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Initial Report
concerning the risk for
Trichinella in pork in Denmark

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1. Introduction

The objective of the present report is to attain for Denmark the status as a region with a negligible risk of *Trichinella* in domestic swine housed indoor for the purpose of fattening and slaughter.

The legislation on *Trichinella* introduces the concept of regions with a negligible risk of *Trichinella*. According to the new rules, regions or countries can be officially recognised as having a negligible risk of *Trichinella* in domestic swine, and thus be granted a reduced surveillance and testing system for *Trichinella* in swine carcasses. The condition is that the member state forwards a notification with an initial report to the Commission and to the other member states containing information on the *Trichinella* situation in the region.

The present report from the Danish Veterinary and Food Administration (DVFA) is this initial report. It is based primarily on a risk assessment report from the Danish Institute for Food and Veterinary Research (*Maddox-Hyttel* 2002 - 2003), for which the more recent data have been added.

Recently, an international scientific report (*Richardson et al.* 2006) also pointed to the fact, that in many countries, which export pig meat, *Trichinella spiralis* is effectively absent from commercial pigs and insignificant as a case of zoonotic disease. Yet importing countries still require individual testing of all pig carcasses by exporters. If all tests are negative, is there any point in continuing individual carcass testing? The country in question (New Zealand) conducted a risk assessment of their situation, and they negotiated with the importing country to stop testing pig carcasses coming from confined commercial herds, and to exclude pigs from non-confined and back-yard herds from export.

2. Trichinella

Trichinella is a group of roundworms (parasites) known all over the world from the arctic areas to the tropics. They can infect most animals including birds, and humans.

Transmission can occur when a host eat meat infected with *trichinella*. *Trichinella* is not infectious between live animals.

Infected humans have a potential risk of developing serious illness or even to die.

3. Legal basis for the notification

The following regulates the official control for *Trichinella* in meat:

- Commission Regulation (EC) No 2075/2005 of 5 December 2005 laying down specific rules on official controls for *Trichinella* in meat
- Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption

The present report is the initial report containing the information set out in Article 3 and Annex 4 in the Commission Regulation No 2075/2005 (Detailed conditions for *Trichinella*-free holdings and regions with a negligible *Trichinella*-risk in domestic swine, Chapter II, Obligations on the competent authority, (D)).

According to this regulation the initial report to the Member States of the European Union and to the European Commission and the subsequent annual reports to the European Commission shall contain the following information:

- 1) the number of cases (imported and autochthonous) of *Trichinella* in humans, including epidemiological data;
- 2) the results of testing for *Trichinella* in domestic swine not raised under controlled housing conditions in integrated production systems; the results must include the age and sex of affected animals, the type of management system, the type of diagnostic method used, the degree of infestation (if known), and any relevant additional information;
- 3) the results of testing for *Trichinella* in breeding sows and boars;
- 4) the results of testing for *Trichinella* in carcasses of wild boar, horses, game and any indicator animals;
- 5) the results of serological tests as referred to in Article 11 once a suitable test has been validated by the Community reference laboratory;
- 6) other cases where *Trichinella* is suspected, either imported or autochthonous, and all relevant laboratory results;
- 7) details of all positive results and the *Trichinella* species verification by the Community or national reference laboratory;
- 8) information is to be submitted on the monitoring programme implemented according to Article 11, or equivalent information;
- 9) information is to be submitted on the risk-based wildlife monitoring programmes.

All data are to be submitted in the format and according to the timetable determined by EFSA for reporting of zoonoses.

4. Trichinella in humans

In Denmark cases of autochthonous trichinosis in humans have not been confirmed since 1930.

Cases among immigrants in Denmark have been reported. The last cases were reported in 2004 where 7 persons from an immigrated family was diagnosed with trichinosis due to consumption of sausage made from pork homeslaughtered in their native country and illegally imported into Denmark.

Even though trichinosis in humans is not a notifiable disease in Denmark cases are so rare that it may be assumed that The National Board of Health would be informed on any case of the disease, such as was the case with the above-mentioned family outbreak.

It is expected that human trichinosis will become notifiable in Denmark in the first half of 2007.

5. Trichinella in animals

Principles of monitoring and testing regime

Monitoring system

All swines housed indoors og outdoors, sows and boars, wild boars, horses and other animals susceptible for trichinella are tested for the parasite when slaughtered.

