RISK BASED APPROACH FOR THE CONTROL OF TRICHINELLA SPP. IN PIGS

REPORT OF AN FAO/WHO EXPERT MEETING

PRELIMINARY REPORT

24th OCTOBER 2014
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1. TRICHINELLA SPP., PUBLIC HEALTH AND TRADE

1.1. Human health impact of Trichinella spp.

Human trichinellosis is a foodborne illness caused by consumption of Trichinella spp. larvae in the muscle of raw or inadequately treated meat from domestic or game animals (e.g., pigs, horses, wild boars, dogs, walruses, foxes, and bears – only carnivores and omnivores). The food animal source has an inapparent or silent infection, and control of this parasite in the animal and their meat is a difficult but important public health issue. Reported trichinellosis cases indicate that clinical illness can range from mild nonspecific symptoms to severe illness and even death. Between 1986 and 2009 there were 65,818 human trichinellosis cases and 42 deaths in 41 countries reported globally (Murrell and Pozio, 2011). The global burden of disease of human trichinellosis has been assessed by the Foodborne Disease Burden Epidemiology Reference Group of the World Health Organization (WHO, 2007, Torgerson, et al. 2014), and the global number of Disability-Adjusted Life Years (DALY) has been estimated to be 76 per billion persons per year, occurring unevenly around the world (Devleesschauwer, et al. 2014). Given the current knowledge of disease surveillance systems around the world, reporting of trichinellosis is likely to be an underestimation of the actual burden of illness related to Trichinella spp. Nevertheless, the global burden of disease appears to be relatively low when compared to other foodborne parasitic diseases, e.g., foodborne toxoplasmosis or cystic echinococcosis which are each responsible for several hundreds of thousands of DALYs (Torgerson, 2013 and Devleesschauwer, 2014). In an international ranking of foodborne parasites, Trichinella spiralis, with pork as the primary food vehicle, was ranked within the top 10 (number 9) in terms of public health and number one in terms of trade importance. Other Trichinella spp. ranked 17 of 24 for public health importance and 7 of 24 for trade importance (FAO/WHO, 2014.).

One analysis of human trichinellosis outbreak data associated with consumption of domestic pigs indicated that in all cases, the pigs were raised in backyard or free-ranging systems as opposed to controlled housing systems (Pozio, 2014). Another study in 2012 found “Trichinella was rarely detected from pigs in the European Union, and the positive findings reported by all member states were from pigs reared under non-controlled housing conditions.” (EFSA, 2014).

1.2. Trichinella spp. in pigs

Trichinella spp. are exclusively meat-borne and meat from pigs is considered to be a primary source of human infection. A summary of Trichinella spp. isolated from pigs in both Europe and the Americas over a similar period of time indicated that infected domestic pigs were predominately from herds not kept in controlled housing systems (Pozio, 2014). Data from 23 countries (Belarus, Bosnia and Herz., Bulgaria, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Latvia, Lithuania, Poland, Macedonia, Montenegro, Romania, Serbia, Slovakia, Spain, Argentina, Canada, Mexico, and the USA) gave test-negative results for over 200 million pigs in controlled housing systems. It was not unusual for many of those countries to report test-positive pigs in non-controlled housing systems. For details see Annex 1. Further, the author (Pozio, 2014) indicated that there are no known, documented human cases of trichinellosis caused by consumption of meat from pigs kept in high containment level systems.

In addition to the summary data mentioned above, a study in the Henan province of China, 2010-11, found no Trichinella spp. infections on industrial farms and a prevalence of 3% and 10% in backyard pigs and pigs reared on small farms respectively (Cui, et al., 2013). In Thailand,
Trichinella spp. infections were documented only in hill-tribe free-ranging pigs (Kaewpitoon, et al., 2008). Similarly, North Vietnam has documented Trichinella spp. only in free-ranging pigs (Thi, et al., 2010. Lastly, there was a paper from Africa reporting that among 7,446 tested carcasses, there were no Trichinella spp. found on controlled, commercial piggeries in Zimbabwe (Vassilev, 1999).

1.3. Global trade in pig meat

The large volume of pigs and pig meat in international trade makes Trichinella test status economically important to many countries. In 2011, more than 36 million live pigs and 12 million tonnes of pig meat were exported and the value of the meat alone exceeded USD37 billion. (FAOSTAT, 2014. Available at http://faostat3.fao.org/home/E). Exported meat comes from countries with a wide range of production sources and sizes. In many producing countries, pig meat still comes from small herds of domestic pigs, with 16% slaughtering under 10,000 per year, and 40% slaughtering under 100,000 per year (Table 1.1). Similarly, there are 50 countries with documented exports under 10,000 tonnes per year (Table 1.2). Thus, any standards developed to ensure food safety and protect consumer health needs to take a risk-based approach so as to not unnecessarily restrict trade.

Table 1.1. Pigs slaughtered per year per country in 2010 (GLiPHA -The Global Livestock and Health Atlas, FAO – Food and Agriculture Organization of the United Nations) Available at http://kids.fao.org/glipha/)

<table>
<thead>
<tr>
<th>Pigs slaughtered per year</th>
<th>Number of countries, n = 186</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 - 10,000</td>
<td>30</td>
</tr>
<tr>
<td>10,001 – 100,000</td>
<td>45</td>
</tr>
<tr>
<td>100,000 – 1 million</td>
<td>47</td>
</tr>
<tr>
<td>1 million – 10 million</td>
<td>45</td>
</tr>
<tr>
<td>10 million – 100 million</td>
<td>17</td>
</tr>
<tr>
<td>&gt; 100 million</td>
<td>2</td>
</tr>
</tbody>
</table>

It should be noted that slaughter numbers presented in Table 1.1 refer to the overall numbers of pigs slaughtered per country. Such pigs are generally a sub-population of the national herd and the size of this sub-population and its proportion in terms of the national herd will vary from country to country.
Table 1.2. Tonnes of porcine meat exported per year per country in 2010 (FAOSTAT)

<table>
<thead>
<tr>
<th>Porcine meat exported per year (tonnes)</th>
<th>Number of countries, n = 75</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 - 1000</td>
<td>37</td>
</tr>
<tr>
<td>1001 – 10,000</td>
<td>13</td>
</tr>
<tr>
<td>10,001 – 100,000</td>
<td>9</td>
</tr>
<tr>
<td>100,000 – 1 million</td>
<td>13</td>
</tr>
<tr>
<td>1 million – 10 million</td>
<td>3</td>
</tr>
</tbody>
</table>

1.4. Development of international standards for control of *Trichinella* spp.

The control of *Trichinella* spp. in meat, in parallel with control of *Taenia saginata* in meat\(^1\), was assigned as priority work at the 42\(^{nd}\) Session of the Codex Committee on Food Hygiene (CCFH) in 2010. Prioritization was on the basis that trichinellosis remained an important risk to public health in many countries and disputes over control measures caused considerable problems in trade. This was subsequently reflected in the FAO/WHO ranking of foodborne parasites where, in terms of trade concerns, *Trichinella spiralis* in pork achieved the highest ranking (FAO/WHO, 2014). The development of draft guidelines began under the ongoing umbrella work programme in CCFH for control of specific zoonotic parasites. At the time of writing of this Report, the draft standard is at Step 5 in the Codex Alimentarius Commission (CAC) procedures for adoption.

In parallel, the World Organization for Animal Health (OIE) carried out a work programme to revise Chapter 8.14 of the OIE *Terrestrial Animal Health Code (Terrestrial Code)* on “Infection with *Trichinella* spp.” (new Chapter 8.15). The revised chapter was adopted in May 2013 and has been included in the *Terrestrial Code* since the 2013 edition (OIE, 2014a). During this work, there was a high level of collaboration between the CAC and OIE. The OIE standard includes the concept of establishing a compartment with a “negligible risk” of *Trichinella* infection in domestic pigs kept under controlled management conditions. The definition for compartment is “an animal subpopulation contained in one or more establishments under a common biosecurity management system with a distinct health status with respect to a specific disease or specific diseases for which required surveillance, control, and biosecurity measures have been applied for the purpose of international trade” (OIE 2014b).

While the OIE standard covers provisions for control of *Trichinella* spp. on farms, and the CAC (draft) standard covers provisions for assuring consumer health, there is a high level of interdependence in application of the standards if risk-based control of the parasite is to be effective.

