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Risk-based examples and approach for control of *Trichinella* spp. and *Taenia saginata* in meat

REVISED EDITION

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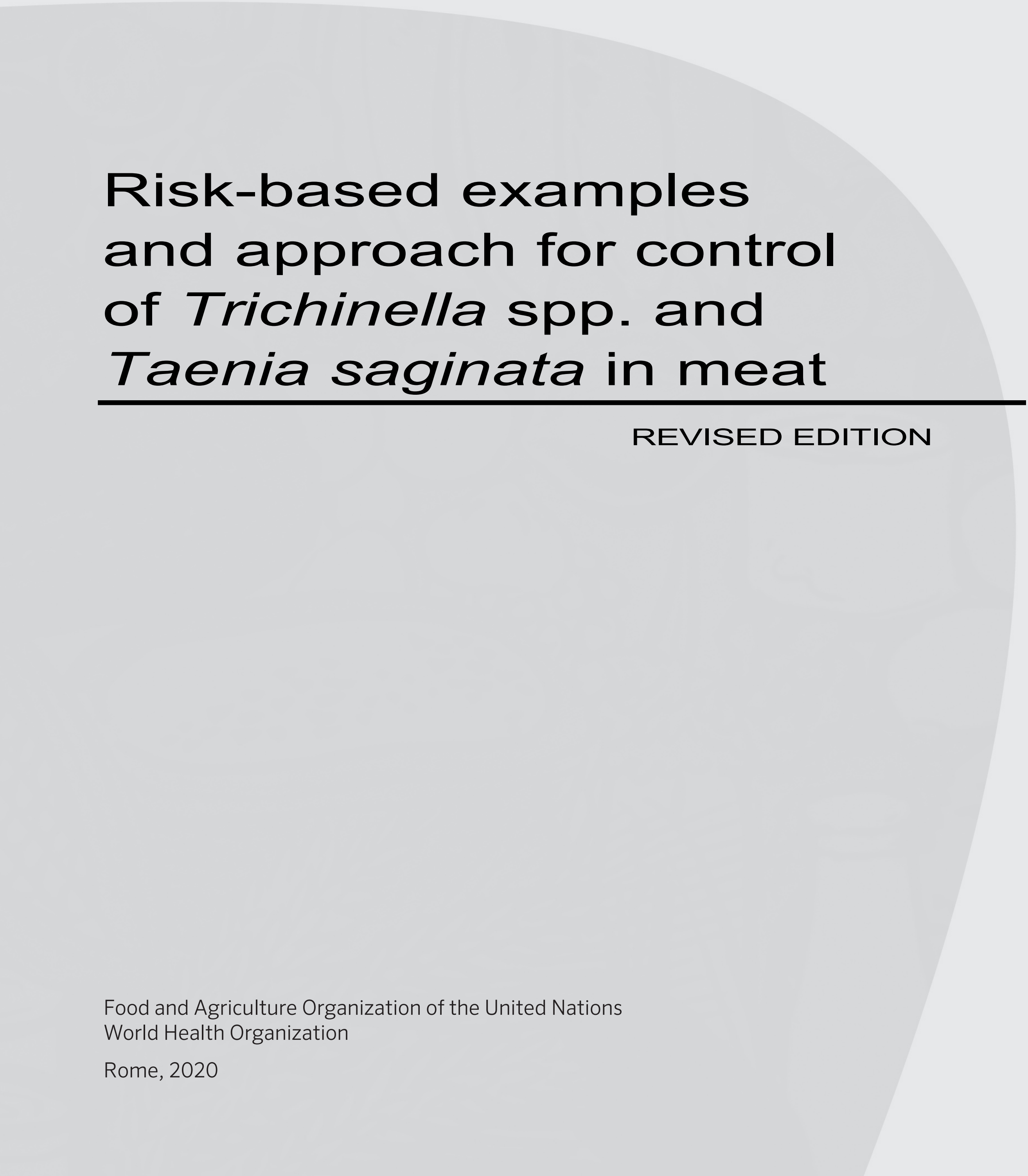

