acute viral disease that attacks the respiratory tract of pigs. The most prominent signs of illness are fever, reduced appetite, nasal discharge, sneezing and coughing. The infection affects a large number of animals in a short period of time, but the mortality rate is low. The infection can be complicated by other bacterial or viral diseases. Infection with influenza virus results in moderate to significant production losses.

Routes of infection: Swine influenza virus spreads via close contact between animals and can be transported with aerosol over short distances. Outbreaks occur mainly in the late autumn or winter. There is no viremic phase, and the virus is not usually detected outside the respiratory tract and associated lymph nodes. It is believed that influenza viruses can contaminate semen, but it is not thought that the disease can be spread via artificial insemination, and there are no reports that this has occurred.

Pathogenesis: Influenza virus in pigs is linked to respiratory receptors. There is no viremic phase.

Laboratory diagnostics: Antibodies against influenza viruses can be detected using the ELISA test and antibodies against specific variants of H_1N_1 and H_3N_2 can be detected using the hemagglutination inhibition test (HI). Sensitive PCR tests exist.

Surveillance in Norway: Swine influenza virus is included in the National Surveillance Program for specific viral infections in pigs. All serum samples collected for examination for AD are also tested for swine influenza. The blood samples are initially tested for antibodies against the Influenza A virus using the ELISA test. Positive samples in the ELISA test are then tested using the HI test to distinguish between

different variants of influenza virus, including pandemic H1N1 2009 virus. The number of samples and the sampling regimen correspond to that described under PRRS (Lium et al 2011).

Import restrictions: There is no OIE standard for influenza virus-specific import conditions.

FOR 2006-02-14 No. 199: Instructions for the Norwegian Food Safety Authority, the District Offices, regarding isolation and examination of animals have provisions for testing for SIv when importing live pigs and boar semen and the livestock industry's requirements both for importing livestock and for importing boar semen specify which measures should be implemented in connection with imports to Norway (see 10.1 – 10.3).

In a risk assessment from AQIS in Australia, which is also free from swine-adapted influenza virus variants, no specific measures are recommended for influenza viruses when importing semen because the risk of transmission via artificial insemination is considered negligible (AQIS, 2000).

Relevant measures may include requiring that the artificial breeding center is free from infection, that relevant boars are serologically negative, that the boars are clinically healthy when semen is collected.

SIv is a B disease and positive results will be managed in accordance with FOR 1990-02-05 No. 144: Regulation on instructions for A, B and C diseases (animal diseases) and FOR 2002-06-27 No. 732: Regulation on measures against contagious animal diseases.

9.6.3 TGE v

The general description is based on Saif et al. 2006.

Agent: TGE is caused by TGEv, a coronavirus. The virus is unstable at room temperature but very stable at low temperatures. It is sensitive to a variety of disinfectants. TGEv is closely related to PRCv and there is cross immunity between the two.

Prevalence: TGEv is endemic in many countries, but has never been detected in Norway. Since PRCv became endemic at many pig facilities around the world, the significance and prevalence of TGE has diminished. Status in the Netherlands is unclear.

Clinical picture: Incubation time is from 18 hours to 3 days. TGEv is a highly contagious viral disease that in susceptible piglets under 2-3 weeks old causes vomiting and watery, yellowish, foul-smelling, greasy diarrhea that may contain components of undigested milk. Morbidity is close to 100% in piglets under 1 week old. high. Mortality is usually less than 10-15%. Piglets over 3 weeks old usually survive but experience delayed growth rates. Older pigs, including susceptible sows, have reduced appetite, short-term moderate diarrhea and vomiting. In endemic infected facilities, symptoms are moderate. There are usually most problems with TGEv during the winter months as the virus survives best in the environment during this season.

Routes of infection: The virus is excreted in large amounts via feces, and the main route of infection is fecal-oral. The virus can also spread via aerosols. Most infected pigs excrete the virus for only a week. Cats, dogs and birds can be reservoirs of infection. It is also stated that flies can act as mechanical vectors. Since the virus is excreted through feces, it can theoretically be introduced to semen via fecal contamination, but no findings in semen have been reported, and there is no suspicion that TGEv is spread via semen in connection with artificial insemination. Even if semen were to be contaminated with TGEv, it is unlikely that the virus will establish itself and spread further from the recipient animal in connection with artificial insemination.