\(^1\) The CCFH completed its work on guidelines for control of *Taenia saginata* in meat at the 45\(^{th}\) Session in 2013 and the standard was adopted at the 46\(^{th}\) Session of the Codex Alimentarius Commission in 2014. In support of application of this standard, FAO / WHO intend to do further work on refining the risk assessment model as described in “Risk-based examples for control of *Trichinella* spp. and *Taenia saginata* in meat – Report of a Joint FAO / WHO Expert Meeting, 22 – 25 October 2013.
1.5. Risk-based approach

1.5.1. Risk-based controls

A risk-based approach to animal or human health incorporates decisions on control measures that are based on estimates of the probability and severity of health impacts. The CAC describes food safety risks as a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food. Similarly, OIE defines risk as the likelihood of the occurrence and the likely magnitude of the biological and economic consequences of an adverse event or effect to animal or human health. In the case of *Trichinella* spp., control measures can include:

- biosecurity controls at the farm level to limit the likelihood of pigs becoming infected
- food safety controls, in the form of testing at the slaughterhouse to monitor the absence of infected pigs.

The draft CAC standard makes reference to the establishment and maintenance of a compartment with a negligible risk of *Trichinella* infection in domestic pigs kept under controlled management conditions as described by the OIE standard.

1.5.2. Development of risk-based examples

As development of international standards for control of *Trichinella* spp. at the farm level and post-slaughter level continued, it was recognized that public health authorities making risk management decisions on the level of public health protection expected at the national level would be much better informed if examples were provided for different choices they might make on control measures. These examples would also strongly inform the finalization of the guidelines on the control of *Trichinella* spp. in meat being developed by the Codex Committee on Food Hygiene (CCFH).

Two expert meetings were convened by FAO / WHO in response to the requests of the CCFH at both the 43rd Session (2011) and the 44th Session (2012) to develop risk-based examples to illustrate the level of consumer protection likely to be achieved with different pre- and/or post-harvest control measures. Initially, a call was made for information on prevalence of infection in pig populations in different countries and the control measures in place, the prevalence of human illness, as well as any risk assessment models that might be available. The information that was supplied formed the basis of a risk profile developed by FAO and WHO2.

The first Expert Meeting3 primarily focused on development of a risk model that could be used to generate examples of the level of consumer protection that is provided when a “negligible risk” compartment of pigs is established. The second Expert Meeting primarily focused on refining the risk model and providing examples of how it could be used to illustrate the public health outcomes of risk management decisions. CCFH also asked the second expert meeting to “Ensure a strong focus on communicating a risk-based approach to control of *Trichinella* spp. in pigs in an effective and easily understood manner in the scientific report.”


2. APPLICATION OF A RISK MODEL

2.1. Establishing the level of consumer protection provided by a “negligible risk” compartment

The establishment and maintenance of a compartment with a “negligible risk” of *Trichinella* infection in domestic pigs kept under controlled management conditions is described by the OIE standard (OIE, 2014a).

In an integrated risk management environment (animal health and public health), there are three primary sources that inform the integrity of the “negligible risk” compartment, and in turn, the public health risks to consumers from pigs kept in a “negligible risk” compartment:

- Information from biosecurity audits of the compartment by animal health authorities during the two-year set-up period
- Information from slaughterhouse testing of carcasses:
  - during the set-up period
  - during previous years (and possibly unknown biosecurity status)
- Optionally, surveillance information from animals and wildlife outside of the compartment

The OIE chapter states that the animal health authority should take into account all sources of information in deciding on the characteristics and implementing the on-farm audit programme. The relative weighting given to each source of information (Figure 2.1) will likely vary in different country scenarios.¹

In contrast, the public health authority will primarily consider information gained from the testing of carcasses during the two-year set-up period of the “negligible risk” compartment when deciding whether the compartment will provide the expected level of consumer protection (Figure 2.1). The public health authority may also draw on the other sources of information when making this decision e.g. available human health surveillance/trace-back data and historical slaughterhouse testing data. The public health authority decision should then be communicated with the animal health authority.

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¹ Animal health authorities in some countries are considering the use of a third party auditor system, appointed by them (Albans, pers. comm., 2014)
2.2. Maintenance of a “negligible risk” compartment

OIE guidelines state that the animal health authority should consider relevant sources of information in deciding on the characteristics and implementing an on-farm audit programme for maintenance of the “negligible risk” compartment. The relative weighting given to each source of information (Figure 2.1) will likely vary in different country scenarios.

The public health authority will want assurance that the level of public health protection provided by the establishment of a “negligible risk” compartment continues to be achieved over time. In principle, any control measure(s) that assure an equivalent public health outcome to that expected by the public health authority can be implemented. These options are illustrated in Figure 2.2. Trace-back information may be sought from any human illnesses that might occur to determine whether pigs housed under controlled housing conditions were involved.

Figure 2.1. Sources of information for the establishment of a compartment with a “negligible risk” of *Trichinella* spp. infection in pigs.
2.3. Description of the risk model for *Trichinella* spp.

The reason to develop this risk model was to provide some relative quantification of the impact of measures for the control of *Trichinella* spp. in pigs in the context of consumer health protection. The word relative is important here, because the risk numbers for both pigs and for people are not absolute but are statistical and describe a "potential or possible" risk.

The risk model consists of two parts: an animal test model (Butler and Devleesschauwer, unpublished) and a food pathway model (Ryan and Hathaway; unpublished). The animal test model supplies the data on estimated prevalence of possible infection in pigs to the food pathway model which then estimates the risk to consumers. It is a deterministic or point estimate model, thus inputs are single values rather than distributions. This has the advantage of simplifying the model; on the downside however it does not allow the consideration of the variability that clearly exists in terms of the inputs. However, this approach was considered adequate for simply illustrating the potential to quantify the impact of establishing a negligible risk compartment in terms of consumer health protection.

A flow diagram that illustrates the structure of the two-part model is shown in Figure 2.3.

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**Figure 2.2.** Different scenarios for sources of information used by the public health authority in assuring public health protection during the maintenance of a compartment with a "negligible risk" of *Trichinella* spp. infection in pigs.
2.3.1. Animal test model

2.3.1.1. General description

The animal test model estimates the possible prevalence of infected pigs in the slaughter population on the basis of sampling statistics and the sensitivity of an imperfect diagnostic test\(^5\). For the purposes of this modeling exercise, the test for which sensitivity and specificity characteristics were estimated is the digestion test as described Chapter 2.1.16 of the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (OIE, 2013b)\(^6\). OIE also recognizes that serological testing is appropriate for surveillance of *Trichinella* infections in pigs.

Given no test-positive carcasses in a sample from a slaughter population, the animal test model is used to estimate the number of infected pigs that might still be present. As the population is finite, a hypergeometric function is used to characterize the sampling process. Uncertainty in the estimated number of possibly-infected pigs that is inferred from the test outcome arises partly because only a proportion of the total population is sampled and partly because the test method has an imperfect sensitivity.

2.3.1.2. Sampling inputs to the animal test model

The sampling inputs for the animal test model are shown in Table 2.1.

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\(^5\) The words “possible prevalence” rather than “true prevalence” are used here. A true prevalence can be estimated in statistical terms from the sampling statistics and the imperfect diagnostic test; however prior knowledge of the test-negative status of slaughter population over a number of years would strongly indicate that the statistical estimate of prevalence was not real

\(^6\) It is also assumed that laboratory proficiency is adequate as per ICT recommendations (http://trichinellosis.org/uploads/ICT_Recommendations_for_Control_English.pdf Accessed 2014-04-05). Reports on Proficiency Testing to detect *Trichinella spiralis* larvae in pork samples according to EU Regulation 2075/2005. (Forbes et al., 1999)
### Table 2.1. Inputs for the animal test model

<table>
<thead>
<tr>
<th>Inputs</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of slaughter pigs in the compartment</td>
<td>10,000 to 100m</td>
</tr>
<tr>
<td>Proportion of slaughter pigs tested</td>
<td>0.1% to 100%</td>
</tr>
<tr>
<td>Number of slaughter pigs testing positive</td>
<td>Maximum of 1</td>
</tr>
<tr>
<td>Sensitivity of the digestion test</td>
<td>40% -70% (expert opinion)</td>
</tr>
<tr>
<td>Specificity of the test</td>
<td>100%</td>
</tr>
</tbody>
</table>

1 Surveillance data could include inputs from serological testing. With adequate quality assurance, the ELISA can achieve 97.1%-97.8% sensitivity and 99.5%-99.8% specificity (Frey, et al., 2009).