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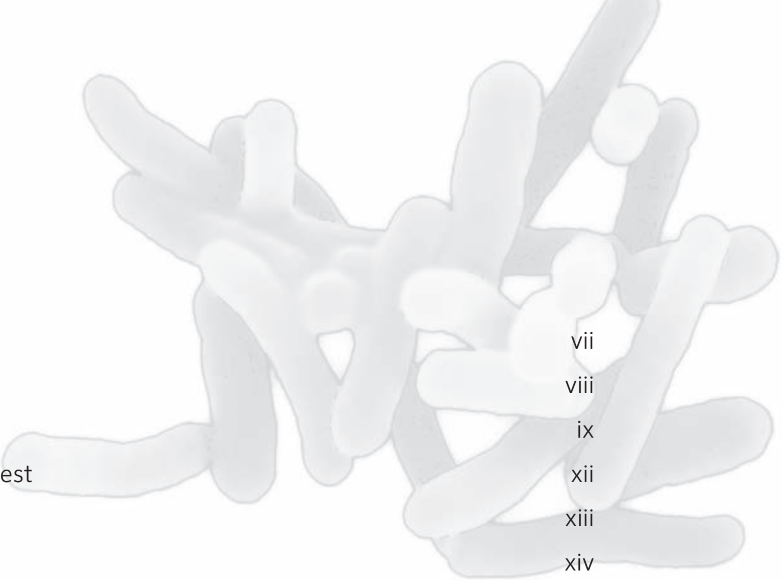

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Preface

The process of developing risk-based control of *Trichinella* spp. and *Taenia saginata* in meat was initiated at an expert meeting hosted by WHO, Geneva, 22–25 October 2013. The subsequent draft report of this meeting was made available to facilitate ongoing discussion in this area in 2014. In response to the request from the 45th Session of the Codex Committee on Food Hygiene (CCFH) to continue working on the examples of *Trichinella* spp., FAO and WHO convened a preparatory meeting to improve risk models for *Trichinella* spp. in pigs in Geneva on 17–18 July, followed by an expert meeting at FAO, Rome on 15–17 September 2014. The discussion and conclusion in these meetings was taken into consideration in finalizing this report. In addition, the document was also subject to peer review before finalization.

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Final editing for language and preparation for publication was completed by Thorgeir Lawrence.

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Declarations of interest

All participants of the two expert meetings completed a Declaration of Interest form in advance of the meeting. None was considered to present any potential conflict of interest.

Abbreviations

APHIS	Animal and Plant Health Inspection Service (of the USDA)
CAC	Codex Alimentarius Commission
CCFH	Codex Committee on Food Hygiene
CL	Confidence level
EFSA	European Food Safety Agency
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FSIS	Food Safety Inspection Service (of the USDA)
ICT	International Commission on Trichinellosis
OIE	World Organisation for Animal Health
UECBV	European Livestock and Meat Trading Union
USDA	United States Department of Agriculture
WHO	World Health Organization

Executive summary

THE FIRST EXPERT MEETING, 2013

This expert meeting was implemented following the request of the Codex Committee on Food Hygiene (CCFH) which has been developing the Proposed Draft Guidelines for Control of Specific Zoonotic Parasites in Meat: *Trichinella* spp. and *Taenia saginata*. In November 2012, the 44th Session of the CCFH re-iterated the request of its 43rd Session to FAO and WHO to develop risk-based examples for *Trichinella* spp. and *Taenia saginata* to illustrate the level of consumer protection likely to be achieved with different pre- and/or post-harvest risk management options, based on evaluation of slaughterhouse information and other data sources such as human illness. To facilitate the response, the CCFH requested the collection and review of existing information on risk-based examples for *Trichinella* spp. and *Taenia saginata*.

The proposed objectives of the meeting were:

1) to reach a common understanding of the risk management options that might be used for risk-based control of *Trichinella* spp. and *Taenia saginata* in meat;
2) to analyse available data and information that contributes to establishing a risk-based approach to the control of these two zoonotic parasites;
3) to develop risk-based examples (scenarios) for *Trichinella* spp. and *Taenia saginata* describing the likely levels of residual risk for consumers with different re- and/or post-harvest risk management options;
4) to provide an information resource for risk managers as an input to their risk management decisions.

The experts were presented with two different spreadsheet models, one for *Trichinella* spp. and the other for *Taenia saginata*, to respond to the requests from the Codex Committee.

Trichinella spp.

The expert meeting aimed to provide examples for the confirmation of the establishment of a negligible risk compartment under controlled housing conditions, taking into account different assumptions relevant for the risk that *Trichinella* spp. might cause through the consumption of pork and pork-derived products.

A spreadsheet model was made available to the experts to develop the examples, which estimates the number of infected portions per million servings from pig populations in controlled housing compartments. The model applies an overarching assumption that every infected edible portion, independent of the number of larvae present in the meat, will cause human infection or illness. It also assumes that *Trichinella* larvae are uniformly distributed in an infected carcass, even though this is seldom the case in real life. Thus, the model is very conservative in its outputs.

Using model input parameters to illustrate the different residual risks to consumers when different testing information is used to establish a negligible risk compartment, seven hypothetical examples were developed that simulated a range of scenarios. Conservative estimates are taken for the percentage of a carcass reaching the consumer as fresh pork and for the percentage that is consumed raw or undercooked.