Pathogenesis: The virus is absorbed orally and binds to epithelial cells in the jejunum and ileum where it replicates and destroys the cells with subsequent atrophy of villi. It results in decreased enzyme activity, malabsorption, osmotic diarrhea and rapid dehydration. The cause of death is dehydration and acidosis. TGEv affects juvenile pigs the most because they are less able to repair damage to the intestinal epithelium.

Laboratory diagnostics: TGEv can be detected using RT-PCR, immunohistochemistry or virus isolation. Antibodies against TGEv can be detected using the ELISA test that differentiates between TGE and PRCV.

Surveillance in Norway: TGEv is included in the National Surveillance Program for specific viral infections in pigs. All serum samples collected for examination for AD are also tested for TGE. The number of samples and the sampling regimen correspond to that described under PRRSv. TGEv has never been detected in Norway (Lium et al. 2010).

Import restrictions: According to the OIE Terrestrial Animal Health Code, Chapter 15.5 Transmissible gastroenteritis, it is recommended that when importing boar semen, a certificate is required stating that the donor boar did not show any signs of TGE at the time of semen collection, and that it has either been at a center for at least 40 days where no boar has shown signs of TGE in the last 12 months and the donor boar has tested negative for TGEv during the last 30 days prior to collection, or the semen comes from a country where TGE is subject to notification and where there have been no registered clinical cases in the last 3 years.

When importing live pigs, it is recommended that the animals to be exported are clinically healthy, and either come from a facility where there has been no evidence of TGE in the last 12 months before export and the animals have tested negative for TGE within the last 30 days before export, or the animals come from a country where TGE is subject to notification and where there have been no registered clinical cases in the last 3 years.

FOR 2006-02-14 No. 199: Instructions for the Norwegian Food Safety Authority, the District Offices, regarding isolation and examination of animals have provisions for testing for TGEv when importing live pigs and boar semen and the livestock industry's requirements both for importing livestock and for importing boar semen specify which measures should be implemented in connection with imports to Norway (see 10.1 – 10.3).

To avoid introducing TGEv when purchasing pigs, a requirement should be made for the selling facility to test serologically negative for antibodies against TGEv. Purchased pigs should be quarantined and tested after 4 weeks of quarantine.

In a risk assessment from AQIS in Australia (2000), which is also free from TGEV, the risk of spreading TGE via semen is considered low. However, the consequence of introducing TGEv is considered severe, and it is recommended that measures are taken to reduce the risk of transmitting TGEv in connection with the import of semen.

The following measures may be considered:

- Import from TGE-free countries only,
- Require serological testing of donor boars (2-4 weeks after last semen collection!)
- Require that the artificial breeding center at which the donor boars are kept has tested free from TGEv and that there have been no clinical signs of TGE in the last 12 months. (NB adult animals rarely show clinical symptoms!)

9.6.4 PRCv

The general description is based on Saif et al. 2006.

Agent: PRCv is a coronavirus that is closely related to and is considered a mutant of TGEv. The virus was first diagnosed in Belgium in 1984. There is strong cross immunity between TGEv and PRCv. In countries that have both TGEv and PRCv (such as the Netherlands), infection with PRCv gives good immunity to infection with TGEv.

Prevalence: PRCv is endemic in many countries, including the Netherlands, but the virus has never been detected in pigs in Norway.

Clinical picture: PRCv occurs in many variants with different pathogenicity, but most variants cause no or only moderate respiratory symptoms. The virus usually infects pigs around the time of weaning.

Routes of infection: PRCv is spread by direct contact with secretions from the nose and with aerosols. The virus is highly contagious. Pigs excrete the virus for approximately 2 weeks. Since PRCv is not, or only to a small extent, excreted with feces, there is considered to be less risk of semen being contaminated with PRCV than with TGEv. There are no reports that PGEv has been detected in semen, and transmission via artificial insemination has not been reported. It is thought to be very unlikely that PRCv will spread to and become established in new populations in connection with artificial insemination.

Pathogenesis: PRCv has an affinity for cells in the respiratory tract (nasal mucosa, trachea, bronchi and bronchioles) and causes necrosis in the epithelium of the bronchi and bronchioles.

Laboratory diagnostics: PRCv is detected using RT-PCR, immunohistochemistry or virus isolation. Antibodies against PRCv are detected using the ELISA test that can distinguish between TGE and PRCv.

Surveillance in Norway: PRCv is included indirectly in the National Surveillance Program for specific viral infections in pigs. All serum samples collected for examination for AD are also tested for PRCv with a test that does not discriminate between PRCv and TGEv. In the event of a positive reaction, additional tests will be carried out to determine if it is TGEv or PRCv. The number of samples and the sampling regimen correspond to that described under PRRSv.