- The number of slaughter pigs in the compartment will be variable, depending on the extent of the negligible risk compartment being defined in the country or region.
- The proportion of pigs tested will be that used in historical testing programmes and / or that decided on by the risk manager seeking a particular level of public health assurance.
- The model is primarily designed to estimate possible risks to consumers when all test results are negative. However, the framework for application of the model includes the scenario where one pig from the compartment may test positive as this is a likely real-world scenario. It was considered by the experts that any more than one positive test in pigs from a “negligible risk” compartment would strongly suggest a failure of biosecurity and the usefulness of the model in illustrating a likely level of public health protection would be diminished.

#### 2.3.1.3. Test sensitivity and specificity

For the purpose of this document, sensitivity refers to the probability of the digestion assay detecting *Trichinella* infection in a carcass, by the recovery and identification of one or more larva in a muscle sample of specified size and site of origin. A minimum standard of quality assurance as stipulated by the International Commission on Trichinellosis (ICT) and OIE guidelines is required to achieve a specified level of sensitivity. The quality assurance measures include an approved and validated digestion method, sample size of ≥1 g from the diaphragm, tongue or masseter of pigs, and trained analysts certified by regular proficiency testing (Gajadhar, et al., 2009).

Differences in the sensitivity of the digestion assay have been reported in different studies. Using replicates of 1 g samples generated from 15 pigs experimentally infected with low doses of *Trichinella spiralis*, the proportion detected positive by digestion assay was 40% (8/20 samples with 0.01-0.09 larvae per gram or LPG), 73% (49/67 samples with 1.0-1.4 LPG), and 67% (16/24 samples with 1.5-1.9 LPG) (Forbes and Gajadhar, 1999). An earlier study using much fewer samples, with 0.88 and 1.5 LPG, reported positive results for 0/4 and 3/4 samples, respectively (Gamble, 1996). In both studies, up to 100% of samples with ≥ 3 LPG were detected in 1 g samples. Increasing the sample size to 3 and 5 g enabled detection of up to 100% of samples containing approximately 1 LPG. However, for detecting carcasses with lower levels of infection, a larger amount of sample would need to be tested to achieve an equivalent level of sensitivity. Conversely, with more than 1 LPG, a 1 g sample size is likely to detect all infected pigs.
From these studies, the sensitivity of the digestion assay with a suitable 1 g sample was taken to be approximately 40-70%. The greatest limiting factor to achieving higher than the approximately 70% sensitivity for 1 g samples appears to be the natural uneven distribution of larvae within tissues.

The risk model assumed 100% specificity, i.e. that the test were done with adequate quality assurance as described by the International Commission on Trichinella (ICT).

2.3.2. Food pathway model

2.3.2.1. General description

The food pathway model uses the output of the animal testing model i.e. the possible prevalence of infected pigs in the slaughter population, to generate a public health risk estimate. Various descriptors can be used for risk estimates and two examples are: mean number of potentially infected meal servings per 1,000,000 servings and mean number of potentially infected meal servings per 1,000,000 slaughtered pigs. Different descriptors can be used to facilitate communication of the outcome of the model to different audiences, and translate the possible risk from one pig carcass (from which, based on expert opinion, there may be 200-600 meal servings) into risk per meal or per eating occasion. While risk managers will probably want information on both, consumers may understand their risk more easily in terms of what is on the plate.

2.3.2.2. Food pathway inputs

The inputs for the food pathway model are shown in Table 2.2. The ranges were elicited by expert opinion and aim to take into account the large differences that may occur around the world. Consequently it is difficult to establish an average value across many countries. This highlights one of the limitations of addressing such issues at the global level and the illustrative nature of the examples below. Applying such an approach at a national level or for a small well-defined group of countries would mean that the inputs can be better characterized to reflect the situation within those countries.

<table>
<thead>
<tr>
<th>Table 2.2. Inputs for the Food Pathway Model</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Inputs</strong></td>
</tr>
<tr>
<td>Percentage of pig meat not subjected to any treatment by industry (including retail) that would inactivate larvae</td>
</tr>
<tr>
<td>Number of meal servings from a pig carcass</td>
</tr>
<tr>
<td>Percentage of pig meat not subjected to any treatment by the consumer that would inactivate larvae</td>
</tr>
<tr>
<td>Percentage of meal servings from an infected carcass that might contain sufficient larvae to infect a consumer</td>
</tr>
</tbody>
</table>
• The percentage of pig meat not subjected to any treatment by industry that would inactivate larvae is clearly different in different national settings. The European Livestock and Meat Trading Union (UECBV) estimate 15-17% fresh pork, 60-66% processed pork and 15-17% frozen pork, with estimates for processed pork being 30% cooked sausages, 20% cooked ham, 10% dried ham and 25% other (De Smet, pers. comm.). The National Pork Producers Council USA reports 13% cured ham, and 10% cured bacon (http://www.pork.org/filelibrary/PorkCheckoff-QuickFacts2013.pdf)

• The number of meal servings per carcass is obviously highly variable and has been reported as being 371 in the USA (http://www.pork.org/filelibrary/PorkCheckoff-QuickFacts2013.pdf) and 200 – 400 elsewhere (Kijlstra and Jongert, 2008).

• The percentage of meal servings from an infected carcass that might contain sufficient larvae to infect a consumer is unknown. Larvae may be present in all striated muscles of an infected carcass although they preferentially accumulate in the diaphragm and the tongue (Kapel and Gamble, 2005 and Forbes and Gajadhar, 1999, and Ribicich, et al., 2001). In the absence of published data to indicate otherwise, a conservative input to the model would be 100%

2.3.2.3. Dose-response

The meeting was aware of only one publication addressing the human dose-response relationship for Trichinella larvae in pork meat, and this was derived from outbreak data (Teunis et al., 2012). Dose-response modeling of the results of eight outbreaks indicated that infectivity for humans is high and the median 50% infectious dose was calculated to be 150 larvae. This paper also noted that a meal serving of 100g and containing 200 larvae might not necessarily be detected in the digestion assay.

In order to apply a dose-response model within the risk model, it would be necessary not only to have information on the prevalence of infection but also on the actual numbers of larvae. As noted elsewhere in the report, while there are predilection sites for Trichinella spp. within the carcass, the larvae can be distributed throughout, although the distribution throughout the carcass will be very heterogeneous (Ribicich, et al., 2001, Gamble, 1996). While it may be possible to utilize dose-response information, the simple deterministic model used in this study would need to be converted to a probabilistic model to make appropriate use of a dose-response curve.
3. MODELING EXAMPLES FOR ESTABLISHING THE LEVEL OF CONSUMER PROTECTION PROVIDED BY A “NEGLIGIBLE RISK” COMPARTMENT

3.1. Model inputs

The purpose of developing the model was to articulate a level of consumer health protection. A key consideration in the modeling was the amount of testing that was required in order to demonstrate that the “negligible risk” compartment provided what the risk managers would then determine to be an appropriate level of consumer health protection. It should be clarified that testing in this context is not considered a measure for the control of *Trichinella* spp. in meat, but rather as a means of demonstrating or verifying the adequacy of all control measures implemented prior in achieving the required level of consumer health protection. Thus in the context of establishing a “negligible risk” compartment, the test data provide the linkage between the control measures and the articulation of what they achieve.

The model inputs for the animal test model and the food pathway model that were used are shown in Table 3.1. It should be noted that there are a number of challenges to applying such a model at the global level as many of the inputs have to be either over generalized or conservative in nature to somehow reflect the disparate global scenario. The possible ranges of such values are reflected in Table 2.2. However, for illustration purposes only, the expert meeting agreed to use the set of point estimate inputs presented in Table 3.3.