The model showed that testing of a substantial number of pigs is needed to reduce residual risks to very low levels. However, there is a point where testing of additional pigs may not result in any further meaningful reduction in residual risk and thus may not result in significant further improvement in public health benefit.

Once a negligible risk compartment is established, maintaining the controlled housing conditions, and thus the negligible risk status, is essential. Verification of the public health status resulting from maintenance can potentially be accomplished by using different approaches either separately or in combination:

- References to audit results at farm level, noting that audits will likely be the responsibility of a competent authority other than that responsible for public health
- Surveillance in the live pig population under controlled housing conditions using test methods recommended by OIE (2018)
- Surveillance of pigs outside the controlled housing compartment
- Reporting of autochthonous human cases when robust public health surveillance and reporting systems are in place

Demonstrating maintenance in a risk-based and cost-effective way is an essential part of the "negligible risk compartment" approach and would be the subject of an expert meeting planned for 2014.

Taenia saginata

The purpose of the model used was to illustrate differences in relative risks to consumers when different intensities of postmortem meat inspection procedures are used, thereby informing decisions by risk managers on the most appropriate procedures to use in populations with different levels of infection. Thus, the outputs of the model provided are very useful in "modernization" of meat inspection.

A simple spreadsheet model was provided to estimate the residual level of risk to consumers following the application of specified postmortem meat inspection procedures to a slaughter population of a known size. Conservative model inputs were used. The model did not include a human dose response but made use of the assumption that one residual cyst can lead to one tapeworm infection in humans. The final output of the model was the number of human infections that is expected to result from the slaughter population of known size.

The expert meeting provided examples of relative risks for four countries (W, X, Y, Z) with high, medium, low and very low number of cases of bovine cysticercosis as detected at abattoirs per year, respectively. Four model scenarios (A, B1, B2, C) were used with different sensitivity of inspection or viability of cysts.

The examples showed that the relative increase in human taeniosis cases associated with less intensive meat inspection was highly dependent on this change in postmortem inspection. In countries with a high prevalence of *Taenia saginata* in cattle, residual risks were relatively high irrespective of the postmortem inspection package used. Conversely, countries with a low prevalence of *Taenia saginata* in their slaughter populations had a very low level of residual risk for consumers, and changes to the intensity of the postmortem inspection package had negligible impact on this risk estimate.

Conclusions

The application of simple spreadsheet models by the expert meeting resulted in effective generation of the quantitative risk-based information that is needed by public health officials when evaluating different meat hygiene programmes for *Trichinella* spp. and *Taenia saginata* in meat.

This innovative approach will significantly benefit from further work to generate more accurate estimates of relative risk, such as by:

- using less conservative model inputs and perhaps different model structures;
- including a dose response module;
- illustrating differences in test regimes for *Trichinella* spp. when establishing a negligible risk compartment cf. verifying maintenance;
- utilizing evidence-based data on consumer cooking habits in relation to beef/pork in a population or country, as well as for meat treatments by food business operators;
- using Bayesian approaches to modelling different combinations of controls.

THE SECOND EXPERT MEETING, 2014

The 45th Session of the Committee requested FAO and WHO to continue working on the examples of *Trichinella* spp., in particular, to:

1) further extend the work already done on illustrating the levels of public health protection that can be achieved when establishing a negligible risk compartment (Section 7.3 and 9 of CXG 86-2015[1]), particularly as the current examples are highly conservative in some model inputs;
2) develop examples to assist competent authorities in deciding on options for ongoing verification of a negligible risk compartment ("maintenance") and for judging the equivalence of different options listed in Section 9 (of CXG 86-2015[1]) "Monitoring and Review"; and,
3) ensure a strong focus on communicating a risk-based approach to the control of *Trichinella* spp. in pigs in an effective and easily understood manner in the scientific report.

The expert meeting used a simple deterministic risk model, the main utility of which is not to determine absolute risk but to describe the level of public health protection associated with a compartment of negligible risk for *Trichinella* spp. infection of pigs. The model inputs different sampling and testing scenarios of slaughter pig populations for *Trichinella* spp. into an animal test model and combines this with a food pathway model to illustrate the relationship between *Trichinella* spp. in the pig population and the current or desired level of public health protection. Examples show how risk managers in different national scenarios can demonstrate the level of public health protection achieved, by a negligible risk compartment, based on testing parameters. Modellers were able to fit a contour or curve to the results which can be used by a risk manager to select a level of public health protection and determine equivalent levels of protection with different model inputs. Modellers also assessed risk with one test-positive pig finding.