Notification system in place

Trichinella spp. are notifiable in all species of animals according to Danish Law no. 432 of 9 June 2004.

Measures in case of the positive findings or single cases would be taken according to Council Directive 64/433/EEC.

Diagnostic/analytical methods used

Methods used are according to Commission Regulation (EC) No 2075/2005.

The results of testing for *Trichinella* in domestic swine raised indoors

Sampling strategy

All pigs slaughtered at export approved slaughterhouses have been tested according to the Council Directive 64/433/EEC.

Samples are taken from the diaphragm muscle. 100 samples of 1 gram are pooled and analysed using the digestion method. Methods used are according to Council Directive Commission Regulation (EC) No 2075/2005.

The trichinella-laboratories are under official veterinary supervision. In Denmark there are 31 approved export-slaughterhouses for pigs. In 2004 ten of these used the approved method no. 4 (the mechanically assisted pooled sample digestion method/sedimentation technique). Twenty one of the approved export-slaughterhouses used the approved method no. 6 (the magnetic stirrer method for pooled sample digestion).

A ring test for all approved laboratories and performed by the Danish Institute for Food and Veterinary Research (DFVF) will take place in March 2007.

All laboratories doing trichinella-tests shall take part in the trial including the three regional laboratories which all are accredited to do the test. 15 laboratories participate in the first ring test.

Ten samples two of which contain no trichinella larvae and the other varying concentrations of larvae are sent to the laboratories for test.

The results of the investigations are sent to DFVF for evaluation. If results are unsatisfactory the test will be repeated and the laboratory approval will be reconsidered.

Ring tests are planned to be run annually.

Results of the investigation

Trichinella has not been shown to be present in any of the tests carried out on slaughter swine.

Year	Number of domestic swine tested for <i>Trichinella</i>
1990	15,874,568
1991	16,342,341
1992	17,723,731
1993	18,926,048
1994	19,472,350
1995	18,988,621
1996	18,806,409
1997	19,153,208

1998	20,422,155
1999	20,193,918
2000	20,114,670
2001	20,905,984
2002	20,943,014
2003	21,297,378
2004	21,395,442
2005	22,147,738
In total	312,707,575
Average	19,944,223

In the period from 1990-2005 there has been one suspicion of *Trichinella*. However, the larva could not be confirmed as a *Trichinella*, neither by further investigation in the laboratory or by further examinations of the pig farms that have been part of the suspicious slaughtering batch in question. A review of the case is attached to this report.

There has not been other suspicions of *Trichinella* in the period.

About 1 % of all pigs slaughtered in the period from 1990-2005 have not been *Trichinella*-tested. These were pigs slaughtered in low capacity slaughterhouses approved for the local market only.

The results of testing for *Trichinella* in domestic swine raised outdoor

Trichinella has not been shown to be present in any of the tests carried out.

Year	Number of organic pigs tested for <i>Trichinella</i>	Number of pigs raised outdoors tested for <i>Trichinella</i>	Total
2000	27,771	57,661	85,432
2001	37,825	69,516	107,341
2002	40,770	85,299	126,069
2003	37,731	92,285	130,016
2004	36,932	98,599	135,531
Total	181,029	403,360	584,389

The results of testing for *Trichinella* in breeding sows and boars

Trichinella has not been shown to be present in any of the tests carried out.

Year	Number of breeding sows and boars tested ¹ for <i>Trichinella</i>
1994	403,426

1995	272,314
1996	402,333
1997	421,708
1998	459,540
1999	437,324
2000	405,499
2001	431,715
2002	439,424
2003	435,689
2004	437,076
In total	4,546,048

¹ Covering the largest sow abattoirs approved for export: Est. 22, DC, Roenne, Est. 25, DC, Ringsted, Est. 71, DC, Saebj, Est. 91, Koopmann, Est. 311, DC, Skaerbaek. Please notice that for the year 1995 the slaughtering number is about 130.000 animals too low because the slaughtering number from Est. 91, Koopmann, is missing from the statistics.

The results of testing for *Trichinella* in wild boars

The so-called wild boars slaughtered in Denmark are all from confined and registered herds of wild types of swine. No true wild-living boars are present in Denmark.