<table>
<thead>
<tr>
<th>Model</th>
<th>Inputs</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Animal test</td>
<td>Size of slaughter population and sample proportion (test negative)</td>
<td>10,000 to 100 m</td>
</tr>
<tr>
<td></td>
<td>Sensitivity of the diagnostic test</td>
<td>70% (except example in 3.3)</td>
</tr>
<tr>
<td>Food pathway</td>
<td>Percentage of pig meat not subjected to any treatment by industry (including retail) that would inactivate larvae</td>
<td>50%</td>
</tr>
<tr>
<td></td>
<td>Number of meal servings from a pig carcass, assuming a serving size of 150g</td>
<td>400</td>
</tr>
<tr>
<td></td>
<td>Percentage of pig meat not subjected to any treatment by the consumer that would inactivate larvae</td>
<td>0.5%</td>
</tr>
<tr>
<td></td>
<td>Probability that every meal serving from an infected pig will contain sufficient larvae to result in a human clinical case of trichinellosis</td>
<td>100%</td>
</tr>
</tbody>
</table>

1 Surveillance data could include inputs from serological testing. With adequate quality assurance, the ELISA can achieve 97.1%-97.8% sensitivity and 99.5%-99.8% specificity (Frey, et al., 2009).
Two infection scenarios were considered. The first scenario was when all pigs tested negative. Estimates were also generated from the animal test model when one test-positive animal was found in the sample of slaughtered animals.

### 3.2. Probability distribution for possibly infected pigs

An example probability distribution for the possible number of infected pigs in a slaughter population of 1,000,000 pigs when sample sizes of 10%, 50% and 100% are all test-negative is shown in Figure 3.1. (The sensitivity of the test for this example is set at 70%). In these sampling scenarios, it can be seen that the most likely outcome for all scenarios is zero, i.e. none of the pigs are infected with *Trichinella* spp. However, there is always some statistical possibility that a small number of infected pigs may be present because of sampling uncertainty and an imperfect test. As the proportion of sampled pigs increases as a percentage of the slaughter population, the overall possibility of infected pigs diminishes. It should be noted that this observation holds true for any slaughter population size.

![Figure 3.1](image.png)

**Figure 3.1.** Probability distribution for the possible number of infected pigs in a slaughter population of 1,000,000 pigs when sample sizes of 10%, 50% and 100% are all test-negative

### 3.3. Changes in probabilities of possible number of infected pigs with different test sensitivities

Figure 3.2 illustrates the impact of changes in sensitivity of the diagnostic test on the probabilities of infected pigs per 1,000,000 slaughtered pigs when the sampling proportion is 50%. It can be seen that the impact of test sensitivity on the probability of identifying a possibly infected pig % are modest, and this is similar when other slaughter populations of different sizes and different sampling proportions are used.
Figure 3.2. The effect of changes in sensitivity of the diagnostic test on the probability distribution of possible number of infected pigs in a slaughter population of 1,000,000 pigs with 50% of the pigs being sampled

3.4. Changes in possible number of infected pigs with different inputs for size of slaughter population and sample proportion

The animal test model was used to generate a matrix of estimates of the mean prevalence of possibly infected pigs in slaughter population sizes from 10,000 to 100 million and a range of sampling scenarios from 0.1% to 100% of the population. The outcome is expressed as potentially infected pigs per 1,000,000 (Table 3.2). This expression follows the conventional use of a 1 million denominator but could also be expressed using a different denominator, e.g., potentially infected pigs per 10,000 or other.

Table 3.2. Mean prevalence of possible infected pigs per 1,000,000 in a test-negative slaughter population according to a range of population sizes and sample proportions

<table>
<thead>
<tr>
<th>Population size</th>
<th>10,000</th>
<th>100,000</th>
<th>1,000,000</th>
<th>10,000,000</th>
<th>100,000,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proportion sampled</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.1%</td>
<td>118970</td>
<td>11897</td>
<td>1190</td>
<td>119</td>
<td>12</td>
</tr>
<tr>
<td>1%</td>
<td>13908</td>
<td>1391</td>
<td>139</td>
<td>14</td>
<td>1</td>
</tr>
<tr>
<td>10%</td>
<td>1326</td>
<td>133</td>
<td>13</td>
<td>1</td>
<td>0.1</td>
</tr>
<tr>
<td>20%</td>
<td>614</td>
<td>61</td>
<td>6</td>
<td>0.6</td>
<td>0.06</td>
</tr>
<tr>
<td>50%</td>
<td>186</td>
<td>19</td>
<td>2</td>
<td>0.2</td>
<td>0.02</td>
</tr>
<tr>
<td>90%</td>
<td>59</td>
<td>6</td>
<td>0.6</td>
<td>0.06</td>
<td>0.006</td>
</tr>
<tr>
<td>100%</td>
<td>43</td>
<td>4</td>
<td>0.4</td>
<td>0.04</td>
<td>0.004</td>
</tr>
</tbody>
</table>
Table 3.2 illustrates that the statistically possible prevalence of infected pigs in a test-negative slaughter population is proportional to the total slaughter population and the sampling percentage. As a population gets smaller, a greater proportion has to be tested to demonstrate the same number of possible infections that might remain. This can be challenging to understand, particularly when dealing with smaller population numbers. This can be challenging to understand, particularly when dealing with smaller population numbers. In the cases of small populations, it may be necessary to test all pigs to demonstrate a very low possibility of infected pigs. It is only in the cases of very large slaughter pig populations that a smaller proportion of sampling will provide a very low possibility of infected pigs remaining in a test-negative population.

When results such as this are run through the food pathway model to generate estimates of risks to public health, outcomes from particular sampling scenarios can be compared in terms of achieving equivalent public health outcomes (see section 3.6).

### 3.5. Estimates of public health risk from the food pathway model

The outputs of the animal test model feed into the food pathway model. The food pathway model is used to generate estimates of public health risks and illustrate their relative rankings. In Table 3.3, risk is described in terms of the possible number of human illness cases per 1m meal servings. In Table 3.4, public health risks are described in terms of the number of human cases per 1m slaughtered pigs.

The model inputs unique to the food pathway model for the human health consideration (calculation) would be the (1) Percentage of pig meat not subjected to any treatment by industry (including retail) that would inactivate larvae-50%, (2) Number of meal servings from a pig carcass, assuming a serving size is 150g. (3) Percentage of pig meat not subjected to any treatment by the consumer that would inactivate larvae –0.5%, and (4) Probability that every meal serving from an infected pig will result in a human clinical case of trichinellosis – 100%.

The calculation: 400 servings X 50%, X .5% = 1, creating a 1:1 ratio between potential pig and potential human infections. If the experts had selected a different value for any of these inputs, from the range of potential values identified in Table 2.2, Tables 3.2 and 3.4 would have different risk descriptor values. This again highlights the illustrative nature of these examples.

**Table 3.3.** Mean estimates of possible human health risks using a risk descriptor of “human cases per 1,000,000 meal servings”

<table>
<thead>
<tr>
<th>Proportion sampled</th>
<th>10,000</th>
<th>100,000</th>
<th>1,000,000</th>
<th>10,000,000</th>
<th>100,000,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.1%</td>
<td>297</td>
<td>30</td>
<td>3</td>
<td>0.3</td>
<td>0.03</td>
</tr>
<tr>
<td>1%</td>
<td>35</td>
<td>3</td>
<td>0.3</td>
<td>0.03</td>
<td>0.003</td>
</tr>
<tr>
<td>10%</td>
<td>3</td>
<td>0.3</td>
<td>0.03</td>
<td>0.003</td>
<td>0.0003</td>
</tr>
<tr>
<td>20%</td>
<td>2</td>
<td>0.2</td>
<td>0.02</td>
<td>0.002</td>
<td>0.0002</td>
</tr>
</tbody>
</table>
Using baseline inputs as per Table 3.1

<table>
<thead>
<tr>
<th>Proportion</th>
<th>10,000</th>
<th>100,000</th>
<th>1,000,000</th>
<th>10,000,000</th>
<th>100,000,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.1%</td>
<td>118970</td>
<td>11897</td>
<td>1190</td>
<td>119</td>
<td>12</td>
</tr>
<tr>
<td>1%</td>
<td>13908</td>
<td>1391</td>
<td>139</td>
<td>14</td>
<td>1</td>
</tr>
<tr>
<td>10%</td>
<td>1326</td>
<td>133</td>
<td>13</td>
<td>1</td>
<td>0.1</td>
</tr>
<tr>
<td>20%</td>
<td>614</td>
<td>61</td>
<td>6</td>
<td>0.6</td>
<td>0.06</td>
</tr>
<tr>
<td>50%</td>
<td>186</td>
<td>19</td>
<td>2</td>
<td>0.2</td>
<td>0.02</td>
</tr>
<tr>
<td>90%</td>
<td>59</td>
<td>6</td>
<td>0.6</td>
<td>0.06</td>
<td>0.006</td>
</tr>
<tr>
<td>100%</td>
<td>43</td>
<td>4</td>
<td>0.4</td>
<td>0.04</td>
<td>0.004</td>
</tr>
</tbody>
</table>