Experts agreed that in many countries, overwhelming human health and animal testing data confirm the effectiveness of a negligible risk compartment to prevent *Trichinella* spp. infection in pigs and subsequently in humans. An example of the use of a Bayesian approach to include historic test data was developed to estimate risk using accumulated test-negative data. This indicated that the number of tests needed to provide confidence in the level of public health protection could be reduced with time.

Overall, the expert meeting made the following conclusions:

- 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

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[1] http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXG%2B86-2015%252FCXG_086e_2015.pdf

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 potentially be 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 the model would be improved with the availability of better data in the areas of exposure and dose response.

In addition, the expert meeting made the following recommendations:
- Risk managers use the current risk models for *Trichinella* spp. 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* spp. 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 the national and/or regional level and at relevant international organizations.
- FAO and WHO and risk managers at the 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 continue.
- 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 the national level.
- Further work should be undertaken by FAO/WHO to develop a “user-friendly” guideline for an integrated food chain approach to the control of *Trichinella* spp. in pig meat, taking into account the risk modelling developed in this report.

1

Introduction

1.1 BACKGROUND

Human trichinellosis is caused by the consumption of raw or inadequately treated meat from domestic or game animals containing the larvae of parasites of the *Trichinella* species. *Taenia saginata* causes bovine cysticercosis, a parasitic disease of cattle, by the larval stage (*Cysticercus bovis*) of the human tapeworm *Taenia saginata*. Taeniosis, infection of humans with the adult tapeworm, ocurrs following consumption of beef with cysticerci that has not been sufficiently heated or frozen to kill the parasite. Both are important for humans and in the meat trade. Traditionally, control of these parasites in host animals and their meat has been undertaken at some level within the food chain, e.g. biosecurity on-farm and inspection in a slaughterhouse.

The control of *Trichinella* spp. and *Taenia saginata* in meat was discussed at the CCFH, with the elaboration of "Draft Guidelines for Control of Specific Zoonotic Parasites". OIE has since revised and adopted the chapter on "Infection with *Trichinella*" (now Chapter 8.17) of the *Terrestrial Animal Health Code* (2019), recommending control measures at the farm level to prevent foodborne illnesses in humans. As a result, the importance of a risk-based approach to control *Trichinella* in meat through the complete farm-to-plate continuum was recognized by both organizations (OIE, 2018).

Applying a risk-based approach to meat hygiene requires re-evaluation of traditional practices and a refocusing of regulatory and industry resources proportionate to risks. While this approach is now strongly advocated by national governments, there has been an uneven uptake on a global basis. As a consequence, the import requirements for meat and meat products of most countries represent a mix of risk-based and traditional procedures and tests. Such is the case of *Trichinella* spp. and *Taenia saginata* in meat, where risk analysis principles can be applied to different types of traditional meat hygiene procedures. The development of this new approach calls for strong cooperation with OIE so as to facilitate a whole food chain approach to risk reduction measures.

A call for data was issued to member countries and a summary of the information can be found in Annex 3.

1.2 CONTEXT

The modernization of food safety systems has brought about a change from reactive to preventive food control activities, moving towards risk-based approaches that require all operators in the food chain to share responsibility for food safety. In the particular case of the parasites considered here, the linkage between control measures (pre-harvest and post-harvest) along the food chain continuum and the public health outcomes (illness in the consumer population), would aid risk managers to pinpoint the location (among the farm, abattoir, processor and consumer steps) for appropriate food safety interventions.

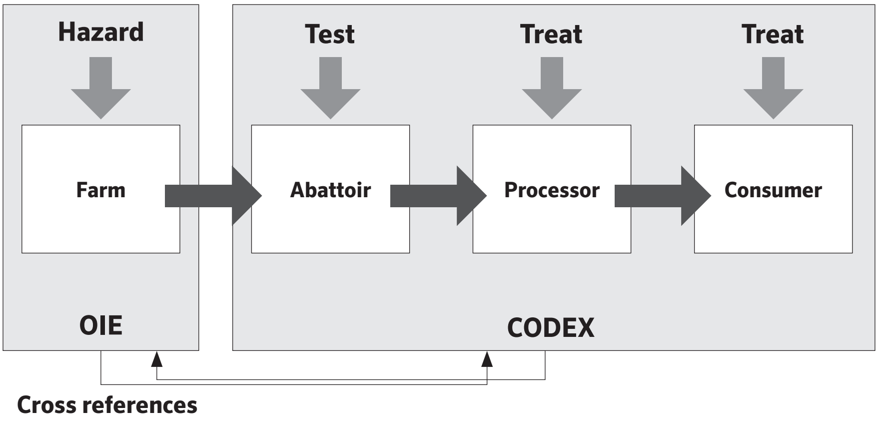

FIGURE 1. Steps in the food chain for application of control measures (Hathaway, 2013).