Sampling strategy

Samples are taken from the diaphragm muscle from all wild boars slaughtered according to Commission Regulation (EC) No 2075/2005 (before January 1, 2006 according to Council Directive 92/45/EEC).

A total of 10 gram per animal is sampled. 20 samples of 5 gram are pooled and analysed. Until January 1, 2006 samples from wild boars were tested in official laboratories in the local food and veterinary control units, using the approved method no.4 and the approved method no. 6.

Results of the investigation

Trichinella has not been shown to be present in any of the tests carried out on wild boars.

Year	Number of wild boars tested for <i>Trichinella</i>
2000	752
2001	1678
2002	1354
2003	1280
2004	1141

In total	6205
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The results of testing for *Trichinella* in horses

Sampling strategy

Samples are taken from the tongue *or Musculus Masseter* from all horses slaughtered at export-approved slaughterhouses according to the Council Directive 64/433/EEC. From 1 January 2006 samples are taken according to Commission Regulation (EC) No 2075/2005.

Horses slaughtered in low capacity slaughterhouses approved for the local market only were not tested before 1 January 2006. These include about half of the horses slaughtered in Denmark.

Methods of sampling

Methods used are according to Commission Regulation (EC) No 2075/2005 (before January 1, 2006 according to Council Directive 77/96/EEC). Specimens weighing at least 10 gram per animal are sampled. 20 samples of 5 gram are pooled and analysed.

Results of the investigation

Trichinella has not been shown to be present in any of the tests carried out on horses.

Year	Number of horses tested for <i>Trichinella</i>
2000	1136
2001	1245
2002	1441
2003	1441
2004	1278
In total	6541

The results of testing for *Trichinella* in wild foxes and other indicator animals

In Denmark national surveys of *Trichinella* in wildlife, especially foxes have been undertaken. The most recent surveys were conducted in the 1970s and two investigations in the 1990s.

The size of the fox population in Denmark today is estimated to be 100,000-150,000 foxes. Of these approximately 40% are hunted yearly.

Muscle tissue from a foreleg (10 g) was examined by trichinostomy and by a pepsin-HCl digestion technique.

Results of the investigation

In the 1970s a total of 5084 foxes and approximately 300 other wildlife specimens (badgers, martens, weasels, polecats and stoats) were examined at the Danish Veterinary Laboratory (DVL) during the period 1969-1975. In the 1970s, *Trichinella* were found in wild boars in and around an animal park south of Skive ("Stubbekloster Plantage", 1973-76: 4 wild boars; 1979: 2 wild boars) and in three foxes in and around the same locality (1974). These findings were attributed to import of wild boars. Furthermore *Trichinella* was found in one fox from North-west Zealand. Each of the infected foxes harboured a very low infection, i.e. about 5-15 larva per 10 g muscle tissue.

In two investigations in the years 1995-1998 a total of 6141 foxes (*Vulpes Vulpes*) were examined for infection with *Trichinella* (Enemark *et al.* 2000). The foxes were killed in Denmark during the hunting season 1995-1996 and 1997-1998, 3133 and 3008 foxes respectively. Foxes included in the investigation came from throughout the country with the exception of the island of Bornholm.

In the investigation from 1995-1996, three foxes were found positive corresponding to a prevalence of 0,1%. Each of the infected foxes harboured a low infection, i.e. about one larva per 10 g muscle tissue. It was not possible to obtain sufficient larval material for species identification. All three foxes were shot in the vicinity of a small village in the northwestern part of Denmark. In 1997-1998 no *Trichinella* cases were found.

Year	Number of foxes tested for <i>Trichinella</i>	Positive test
1995-1996	3133	3
1997-1998	3008	0
In total	6141	3

A new survey of the prevalence of trichinella in foxes is started in December 2006.

6. The future monitoring programme

DVFA proposes to establish a risk-based monitoring system for *Trichinella* in Danish slaughter swine to be implemented as part of the requirements for establishing Denmark as a negligible risk region.

The monitoring system will meet the following criteria:

1. High risk sub-populations will be monitored
2. Internationally accepted definitions and sampling principles will be applied
3. The monitoring system will outline minimum requirements

Monitoring of high-risk sub-populations

According to general risk considerations, the following high-risk sub-populations can be listed:

- Older swine, i.e. breeding animals (sows, boars), due to the extended period of risk of exposure
- Swine raised outdoors in the fattening period, due to potential future exposure to *Trichinella* from the wild fauna and to the scavenging nature of outdoor swine

Sows and boars

All sows and boars slaughtered on Danish abattoirs are examined for *Trichinella* from 1 January 2006.