*Using baseline inputs as per Table 3.1

Table 3.4. Mean estimates of possible human health risks using a risk descriptor of “human cases per 1,000,000 slaughtered pigs”

Table 3.3 illustrates a wide range of estimates for the mean number of potential human cases per 1,000,000 meal servings when different sampling scenarios are used as a means of illustrating the impact of control measures. As an example, sampling of 1% of a slaughter population of 1m with test-negative results would mean that the potential number of human cases would be less than one per 1m meal servings. For this example scenario, table 3.4 shows that testing 90% of a slaughter population of 1 million pigs, 20% of a population of a population of 10 million pigs or 10% of a population of 100 million pigs would be required to demonstrate that the negligible risk compartment, and related control measures provided the assurance that there would be less than one potential case of trichinellosis per million slaughtered pigs. For herds smaller than one million pigs, 100% testing would be required in the establishment phase.

These example scenarios illustrate how test data can be used to translate the impact of control measures into a description of consumer health protection. As the model is conservative in nature the level of public health protection achieved should at least be that described by the model. If there is prior knowledge of no infection then the level of public health protection will likely be much greater than that described by the model, and may even be 100%. It was not possible to model this in the current phase of work, but development of a model which could take into account prior knowledge may in the future be able to demonstrate this.
3.6. Development of a risk “contour”

Outcomes from particular sampling scenarios can be compared in terms of achieving equivalent public health outcome. To illustrate this, a range of sampling options could be used to describe a level of public health protection represented by a contour of, for example, one or less potential human cases per 1,000,000 slaughtered pigs. These options are represented in Table 3.5 as gray shaded cells i.e. the pig population size and percentage sampled for each of these shaded cells would achieve the desired public health outcome.

It is clear from this Table that smaller populations of slaughtered pigs (10,000 and 100,000) are outside of the example contour and could not statistically speaking demonstrate achievement of a level of public health protection of one or less potential human cases per 1m slaughtered pigs even if 100% of the slaughter population were sampled. It is important to re-iterate here that this phenomenon is, in large part, a result of statistical and test sensitivity limitations, for example the model outcomes here are taking into consideration the fact that the test sensitivity used for these examples is only 70%. However, in practice, the documentation of an overwhelming number of negative test results for a given population will be considered by animal and human health officials.

Of course, it is the role of the risk manager to decide on what will be the “acceptable risk” contour. For example, a less conservative decision of 10 or more potential human cases per 1m slaughtered pigs being deemed acceptable would result in more sampling options to demonstrate an equivalent level of public health protection.

Table 3.5. Example of a “risk contour” of one or less human cases per 1,000,000 slaughtered pigs (Gray shaded area)

<table>
<thead>
<tr>
<th>Proportion sampled</th>
<th>Population Size</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>10,000</td>
<td>100,000</td>
<td>1,000,000</td>
<td>10,000,000</td>
<td>100,000,000</td>
</tr>
<tr>
<td>0.1%</td>
<td>118970</td>
<td>11897</td>
<td>1190</td>
<td>119</td>
<td>12</td>
</tr>
<tr>
<td>1%</td>
<td>13908</td>
<td>1391</td>
<td>139</td>
<td>14</td>
<td>1</td>
</tr>
<tr>
<td>10%</td>
<td>1326</td>
<td>133</td>
<td>13</td>
<td>1</td>
<td>0.1</td>
</tr>
<tr>
<td>20%</td>
<td>614</td>
<td>61</td>
<td>6</td>
<td>0.6</td>
<td>0.06</td>
</tr>
<tr>
<td>50%</td>
<td>186</td>
<td>19</td>
<td>2</td>
<td>0.2</td>
<td>0.02</td>
</tr>
<tr>
<td>90%</td>
<td>59</td>
<td>6</td>
<td>0.6</td>
<td>0.06</td>
<td>0.006</td>
</tr>
<tr>
<td>100%</td>
<td>43</td>
<td>4</td>
<td>0.4</td>
<td>0.04</td>
<td>0.004</td>
</tr>
</tbody>
</table>

*Using baseline inputs as per Table 3.1

3.7. Outputs from the risk model when one test-positive pig is found

When very large numbers of diagnostic tests are being undertaken over considerable time periods, it is quite likely that one (or more) tests may be positive. Whether a positive test is truly
representative of an infection in a pig or is an artifact, it does have the potential to disrupt the establishment of a "negligible risk" compartment at the farm level as described by OIE. Modeling of the possible impact on public health of a single positive test in a slaughter population compared with a test-negative population is shown in Table 3.6.

The relative increases in possible human health risks are obviously much greater for smaller slaughter populations compared with larger populations. This suggests that subject to appropriate trace-back and investigation at farm level, a single positive test might not be sufficient in itself to invalidate the setting up of a "negligible risk" compartment at farm level from a public health perspective when large amounts of test-negative data are available.

Table 3.6. Mean estimates of possible human health risks per 1,000,000 slaughtered pigs” when test-negative slaughter populations are compared with slaughter populations with one test-positive pig

<table>
<thead>
<tr>
<th>Population size</th>
<th>10,000</th>
<th>100,000</th>
<th>1,000,000</th>
<th>10,000,000</th>
<th>100,000,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proportion sampled</td>
<td>Test negative</td>
<td>One test positive</td>
<td>Test negative</td>
<td>One test positive</td>
<td>Test negative</td>
</tr>
<tr>
<td>0.1%</td>
<td>118970</td>
<td>238005</td>
<td>11897</td>
<td>23800</td>
<td>1190</td>
</tr>
<tr>
<td>1%</td>
<td>13908</td>
<td>27916</td>
<td>1391</td>
<td>2792</td>
<td>139</td>
</tr>
<tr>
<td>10%</td>
<td>1326</td>
<td>2752</td>
<td>133</td>
<td>275</td>
<td>13</td>
</tr>
<tr>
<td>20%</td>
<td>614</td>
<td>1327</td>
<td>61</td>
<td>133</td>
<td>6</td>
</tr>
<tr>
<td>50%</td>
<td>186</td>
<td>471</td>
<td>19</td>
<td>47</td>
<td>2</td>
</tr>
<tr>
<td>90%</td>
<td>59</td>
<td>217</td>
<td>6</td>
<td>22</td>
<td>0.6</td>
</tr>
<tr>
<td>100%</td>
<td>43</td>
<td>186</td>
<td>4</td>
<td>18</td>
<td>0.4</td>
</tr>
</tbody>
</table>

*Using baseline inputs as per Table 3.1

3.8. Analysis of some of the uncertainties associated with the model and their potential impact on model outcomes.

The food pathway model sets the proportion of infective meal servings from an infected pig at 100% and assumes that every infected meal serving will result in a human case. As discussed in the previous Section, these are highly conservative values (i.e., likely to overestimate risk). As mentioned under 2.3.2.2, published data indicate that the infected (experimentally) pig tissues can differ significantly in the number of larvae per gram (Ribicich, 2001 and Forbes and Gajadhar, 1999). It is difficult to obtain infective dose (actual number of larvae ingested) data to know the infectivity of low numbers of larvae in a meal serving.

Figure 3.3 aims to illustrate the impact of these uncertainties on the model outcome. It compares the existing model inputs with a different model input on the percentage of infective
meal servings from an infected carcass, likely to cause illness. In the model as described above when it is assuming that every serving from an infected pig will cause illness Table 3.5) and the example risk contour is set at one or less human cases per 1m slaughtered pigs (Contour A), it can be seen that smaller populations of slaughtered pigs (below 1m) are to the left of the contour and could not statistically demonstrate achievement of that level of public health protection, even if 100% of the slaughter population were sampled.