Controls for the parasites can be applied at several steps in the food chain, and those applicable at the pre-harvest (farm) and post-harvest (primary processing in the slaughterhouse) (Figure 1) are well described in the scientific literature and guidelines developed by international bodies such as OIE, FAO and WHO.

The *OIE Terrestrial Animal Health Code* (OIE, 2019a) provides guidelines for on-farm prevention of *Trichinella* infection in domestic pigs and includes requirements for establishing a compartment with a negligible risk of *Trichinella* infection for domestic pigs kept under controlled management conditions. OIE did not provide such guidance for *Taenia saginata*. CCFH developed guidance on the control of *Trichinella* and *Taenia saginata* using a whole-of-food-chain approach, including guidance to national governments on making public health decisions on the appropriate level of consumer protection.

A negligible risk compartment refers to a compartment with a negligible risk of *Trichinella* infection (OIE, 2019). This term, "negligible of *Trichinella* infection", was amended from the former "*Trichinella*-free" because the determination of a "free" status is not feasible given the sensitivity of currently available tests and the limited statistical power of most surveillance data (OIE, 2018).

1.3 RISK ASSESSMENT

In responding to the above objectives, the experts were tasked with quantitatively illustrating the risks associated with selecting different risk management options by risk managers. Two spreadsheet risk models were provided to the experts as a baseline resource (Annex 1 and 2) (Ryan and Hathaway, unpubl.; Van der Logt and Hathaway, unpubl.). The spreadsheet models are based on a relative assessment of the risk under different scenarios.

An important aspect of the task was the illustration of the residual risk to consumers following the implementation of selected control measures, especially in the context of different intensities of post-slaughter testing (*Trichinella* spp.) and postmortem inspection (*Taenia saginata*). It is important to note that it is not the role of the scientific expert to make the actual decision on what constitutes a negligible risk to the consumer.

2

Risk-based examples and approach for control of *Trichinella* spp. in meat

2.1 NECESSARY INPUTS FOR MODELLING THE FOOD CHAIN FOR CONTROL OF *TRICHINELLA* SPP. IN MEAT

The components of relevance to a risk-based approach were defined by the experts at the meeting. On the farm, the focus was centred on domestic pigs under controlled housing conditions. Non-controlled housing status was considered in one scenario for comparison purposes only. A description of inputs required for modelling of the food chain for control of *Trichinella* spp. in pig meat is shown in Table 1. In addition, the experts mentioned that the exchange of food chain information with the abattoir stage was important to derive the necessary data.

At the abattoir level, there was agreement over the factors to consider, but there was some discussion on the test type, and on the evidence of differences in current food safety systems.

The test method was selected in accordance with the diagnostic techniques recommended in Chapter 3.1.20 of the *OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (2018).

For the purposes of this expert meeting, risk modelling did not include serological testing as a possible control measure because of the lack of knowledge on performance characteristics (sensitivity and specificity).

TABLE 1. Inputs required for modelling of the food chain for control of *Trichinella* in pig meat

Stage	Factors	Values	Justification
Farm	Prevalence of carcasses that test positive post-slaughter as a determinant of negligible risk status (OIE)		To establish and maintain negligible risk status
	Population size of pigs in controlled housing compartments		
	Age of the animals at slaughter		
Abattoir	Prevalence of test-positive animals		To establish and maintain negligible risk status
	Performance characteristics of digestion test (sensitivity and specificity; detection limit)	50-70%	The limits of the model were 50-100% sensitivity in digestion testing.
	Sampling plan and sites sampled test		
	Sample size		
Processing	Percentage of pig meat placed on the market as fresh meat or processed meat	The limits of the model are 10-100% fresh pork	United States of America, Fresh: 25%
			European Union (UECBV) Fresh: 15-17% Processed: 60-66% Frozen: 15-17%
	Processing treatments (freezing, heat treatment, drying, curing (cold and hot) and their validation		As regards processing: 30% cooked sausages; 20% cooked ham; 15% dried sausages; 10% dried ham; 25% others, such as bacon (cured).
Consumer	Number of edible portions from 1 pig carcass	400	Reference (United States of America) The model establishes between 50 and 150 meals/carcass.
	Percentage of edible portions eaten raw or fresh	1-2%	United States of America, 1%; New Zealand, 1%; European Union, 5% The model sets a range of between 0 and 10% meals not rendered safe by cooking (undercooked or raw)

2.2 RISK-BASED EXAMPLES FOR CONTROL OF *TRICHINELLA* SPP.

2.2.1 Establishing a negligible risk status

2.2.1.1 Purpose

The purpose of this section is to provide examples for the confirmation of the establishment of a negligible risk compartment under controlled housing conditions, taking into account different assumptions relevant for the risk that *Trichinella* spp. may cause through the consumption of pork and pork-derived products. It provides a tool for risk managers to decide on the acceptable residual risk for consumers. The main aim is to illustrate relative risk, depending on the scenarios being considered.