It is estimated, that about 450,000 sows and boars are slaughtered in Denmark per year.

Organic pigs and other outdoor raised pigs

In Denmark about 150,000 outdoor raised pigs including 40,000 organic pigs are slaughtered every year. All these animals will be tested.

It is the intention that producers have to declare the conditions under which the pigs have been raised. This information will be given as a part of the food chain information.

The scientific basis and arguments for the monitoring program

Internationally accepted definitions and sampling principles will be applied

Designation of a region as being one with a negligible risk implies that the expected prevalence of the condition in the population at risk is very low. The exact tolerance level for *trichinella* infections in a negligible risk region has not been defined, neither in the EU *trichinella* regulation, nor in the OIE Terrestrial Animal Health Code 2005 chapter on trichinosis.

In the EFSA Opinion “Risk assessment of a revised inspection of slaughter animals in areas with low prevalence of *Trichinella*” adopted 9-10 March 2005, however, there is reference to “Suggested semi-quantification of probabilities” in chapter 5 “Risk characterisation of *Trichinella* infections”. In this section “Negligible” is defined as “less than one in a million”. Thus all subsequent estimates of probability to be met by the surveillance system will use this target or even lower values (to be specified). The term “design prevalence” will be used to nominate the chosen value of prevalence for which the surveillance system will be designed or evaluated.

Furthermore, application will be made of recently developed methodology for combining evidence from different sources and deriving the combined confidence of this type of information (Cannon 2002, Martin et al. 2006, Martin et al. in press, Martin et al. submitted).

Similar approaches were used for the OIE chapter on surveillance for another zoonotic condition with a very low prevalence namely bovine spongiform encephalopathy (BSE) (Chapter 3.8.4) This chapter prescribes a surveillance level to meet the requirements for “negligible risk”, which for large populations over 1,000,000 individuals and a “design prevalence” of 1 in 50,000 requires the testing of 150,000 “target points” (equivalent to a number of individuals weighted by the proportional risk of the respective source sub-population of that individual. The weights vary around 1, with weights lower than 1 for low risk category animals and weights above 1 for high risk category animals). Thus, also in BSE, the surveillance system shall recognise and sample from high-risk subpopulations, as described in Chapter 3.8.4. BSE as well as trichinosis are diseases that are transmissible through contaminated feed, but which are not contagious and therefore require monitoring at quite low design prevalence levels.

Following from these examples, DVFA has designed the monitoring for *Trichinella* in Denmark as a negligible risk region on similar principles. DVFA propose to carry out *Trichinella* tests on all outdoor raised and organic slaughter pigs amounting to 150,000 individuals per year. If this number is not reached, indoor raised slaughter pigs from the same slaughterhouses will supplement all of the outdoor raised pigs up to 150,000 per year. This number of tests is enough to reach a design prevalence of 1 in 50,000 with 95% confidence, which is similar to the BSE example described above. In addition, however, also all sows and boars slaughtered will be tested for trichinella, as suggested by the EFSA opinion for the surveillance of trichinella free farms.

A number of figures are enclosed showing the results of simulations using the above-mentioned procedure (Martin et al. 2006) with the following parameters being applied:

- The number of time periods considered with surveillance data are 16, corresponding to the period 1990 – 2005 for which data have been presented in detail (Risk Assessment Report 2002)
- The annual risk of reintroduction of trichinella is estimated at the reciprocal of the number of years since the last case was found, i.e. 76 years after 1930. To take account of the uncertainty around this estimate, variation is allowed in the interval 50 – 100 years. For high-risk animals intended for inclusion in the proposed modified surveillance system, the risk of re-introduction was for reasons of precaution raised with a factor of between 2 and 3 compared to the estimated current risk.
- The sensitivity of detecting a trichinella carcass is set to 0,40 according to the above-mentioned report. To take account of the uncertainty, variation is allowed in the interval 0,35 – 0,45.
- The system sensitivity is estimated as the probability of detecting at least one of the number of positives expected with the chosen design prevalence.