However, if, for example, only 10% of meal servings from an infected pig had sufficient larvae to infect a human (Contour B), the risk contour shifts considerably to the left. In this scenario, the risk contour shows that smaller slaughter populations with test negative results, albeit with high sampling percentages, could demonstrate achievement of a level of public protection of one human case or less per 1m slaughter pigs.

This theoretical exercise highlights the sensitivity of the risk model to changes in inputs particularly in relation to potential exposure to infected servings as well as dose response and the importance of a better understanding of these aspects in efforts to illustrate the linkage between control measures and risk. The more evidence we have on which we can base the model inputs; the more confident we can be in terms of representativeness of the risk contour line of reality. Combining this with prior knowledge can also facilitate better anchoring of such risk contours in reality. In that respect, if the number of larvae in servings becomes available, the dose-response model could be incorporated into the risk pathway to determine the probability of human infections.
Figure 3.3. Impact of variations in potential exposure and dose response on illustrating the level of protection achieved through the establishment of a negligible risk compartment and the related control measures. Line A illustrates the contour of estimated risk (one or less human cases per 1m slaughtered pigs) generated from slaughter populations of different sizes and sampling proportions according to the original model inputs. Line B illustrated the impact of inputs which indicate reduced exposure to or likelihood of human clinical infection when exposed to *Trichinella*.

For the food pathway model to better reflect the perceived situation, it is important to determine the density of larvae in an infective dose and to use that for a less conservative risk assessment. It is important again to realize that the value of risk assessments may be more in their use for comparative purposes, e.g., relative risk or changes to risk with implementation of different risk mitigations strategies by managers.
4. MODELING EXAMPLES FOR THE LEVEL OF CONSUMER PROTECTION PROVIDED BY A “NEGLIGIBLE RISK” COMPARTMENT ONCE ESTABLISHED

4.1. Possible approaches to be considered to demonstrate a chosen level of consumer protection

Once a negligible risk compartment has been established and the level of consumer protection it achieves articulated, the challenge that remains in terms of consumer protection is how to ensure that the level of protection is being continued.

Risk managers and public health officials need to consider practical approaches to maintaining the desired level of public health protection as defined in establishing the negligible risk compartment. As noted in the previous section, extensive amounts of test data are required in the establishment phase, and subsequent continuation of testing should only be carried out if scientifically justified. In this context the expert meeting identified alternative (to testing) sources of risk-based evidence, and also considered potential pragmatic uses of some level of testing.

The meeting noted that sources of information that could be considered by the risk managers included:

- The relative low global burden of disease by trichinellosis (Devleeschauwer et all, 2014)
- The strength of evidence that this burden is mainly coming from the consumption of meat of pigs, not kept under controlled housing condition and from meat of other susceptible species (e.g. wild boars), in which the prevalence is much higher while negligible and often completely absent in pigs kept under controlled housing conditions (EFSA/ECDC annual reports on zoonoses monitoring, 2012 and Pozio, 2014)
- The results of monitoring carried out to establish the compartment and demonstrating the reliability of preventive measures in the compartment
- The increasing scientific evidence from monitoring for the establishment of a negligible risk compartment and other monitoring (e.g. EFSA 2014 (the 150 million pigs per year), that controlled housing conditions is a very robust system to prevent Trichinella infections in pigs.

In addition, consideration could be given to human illness data collected by public health officials, although this may be challenging if trichinellosis in not a reportable disease. Nevertheless better data on the human health side would be important to better define the dose-response relationship. To achieve this, risk managers could establish a robust system of human surveillance and routine investigation of the source of all human cases. Taking all of these approaches into account, the continued testing of a limited proportion of pigs (smaller populations) with a maximum sufficient to demonstrate a negligible prevalence (large populations) may be justified from a risk perspective.
4.2. Application of a limited testing approach for pigs within a negligible risk compartment

As noted above, continued testing of a limited number of pigs may be considered in the context of demonstrating ongoing public health protection after a negligible risk compartment is established. The number of tests required to maintain the level of consumer protection for a compartment of negligible risk may be reduced over time in comparison to the number of tests required to establish the level of consumer protection for a negligible risk compartment, without necessarily reducing the level of public health assurance that is provided. A limited testing approach could also focus on animals within the negligible risk compartment but which are remaining there for a longer period. For example, sows and boars within a compartment herd live longer and therefore have increased risk of becoming exposed to *Trichinella*. Available data suggest a relative risk of around 2 compared to finishing pigs (Alban et al., 2008).

One option is for a country to continue testing on a limited basis; the meeting noted that a key aspect of this was the accumulation of test data over a number of years. There are modeling approaches available which allow consideration of such data (C/F Appendix 1) so that the results that have been accumulated may be combined to give an equivalent estimate of the possible number of infected pigs in a slaughter population but with a lesser overall number of tests.

In modeling this, a number of subjective choices have to be made, particularly with respect to the number of years of historical data to be included in the analysis. No guidance is available in the published literature as to how long this period should be. However, a suggestion from the Expert Meeting is that a time frame of three years might be appropriate. An example of how additional data generated during a three year maintenance period could be combined using a Bayesian approach was developed and is presented in Annex 3. While this gives a sense of how testing could be reduced over time the meeting considered that there was still a need to further explore the modeling options to better consider in particular historical data.

4.3. Utilizing test data from pigs not kept under controlled housing conditions

Several studies have shown that outdoor-reared pigs have a higher risk of being infected than indoor-reared pigs (Nöckler, et al., 2004; EFSA, 2005, Van der Giessen et al., 2007, and Pozio, 2014). Gamble, et al. (1999) found that farms where pigs had access to wildlife were six times more likely to be *Trichinella* positive than farms where pigs did not have access to wildlife. There are additional studies again documenting the risk of wildlife exposure (Hill, et al.,2010 and Pozio, et al., 2009). In general, the better the biosecurity the higher the relative risk of outdoor-reared pigs compared to indoor pigs. While not developed at this expert meeting, such an approach could also be modeled by giving a much higher weighting to test-negative results from “high risk” pigs from outside of the “negligible risk” compartment compared to those from within. If a reasonable number of test data were available, this might significantly reduce the number of tests needed from pigs from the “negligible risk” compartment while providing an appropriate level of public health assurance.

4.4. Conclusion

In general the meeting identified the challenges with providing specific guidance on testing for public health assurance during maintenance of a negligible risk compartment. While possible, testing in this context can only be considered as a means of verification that the appropriate
control measures are being implemented. It needs to be considered in the context of other data sources which may also contribute to the ongoing assurance of the required level of consumer health protection. Testing may also have a role in guiding the frequency of other monitoring approaches such as auditing of on-farm control. The meeting highlighted that the critical consideration for continued public health protection is implementation of the key control measures, which can be verified in a number of ways, including a mix of audits and targeted testing.

5. DISCUSSION AND RECOMMENDATIONS

In response to the request from CCFH for quantitative examples of risk-based control measures for pigs kept under controlled housing conditions, the Expert Meeting used a simple deterministic model for estimating risks to consumers. The main utility of the model is not to determine absolute risk but in illustrating public health risks associated with different sampling scenarios when testing the carcasses of slaughter pigs for evidence of infection with *Trichinella* spp. larvae.

The variability in possible inputs, to the animal test model (sensitivity) and the food pathway model (at each step), means that the examples in this Report are indicative only and risk estimates may vary significantly in different national situations. Nevertheless, the examples provide an illustration of relative risks across a range of slaughter pig population sizes. In this context, it is probably more important to know the relationship between *Trichinella* in the pig population and the current (or desired) level of public health protection than to calculate estimates of actual risk.

5.1. Estimating public health risks when setting up a negligible risk compartment of pigs at the farm level

The examples presented demonstrate that when setting up a “negligible risk” compartment of pigs at the farm level, the provision of an adequate public health assurance on the basis of test-negative results requires testing very large numbers of pigs. The actual number that will need to be tested in a particular (national) situation will depend on the level of public health protection that has been decided on by the risk manager and the availability of a sufficient number of test results as indicated by the examples.

Using this deterministic model, mean estimates of possible human health risks when the test sample and the slaughter population vary in size appear to follow a pattern. This allows modelers to fit a contour or curve to the pattern when plotting slaughter pig population against proportion of pig population sampled. A risk contour or curve can be selected on the basis of a decision on an acceptable level of risk by the risk manager. The contour can then be superimposed on model outputs for different sampling scenarios. Any sampling scenario that illustrates achievement of the level of public health protection described by the risk contour can be considered as providing an equivalent level of public health protection. The Report provides examples of risk contours but it is up to the risk manager to set these in the national situation.