A negligible risk compartment refers to a compartment with a negligible risk of *Trichinella* infection (OIE, 2019a).

2.2.1.2 Model

A spreadsheet model (Annex 2) was made available to the experts to develop the examples. The model estimates the number of infected portions per million servings from pig populations in controlled housing compartments. The model does not include a quantitative description of the risk in terms of a human dose response model, so the overarching assumption is that every infected edible portion, independent of the number of larvae present in the meat, will cause human infection or illness. It also assumes that *Trichinella* larvae are uniformly distributed in an infected carcass, even though this is seldom the case in real life. Thus, the model is very conservative in its outputs.

2.2.1.3 Model inputs

To illustrate the different residual risks to consumers when different testing information is used to establish a negligible risk compartment, the following model input parameters were used:

- Number of pigs slaughtered
- Number of pigs tested within the controlled housing compartment
- Number of pigs testing positive
- Diagnostic sensitivity of testing under acceptable proficiency conditions
- Percentage of fresh pork reaching the retail market
- Percentage of undercooked or raw pork consumed

2.2.1.4 Overview of examples

Seven hypothetical examples were developed that simulated a range of scenarios. All test results for pigs from controlled housing are assumed to be negative. Conservative estimates are taken for the percentage of a carcass reaching the consumer as fresh pork and the percentage that is consumed raw or undercooked.

Example 1 is a population of 100 million pigs in a controlled housing compartment from which 1 million to 100 million are tested at slaughter. All test results for pigs from controlled housing are assumed to be negative. The model produces results that are probably generated from near the upper bounds (50% of fresh meat at retail and 2% of undercooking or raw by consumers).

Example 2 (Reference example) represents a population of 10 million pigs in a controlled housing compartment in a farm/region/country. Of these pigs, a range of 1000 to 1 million are tested at slaughter, keeping all other parameters of Example 1 the same.

Example 3 represents a population of 1 million pigs, keeping all other parameters of Example 1 the same.

Example 4 is a small population of 100 000 pigs from which 1000 to 100 000 are tested, with all other parameters being the same as in Example 1.

Example 5 is the same as Example 2, which tests 1 million pigs but only 25% of the pork reaches the consumer fresh and only 1% is consumed raw or undercooked.

Example 6 is the same as Example 2, but testing all pigs, from which 1 was positive.

Example 7 considers a small population of pigs, which are not reared under controlled housing conditions, all tested at slaughter, in which 36 were positive. It illustrates the potential residual risk from small populations compared with much larger populations under controlled housing conditions.

2.2.1.5 Outcomes

The different scenarios and results of each example are presented in Table 2, and the model used for calculation of these outputs is presented in Annex 1.

TABLE 2. Numbers of *Trichinella* spp. infected portions per million servings in seven scenarios

Example	No. of pigs slaughtered	No. of pigs tested	No. testing positive	% of fresh meat at retail	% of undercooking by consumers	Residual infected portions	Infected portions per million servings
1	100 million	1 million to 100 million	0	50	2	666 000–7	16.7–0.017
2	10 million	1 000 to 1 million	0	50	2	66 600–67	16.7–0.017
3	1 million	1 000 to 1 million	0	50	2	6 660–7	16.7–0.017
4	100 000	1 000 to 100 000	0	50	2	666–7	16.7–0.017
5	Example with low percentages of fresh meat at retail and undercooking by consumers, respectively						
	10 million	1 million	0	25	1	17	0.00425
6	Example with 1 pig testing positive for *Trichinella* spp.						
	10 million	10 million	1	50	2	133 200–133	33.3–0.033
7	Example from non-controlled housing, pigs testing positive for *Trichinella* spp.						
	13 000	13 000	36	50	2	321	61.7

The results for Examples 1 to 4 are presented in Figure 2 and Table 3. The model shows that the average number of infected meals after cooking drops proportionally as the number of animals in the population tested increases.

The model also shows that reducing the test sensitivity from 70 percent to 50 percent, using Examples 1 through 4, has little effect on the outcome for a given level of testing.

TABLE 3. Variation in the average number of infected meals after cooking depending on the test sensitivity (50 to 70 percent) assuming no animals tested positive*

Number of animals tested	Test sensitivity		
	50%	60%	70%
1 000	19.98	16.65	14.2725
10 000	1.99975	1.6675	1.4275
100 000	0.2	0.16675	0.1425
1 000 000	0.02	0.0175	0.015

Notes: *Assuming 400 edible portions of pork from a carcass; 50% of the carcass used for fresh pork sales; 2% of meals that might not be rendered safe by cooking.