Import restrictions: There is no OIE standard for import conditions specific to PRCV.

FOR 2006-02-14 No. 199: Instructions for the Norwegian Food Safety Authority, the District Offices, regarding isolation and examination of animals have provisions for testing for PRRSv when importing live pigs and boar semen and the livestock industry's requirements both for importing livestock and for importing boar semen specify which measures should be implemented in connection with imports to Norway (see 10.1 – 10.3).

To avoid the introduction of PRCv when purchasing pigs, a requirement should be made for the selling facility to test serologically negative for antibodies against PRCV. Purchased pigs should be quarantined and tested after 4 weeks of quarantine.

A risk assessment from AQIS in Australia (2000), which is also free from PRCV, concludes that no specific measures are necessary in relation to PRCV when importing semen because the risk of transmission via artificial insemination is considered very low and the consequences of introduction are considered small.

9.6.5 Salmonella

The general description is based on Griffith et al. 2006.

Agent: There are over 2500 variants within the *Salmonella* bacterial genus. These are gastrointestinal bacteria that can cause diarrhea in many species including pigs and humans. The ability to cause disease varies greatly between different varieties.

Prevalence: Salmonella bacteria occur all over the world, often in symptom-free carriers among both animals and humans. The prevalence of *Salmonella* in Norwegian livestock, including pigs, is very low. This is well documented through the National Surveillance Program for *Salmonella* in livestock.

The prevalence of *Salmonella* in lymph nodes in slaughter pigs (0-0.15%) is very low compared to most other countries. In the 2008 EFSAS baseline study of *Salmonella* in pigs, *Salmonella* was detected in samples from 60% of breeding stock facilities in the Netherlands, and 8% of slaughter pigs tested positive regarding lymph nodes (EFSA 2009a).

Clinical picture: Infection with *Salmonella* in pigs can cause watery, yellowish diarrhea, especially in juvenile pigs and slaughter pigs. However, most cases of infection with *Salmonella* in pigs will progress without signs of disease. In Norway, no disease has been diagnosed in pigs caused by infection with *Salmonella* for decades. *Salmonella* is an important zoonosis that can be transmitted to humans via contact with infected pigs or indirectly via contaminated foods, drinking water or objects.

Pathogenesis

Route of infection: The bacterium is excreted with feces and can spread via direct contact with animals that excrete the bacterium, via contaminated feed, drinking water and objects, or via contact with wild birds, rodents and hedgehogs. Humans can be an important source of infection for *Salmonella*. *Salmonella* survives well outside the body of a pig and can be detected in things such as fertilizer several months after the bacteria were deposited. We have not found any publications indicating that *Salmonella* spreads between facilities via semen and artificial insemination in pigs. However, there are publications indicating that *Salmonella* can spread via semen in poultry (Iaffaldano et al 2010, Rieber et al 1995).

Laboratory Diagnostics: *Salmonella* is usually detected through cultures taken from fresh feces or environmental samples. In connection with facility controls, it is also relevant to consider serological testing. When using a serology test, different varieties of *Salmonella* cannot be distinguished, and positive serology does not mean that the animals in question are still excreting *Salmonella*.

Disease prophylaxis

Surveillance in Norway: Norwegian breeding stock facilities are surveilled annually for the presence of *Salmonella,* and there have been no positive samples for the past 10 years. In addition, lymph nodes are annually tested from approximately 3000 slaughter pigs and sows. The prevalence of *Salmonella* has been stably low every year since 1995.

Existing import restrictions: There is no OIE standard for *Salmonella*-specific import conditions

FOR 2006-02-14 No. 199: Instructions for the Norwegian Food Safety Authority, the District Offices, regarding isolation and examination of animals have provisions for testing for PRRSv when importing live pigs and boar semen and the livestock industry's requirements both for importing livestock and for importing boar semen specify which measures should be implemented in connection with imports to Norway (see 10.1 – 10.3).

9.6.6 MRSA ST 398

Agent: Variants of *Staphylococcus aureus* are considered part of the normal flora in pigs. MRSA ST398 is a special variant of MRSA that has been detected in pigs in many countries over the past 5-6 years. (de Neeling et al. 2007, Khanna et al. 2008, Voss et al. 2007, Weese et al. 2010)

Prevalence: MRSA ST 398 was first reported in pigs in 2005. Later, the bacterium has been reported to occur frequently in pigs in many countries. In a baseline study conducted under the auspices of EFSA, MRSA ST398 was detected in pigs in most countries (EFSA 2009b). The average proportion of MRSA positive pig facilities throughout the EU was 26.9% and the proportion of positive breeding stock facilities in the Netherlands was 12.8%.