Agreed public health outcomes can be achieved using scientifically-justified control measures and unjustified restrictions on trade can be avoided. The results from the risk model clearly
demonstrate the value of a risk-based approach to establishing food safety controls for decision making. However, further improvement of the risk model, e.g., number of larvae in a meat serving before consumption and incorporating the dose-response model for humans, will likely reduce an important source of uncertainty in the outputs of the model.

A further consideration in application of the outputs of this risk model is to take into account historical information even though it may not have been accumulated during the setting up of a “negligible risk” compartment at the farm level. The animal test model estimates the risk of an infected pig remaining in a test-negative slaughter population but this statistically-based estimate is dependent on the likelihood that infection does actually occur at some very low level. However, test-negative data accumulated from housed pigs in some countries strongly suggests that there is “no possibility” of infection. In the EU, over 200 million pigs were tested in 2012, and none of the 332 test-positive pigs were from fattening pigs raised under controlled housing conditions (EFSA, 2013, Pozio, personal comm., and De Smet, personal comm., September 2014). While there are no risk modeling “rules” for the risk manager to take this prior knowledge into account, this situation suggests that sample numbers could be even further reduced during the setting up of a negligible risk compartment (and maintenance).

5.2. Discussion on current quantitative provision for testing pigs in the draft CCFH

The current CCFH draft guideline presents an animal test statistic of one or less positive pigs per 1m slaughtered, at the 95% confidence level, as a monitoring target for control of *Trichinella* spp. in pig meat. This target is not risk-based and the model presented in this report illustrates the challenges of demonstrating this, particularly in smaller pig populations. Thus it was concluded by a majority of the expert meeting attendees that this draft provision is not scientifically justifiable and is prejudicial to equitable trade, especially between countries with small populations of slaughter pigs.

5.3. Limitations and Caveats

Estimates generated from statistical computations are at best hypothetical and do not necessarily reflect what is actually happening in the real world. They can provide valuable inputs to the decision making process but should not be considered in isolation from other sources of information. The risk assessor should ensure that the risk manager is fully aware of the context in which particular risk estimates are generated and consider this together with other inputs. For example, as mentioned above, in some countries there may be a large amount of test-negative historical data. Outputs from any model are only as good as the inputs and so the limitations of those (e.g. an imperfect test; test negative data only; data only on pigs from a negligible risk compartment) must be taken into account. Also the way in which the model is used is an important consideration, i.e. whether outputs are considered in terms of relative risk or absolute risk.

With limited data, presenting the outputs in terms of absolute risk can be very challenging to communicate, particularly if it contrasts sharply with what many years of surveillance data are indicating. In the area of microbiological risk assessment some efforts to address this have been undertaken by for example anchoring the risk model with real world epidemiological data. The use of the outputs of the model in a relative sense where the difference in outputs between different scenarios modeled is what is being considered rather than the actual risk of each scenario can help overcome this issue.
5.4. Conclusions and Recommendations

The expert meeting concluded that:

- Risk based models can be used to support the articulation of the level of consumer health protection that is achieved by the implementation of a defined set of control measures such as those included in the establishment of a negligible risk compartment.

- Risk models are only an attempt to model what is happening in reality and should always be presented and used in conjunction with a range of other inputs relevant to risk management.

- The amount of sampling and test data required in the establishment of a negligible risk compartment to demonstrate the level of consumer health protection is extensive and varies according to population size and the proportion sampled.

- There are a number of data sources that can be potentially used to provide evidence of ongoing maintenance of the level of consumer health protection, that need to be further explored. In some cases this may mean increased human illness data collection by public health authorities.

- In some areas there are significant limitations in the data available to serve as inputs to the model which contribute to the uncertainties in the outcome and that the model would be improved with the availability of better date in the areas of exposure and dose response.

The Expert Meeting recommended that:

- Risk managers use the current risk models for *Trichinella* primarily as a way to compare means of assuring public health protection (e.g., test regimens) during the establishment of a negligible risk compartment, together with other relevant information when available.

- Risk managers recognize the use of controlled housing systems and the creation of a negligible risk compartment by animal health authorities in the effective control of *Trichinella* in pigs.

- Further work on the relative effectiveness of farm audit and/or limited slaughterhouse monitoring in assuring that expected levels of public health protection continue to be provided be undertaken by risk managers at national and/or regional level and relevant international organizations.

- FAO and WHO and risk managers at national level undertake further work on the use of historical slaughterhouse data and data from sources outside of the compartment for assuring that expected levels of public health protection continues.

- FAO and WHO explore the potential to extend the work on the *Trichinella* spp. model in order to further develop (e.g. consideration of historical data, years of test-negative pig slaughter data existing for some countries) and review the risk model with the view to potentially making it available as a robust tool for application by risk managers at national level.
Further work should be undertaken by FAO/WHO to develop a “user-friendly” guideline for an integrated food chain approach to control of *Trichinella* spp. in pig meat, taking into account the risk modeling developed in this Report.

CCFH develop scientifically sound and risk-based provisions for public health assurance associated with establishment and maintenance of a compartment with a negligible risk of *Trichinella* infection in domestic pigs kept under controlled management conditions.
6. PUBLICATIONS USED IN THE PREPARATION OF THIS DOCUMENT


**ANNEX 1: TRICHINELLA SPP. INFECTIONS IN DOMESTIC PIGS OF EUROPE AND AMERICA**

*Trichinella* spp. Infections in domestic pigs of Europe and America, (derived from Pozio, 2014):

<table>
<thead>
<tr>
<th>Country</th>
<th>Controlled systems</th>
<th>Non-controlled systems</th>
<th>Reference period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belarus</td>
<td>No data</td>
<td>0.0005%</td>
<td>1980-89</td>
</tr>
<tr>
<td>Bosnia and Herz.</td>
<td>No data</td>
<td>~300/unknown</td>
<td>1997-2000</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>0.0/0.36 million</td>
<td>~40/unknown</td>
<td>2006-12</td>
</tr>
<tr>
<td>Estonia</td>
<td>0.0/0.48 million</td>
<td>1 in 1994, 1 in 1999</td>
<td>1994-2012</td>
</tr>
<tr>
<td>Finland</td>
<td>0.0/4.8 million</td>
<td>343/unknown</td>
<td>1995-2004</td>
</tr>
<tr>
<td>France</td>
<td>0.0/16 million</td>
<td>19/unknown Corsica island</td>
<td>2004-12</td>
</tr>
<tr>
<td>Germany</td>
<td>0.0/49 million</td>
<td>8/unknown</td>
<td>2003-12</td>
</tr>
<tr>
<td>Greece</td>
<td>0.0/4.5 million</td>
<td>36/12,717</td>
<td>2009-12</td>
</tr>
<tr>
<td>Hungary</td>
<td>0.0/4 million</td>
<td>2 in 2000, 6 in 2003, 4 in 2009</td>
<td>2000-12</td>
</tr>
<tr>
<td>Italy</td>
<td>0.0/9 million</td>
<td>17/unknown</td>
<td>2006-12</td>
</tr>
<tr>
<td>Latvia</td>
<td>0.0/0.3 million</td>
<td>2/unknown</td>
<td>2011</td>
</tr>
<tr>
<td>Lithuania</td>
<td>0.0/0.8 million</td>
<td>84/unknown</td>
<td>2006-11</td>
</tr>
<tr>
<td>Poland</td>
<td>0.0/20 million</td>
<td>342/unknown</td>
<td>2001-11</td>
</tr>
<tr>
<td>Macedonia</td>
<td>0.0/0.1 million</td>
<td>Not available</td>
<td>2000-03</td>
</tr>
<tr>
<td>Montenegro</td>
<td>0.0/0.05 million</td>
<td>26-42/unknown</td>
<td>2000-03</td>
</tr>
<tr>
<td>Romania</td>
<td>0.0/3.0 million</td>
<td>404/unknown</td>
<td>2007-11</td>
</tr>
<tr>
<td>Serbia</td>
<td>0.0/1.7 million</td>
<td>416-2875/unknown</td>
<td>2001-10</td>
</tr>
<tr>
<td>Country</td>
<td>Prevalence or number of infected pigs per number of tested pigs</td>
<td>Year</td>
<td></td>
</tr>
<tr>
<td>--------------</td>
<td>---------------------------------------------------------------</td>
<td>------------</td>
<td></td>
</tr>
<tr>
<td>Slovakia</td>
<td>0.0/0.8 million</td>
<td>2000-11</td>
<td></td>
</tr>
<tr>
<td>Spain</td>
<td>0.0/38 million</td>
<td>2004-08</td>
<td></td>
</tr>
<tr>
<td>Argentina</td>
<td>0.0/1.5 million</td>
<td>2008-12</td>
<td></td>
</tr>
<tr>
<td>Canada</td>
<td>0.0/30,000</td>
<td>1998-2012</td>
<td></td>
</tr>
<tr>
<td>Mexico</td>
<td>0.0/10 million</td>
<td>2009-12</td>
<td></td>
</tr>
<tr>
<td>USA</td>
<td>0.0/85 million</td>
<td>2003-12</td>
<td></td>
</tr>
</tbody>
</table>