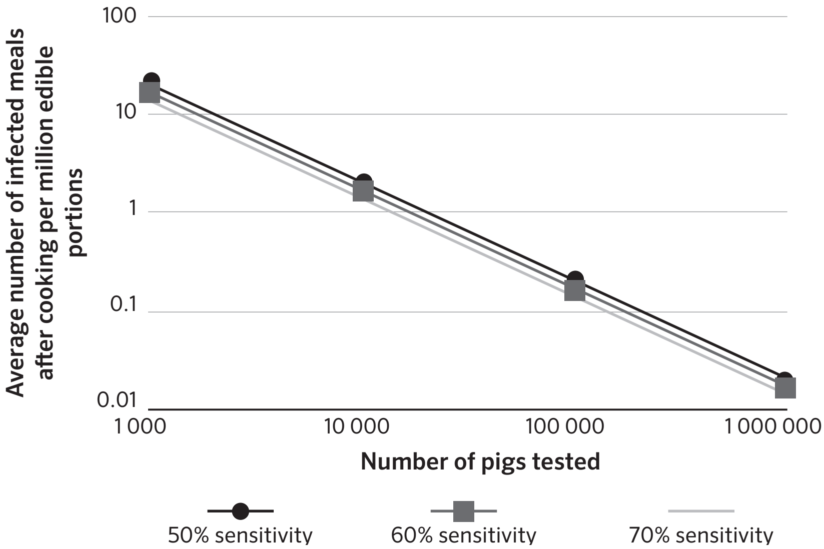

FIGURE 2. Variation in the average number of infected meals after cooking depending on the test sensitivity (50–70%) assuming no animals tested positive*

Notes: *Assuming 400 edible portions of pork from a carcass; 50% of the carcass used for fresh pork sales; 2% of meals that might not be rendered safe by cooking.

TABLE 4. Variation in the average number of infected meals after cooking depending on the number of animals tested, assuming one animal tested positive*

No. of animals tested	Test sensitivity 60%	
	0 animal positive	1 animal positive
1 000	16.7	33.3
10 000	1.67	3.33
100 000	0.167	0.333
1 000 000	0.017	0.033

Notes: *Assuming 400 edible portions of pork from a carcass; 50% of the carcass used for fresh pork sales; 2% of meals that might not be rendered safe by cooking, test sensitivity 60%.

The results for the comparison of having one animal tested positive (Example 6) versus zero animals tested positive (Example 5) are shown in Figure 3 and Table 4. The values indicate that if a large number of animals is being tested (100 000–1 000 000), there may not be a large difference in the average number of infected edible portion at 60 percent sensitivity of testing.

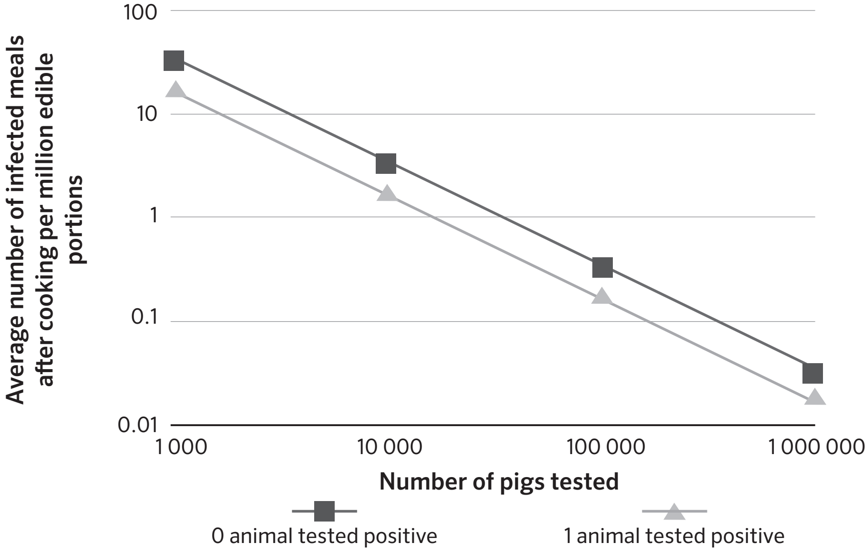

FIGURE 3. Variation in the average number of infected meals after cooking depending on the number of animals tested, assuming one animal tested positive*

Notes: *Assuming 400 edible portions of pork from a carcass; 50% of the carcass used for fresh pork sales; 2% of meals that might not be rendered safe by cooking, test sensitivity 60%.