Clinical picture: MRSA ST398 is no more pathogenic in pigs than other variants of *Staphylococcus aureus*. Staphylococci are sometimes isolated from skin infections, endocarditis and abscesses.

Pathogenesis: Pyogenic bacteria primarily found on the nasal mucosa and skin and infect wounds.

Routes of infection: MRSA ST398 is primarily spread via direct contact. It is believed that semen can be contaminated with MRSA ST398 due to dust and fecal contamination. We have not found any publications documenting findings of MRSA ST398 in semen, nor the transmission of MRSA ST 398 via semen.

Laboratory Diagnostics: MRSA ST398 is detected through bacteriological samples from nasal mucosa, skin, or environmental samples.

Disease prophylaxis: Good routines for infection protection when purchasing animals, personnel traffic and animal transport.

Surveillance in Norway: MRSA ST398 was not detected in samples taken from pigs at Norwegian pig facilities in connection with the EFSA baseline study in 2008, nor in a study conducted by the Norwegian

Pig Health Service in collaboration with the Norwegian Veterinary Institute and NVH where 1000 pigs from 200 facilities were tested. In a 2011 study conducted by NORMVET, MRSA ST398 was detected in samples taken from pigs after slaughter at a particular slaughterhouse. NORMVET will conduct a retest for MRSA in 2012 when sampling at 200 pig facilities.

Existing import restrictions: OIE has no guidelines regarding MRSA in connection with the import of live pigs or semen. There are no import restrictions associated with MRSA except that KOORIMP requires testing for the bacterium when importing pigs.

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11. Consultation

The preliminary report was sent for a brief consultation to KOORIMP c/o Nina Svendsby, ETT Finland (equivalent to the Norwegian KOORIMP) c/o Pirjo Kortesniemi, Svensnka Djurhälsovården c/o Sten-Olof Dimander, and Per Wallgren at the Swedish Veterinary Agency. Here is a summary of the input.

KOORIMP has no objections to the assessments and conclusions in the report, but emphasizes that it is important for Norsvin and the industry to ensure that any organized import of pregnant sows and boar semen from the Netherlands does not result in the spread of *Salmonella* to Norwegian pig facilities.

ETT, Finland refers to experiences regarding imports of boar semen from Denmark and Germany in 2009 and 2010 respectively. The semen was imported into two quarantine facilities. The following risk estimates were used in Finland when importing semen:

- PRCV and SIv: negligible risk
- Salmonella: negligible risk
- PRRS: low risk.

The following requirements/tests were carried out:

- In the exporting country
    - PRRS-free center
    - PRRS testing of the facilities from which the boars are recruited
    - Test results from the center including donor boars within the last 60 days
    - Additional test of donor boars 14 days after semen collection
- In Finland
    - Testing (serology) of all inseminated sows at 4 and 8 weeks (this testing also included TGE/PRCV and SIv)

Svenska Djurhälsovården (SDV) expresses that the risk assessment seems reasonable, but points out that, due to a short response deadline, there has not been time to go thoroughly through the report. It is emphasized that when importing from the Netherlands, Norway must pay special attention to the risk of introducing MRSA to Norwegian pigs. When assessing the import of pig genes from Denmark to Sweden in 2009, it was decided to only allow imports of fresh semen that was frozen in Sweden until all test results were confirmed negative.
It is signaled that if imports from the Netherlands are realized, SVD will reassess the requirements when importing pigs and semen from Norway to Sweden.

Per Wallgren (SVA) has made a comprehensive assessment of the proposal for risk assessment (attached). He initially refers to a Swedish risk assessment "Report regarding Proposal from SDS/SvDHV concerning the import of fresh semen from Denmark for freezing in Sweden", Report 2009-09-30 made by SVA and commissioned by the Swedish Farmers Disease Control Program in 2009.
Per Wallgren believes that one must assume that TGE occurs in the Netherlands even though there have been no clinical cases in recent years. He calls for more testing for the presence of *Salmonella* and MRSA in juvenile boars, and believes the conclusion LOW/Moderate for MRSA may be too optimistic.
Wallgren requests a more precise description of the measures to be taken in the event of any positive findings regarding the agents being tested for.