*Prevalence or number of infected pigs per number of tested pigs in controlled systems per year

*Prevalence or number of infected pigs per number of tested pigs in non-controlled systems per year
1. Model structure

The Figure below presents a schematic representation of the Excel-based *Trichinella* model.
2. Detailed description

The starting point of the model is based on the number of pigs slaughtered per year in a given national or regional situation, the proportion of those tested per year, and an estimate of the test sensitivity (SE). Based on an apparent prevalence (AP) of zero, the model estimates the true (possible) prevalence (TP) of *Trichinella* infection using a Bayesian approach, in which a prior distribution needs to be specified for the TP, which is then updated based on the observed test results.

In a Bayesian approach, essentially three steps are involved: (1) determining a prior estimate of the parameter in the form of a confidence distribution; (2) finding an appropriate likelihood function for the observed data; (3) calculating the posterior estimate of the parameter by multiplying the prior distribution and the likelihood function (Vose, 2008).

The model applies a Beta \((1, 0)\) prior distribution for TP and a Binomial likelihood for the observed results, leading to a Beta posterior distribution. For instance, if \(s\) samples tested positive from a sample size of \(n\), the posterior distribution will be a \(Beta(s + 1, n - s)\). The mean of this distribution will be \((s + 1)/(n + 1)\). The model further corrects this result for the test sensitivity (SE), but assumes a perfect (100%) test specificity. Overall, the average true prevalence corrected for test sensitivity is calculated as follows (cell O24, on the spreadsheet):

\[
TP = \frac{(s + 1)/(n + 1)}{SE}
\]

The model also calculates the 95\(^{th}\) percentile for the TP (cell O32). Implicitly, the Binomial likelihood implies that the number of tested pigs is derived from an infinite population.

The number of infected but test negative pigs that enters the food chain is obtained by multiplying the TP with the total number of pigs slaughtered per year. The model then goes on to calculate the mean (cell O42) and 95\(^{th}\) percentile (cell O52) for the number of infected meals prior to cooking based on this total number of infected pigs, using the number of edible portions of fresh pork that would come from a carcass (cell L45) and the proportion of the carcass that would be used for fresh pork sales (cell L53). Finally, model calculates the mean (cell O63) and 95\(^{th}\) percentile (cell O70) for the number of infected meals after cooking by multiplying the previous result by the percentage of meals that might have been rendered safe by cooking (cell L65).

3. Model assumptions and limitations

3.1. Bayesian assessment of true prevalence

The model uses a Beta\((1, 0)\) prior for the TP. This can interpreted as adding one case to the observed results. It is recognized that other priors (e.g. Beta\((1, 1)\), Beta\((0.5, 0.5)\)) could potentially be used.

3.2. Finite population

The model inherently assumes an infinite population, as part of Binomial likelihood used in the calculation of the TP. In reality, the sample population can be (very) large in comparison to the overall number of pigs slaughtered per year. In this situation, the assumptions underpinning the Binomial distribution may be invalid and a Hypergeometric distribution
may be more appropriate. Vose (2008) suggests that if the total population is less than ten times the size of the sample, one should not make a binomial approximation to the hypergeometric. Caution should be exercised if the model is being used in situations where this is an issue.

### 3.3. Test sensitivity and specificity

The model assumes constant test sensitivity, irrespective of larval density in the carcass. Data on the distribution of larval density across positive carcasses would allow modeling of SE in terms of larval density. The model also assumes a perfect (i.e., 100%) test specificity.

### 4. Model for maintenance

The model was initially developed as a tool to support the risk management decisions associated with the establishment of a negligible risk compartment. A statistically-based model can also be used as a tool to assess slaughter surveillance programmes for maintenance of negligible risk compartments. As one aspect of this model, a Bayesian approach needs to be adopted to assess utility of historical test results as a prior in ongoing surveillance.

In a Bayesian approach, as mentioned above, essentially three steps are involved: (1) determining a prior estimate of the parameter in the form of a confidence distribution; (2) finding an appropriate likelihood function for the observed data; (3) calculating the posterior estimate of the parameter by multiplying the prior distribution and the likelihood function (Vose, 2008).

During the maintenance phase, additional test data will become available, which can be combined with the data used for establishment. The following example shows how the Beta posterior can be updated sequentially given a further year of test results:

**Establishment:**

Prior = Beta(1, 0)

Test data = 0 positives out of 100,000

Posterior = Beta(1 + 0; 0 + (100,000 − 0)) = Beta(1; 100,000)

Mean = 1 / 100,001

**Subsequent sampling:**

Prior = Beta(1 + 0; 0 + (100,000 − 0)) = Beta(1; 100,000)

Test data = 0 positives out of 50,000

Posterior = Beta(1 + 0 + 0; 0 + (100,000 − 0) + (50,000 − 0)) = Beta(1; 150,000)

Mean = 1 / 150,001

In this example, we have only included one additional year of test data and have assigned the same weight to the historical data. It is feasible to combine data for a number of years and to qualitatively assign weights to the value of the historical data. For example, with two years of historical data, a weighting could be assigned as follows: 25% first year, 50% second year, 100%
current year. By its nature, the Bayesian approach and the choice of the appropriate prior is subjective. However, the approach gives an indication of how much the intensity of testing can be relaxed in the maintenance phase.

References


The following example gives an indication of how additional data generated during a three year maintenance period could be combined using a Bayesian approach. The example considers a country with a large pig population (> 10,000,000) that gathers 500,000 test results over two years with zero cases positive. During the subsequent maintenance programme, 50,000 pigs are tested per annum, again with zero cases positive each year. Table A.1 summarizes the outcomes of a Bayesian analysis assuming equal weighting assigned to the three years of test data. Using the data accumulated over the three years of the maintenance phase, a Bayesian analysis would estimate the mean prevalence of potentially infected pigs to be 1/150001, which is considerably less than the estimate of 1/50001 if only one year’s data was used. While this example is only indicative of the Bayesian approach that can be adopted, it demonstrates that the number of tests required to maintain a compartment of negligible risk can be reduced over time in comparison to the number of tests initially required to establish a negligible risk compartment while still providing an equivalent level of public health assurance.

Table A.1. A Bayesian approach to estimate the mean prevalence of possibly infected pigs

<table>
<thead>
<tr>
<th>Year</th>
<th>Prior</th>
<th>Test data</th>
<th>Posterior</th>
<th>Mean prevalence of possibly infected pigs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Establishment phase (2 years)</td>
<td>Beta(1:0)</td>
<td>0:500,000 positive</td>
<td>Beta(1:500000)</td>
<td>1/500001</td>
</tr>
<tr>
<td>Maintenance – year 1</td>
<td>Beta(1:500000)</td>
<td>0:50,000 positive</td>
<td>Beta(1:550000)</td>
<td>1/550001</td>
</tr>
<tr>
<td>Maintenance – year 2</td>
<td>Beta(1:550000)</td>
<td>0:50,000 positive</td>
<td>Beta(1:350000)</td>
<td>1/350001</td>
</tr>
<tr>
<td>Maintenance – year 3*</td>
<td>Beta(1:350000)</td>
<td>0:50,000 positive</td>
<td>Beta(1:150000)</td>
<td>1/150001</td>
</tr>
</tbody>
</table>