- Figures show both data from one simulation across the 16 years as well as the distribution of the end confidence estimates for each of the 1000 simulations carried out.
- The following scenarios were chosen:
 - 1) All slaughtered swine tested (23 million per year) – DP: 1 per million, i.e. 23 cases expected
 - 2) High-risk sample tested (0,6 million per year) – DP: 1,7 per million of high-risk animals equivalent to 1 per 23 million slaughter swine, i.e. 1 case expected
 - 3) High-risk sample tested (0,6 million per year) – DP: 1,1 per million of high-risk animals, i.e. 0,7 case expected
 - 4) High-risk sample tested (0,6 million per year) – DP: 1 per million of high-risk animals, i.e. 0,6 case expected
 - 5) High-risk sample tested (0,6 million per year – DP: 25 per million of high-risk animals, i.e. 15 cases expected

The attached draft manuscript “Towards a risk-based surveillance for *Trichinella* in Danish pig production” (*Alban et al. in prep.*) contains details and comments on model output from models 1) and 5).

The resulting monitoring system will outline minimum requirements

For practical reasons, many more *Trichinella* tests will be carried out in Denmark over the next coming years than what has been described above. The reason for this is, that the export of pork to third countries will continue under the total testing system, until negotiations may be concluded about the certificate requirements for *Trichinella* to recognise the negligible risk status of Denmark.

In the meantime, the results of all tests carried out will of course be included in the annual report on the *Trichinella*-situation from Denmark.

The risk-based wildlife monitoring programme

Foxes are the best-suited indicator animals for *Trichinella* in Denmark but other carnivores and scavengers from the wild fauna can be taken into consideration.

To obtain a confidence-level over 95 %, 300 foxes will be examined every year to be able to verify, that the prevalence of *Trichinella* in wildlife in Denmark is less than 0.1 % after ten years of investigation (if no positive cases are found).

As a supplement to the wildlife monitoring programme 50 other carnivores and scavengers from the wild fauna will be investigated for *trichinella* every year. These other species could be badgers, mink, martens, birds of prey and necrophagous birds.

More foxes are tested from the southern Jutland and from the region in the northern Jutland where infected foxes was found in the last survey. The program for the survey is attached to this report.

If other susceptible species e.g. raccoon dog are established in Denmark they will be included in the monitoring program and the species will be controlled and exterminated if possible.

The plan for the test program is attached this report.

The wildlife monitoring program will continuously be validated according to progress in scientific knowledge e.g. serological methods.

7. National regulation and contingency plan

A circular concerning trichinella in susceptible animals has come into force in July 2006.

A contingency plan for the situation of suspicions or detection of trichinella in swine or other susceptible or in case of an increasing prevalence in the wildlife has been prepared. Both follow the guidelines laid down in Regulation No. 2075/2005.

The contingency plan is attached to this report.

8. Conclusion

- No cases of autochthonous trichinosis attributable to Danish produced meat including pork have been registered in human beings since 1930.
- In Denmark Trichinella has not been detected in domestic swine since 1930.
- In the last 15 years (in the years 1990- 2004) more than 290 million pigs have been slaughtered. About 99 % has been sampled and examined for Trichinella with a negative result.
- In the last 5 years more than half a million pigs outdoor raised swine have been tested for Trichinella with a negative result.
- There is documentation for a very low prevalence of Trichinella in wild life in Denmark. In two investigations in the years 1995-1998 a total of 6141 foxes were examined for infection with Trichinella. In the investigation from 1995-1996, three foxes were found positive corresponding to a prevalence of 0,1 %. Each of the three infected foxes harboured an extremely low level of infection.

The Danish Veterinary and Food Administration is of the opinion that Denmark fulfils the requirements for obtaining status as a region where the risk of *Trichinella* in domestic swine is officially recognised as negligible. The objective is to exempt most carcasses and meat of domestic swine kept solely for fattening and slaughter and raised under confined housing conditions from the individual examinations for *Trichinella*, since no public health benefits are apparent.

Instead Denmark intends to effectuate a risk-based monitoring programme for *Trichinella* in domestic pigs as well as a monitoring programme for wildlife that will demonstrate any occurrence and variation of prevalence in indicator animals.

All suspicions and verified cases of trichinosis in domestic animals and in wildlife will be reported to the Commission. All *trichinella* larvae found by the laboratories and all suspicions will be send to the NRL for verification and in case of doubt the CRL will be involved in the final evaluation.

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