The output of the model estimates the average number of infected edible portions reaching the consumer. The average number of infected animals that may persist in the tested population can also be reported as an output of the model. The model should also show the number of potentially infected carcasses, as the number of portions as well as the number of preparations per carcass may vary.

2.2.2 Ongoing verification for the maintenance of the compartment with a negligible risk

Once established, maintaining the controlled housing conditions and thus the negligible risk status, is essential. Verification of the public health status resulting from maintenance can potentially be accomplished by using different approaches either separately or in combination:

- Reference to audit results at farm level, noting that audits will likely be the responsibility of a competent authority other than that responsible for public health
- Surveillance in the live pig population under controlled housing conditions using test methods recommended by OIE (2018)
- Surveillance of pigs outside the controlled housing compartment
- Reporting of autochthonous human cases when robust public health surveillance and reporting systems are in place

Different approaches to verification of the maintenance of a negligible risk compartment were not evaluated by this expert meeting. Demonstrating maintenance in a risk-based and cost-effective way is an essential part of the "negligible risk compartment" approach and will be the subject of a further expert meeting.

In this context, prior knowledge (for example: number of animals tested in the past, the quality of test performance, test results and incidence of trichinellosis in the human population) may potentially be used to reduce the number of carcass tests that might be needed to verify the ongoing success of the negligible risk compartment.

2.2.3 Conclusions

By referring to the outputs from different control scenarios, risk managers can choose the control measures for the establishment of a negligible risk compartment that deliver the level of consumer protection that is required at the national level.

- It is clear that testing of a substantial number of pigs is needed to reduce residual risks to very low levels. However, there is a point where testing of additional pigs may not result in any further meaningful reduction in residual risk, and thus may not result in significant further improvement in public health benefit.
- More work is needed to complement the outcomes of this expert consultation. The model is conservative in use of input parameters (e.g. one larva in an edible portion causes human illness), and additional modelling will provide clearer indications of the merits of an agreed level of testing relative to residual risk. Further, additional investigation and modelling is needed to support public health decisions on assurance of maintenance of a negligible risk compartment according to different measures (e.g. slaughterhouse testing, audits, human surveillance and other parameters).

More general conclusions and recommendations could also be found in Chapter 3.3.

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

2.3.1 *Trichinella* spp. public health and trade

2.3.1.1 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, non-specific 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 WHO (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*. 2015). 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; Devleesschauwer *et al*., 2015). 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-ECDC, 2014).

2.3.1.2 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 (Argentina, Belarus, Bosnia and Herzegovina, Bulgaria, Canada, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Latvia, Lithuania, Poland, Macedonia, Mexico, Montenegro, Romania, Serbia, Slovakia, Spain, and the United States of America) 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 4. 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 from 2010 to 2011 found no *Trichinella* spp. infections on industrial farms and a prevalence of 3 percent and 10 percent 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).

2.3.1.3 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 percent slaughtering under 10 000 per year, and 40 percent slaughtering under 100 000 per year (Table 5). Similarly, there are 50 countries with documented exports under 10 000 tonnes per year (Table 6). 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 5. Pigs slaughtered per year per country in 2010 (GLiPHA -The Global Livestock and Health Atlas, FAO, Available at http://kids.fao.org/glipha/)

Pigs slaughtered per year	Number of countries, n = 186
0–10 000	30
10 001–100 000	45
100 000–1 million	47
1 million–10 million	45
10 million–100 million	17
> 100 million	2

It should be noted that slaughter numbers presented in Table 5 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 6. Tonnes of porcine meat exported per year per country in 2010 (FAOSTAT)

Porcine meat exported per year (tonnes)	Number of countries, n = 75
1–1000	37
1001–10 000	13
10, 001–100 000	9
100 000–1 million	13
1 million–10 million	3

2.3.1.4 *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, was assigned as priority work at the 42nd Session of the 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.

The World Organisation for Animal Health has continually worked to update the chapter on "Infection with *Trichinella* spp., Chapter 8.7" in their *Terrestrial Animal Health Code*, the most recent version was revised and adopted in 2016 (OIE, 2019a). 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, separated from other susceptible populations by a common biosecurity management system, and with a specific animal health status with respect to one or more infections or infestations for which the necessary surveillance, biosecurity and control measures have been applied for the purposes of international trade or disease prevention and control in a country or zone (OIE, 2019b).

While the OIE standard covers provisions for control of *Trichinella* spp. on farms, and the CAC 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.

2.3.1.5 Risk-based approach

2.3.1.5.1 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 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.

2.3.1.5.2 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 that 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 CCFH.

2.3.2 Application of a risk model

2.3.2.1 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, 2019).

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 4) will likely vary in different country scenarios.

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 4). 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.

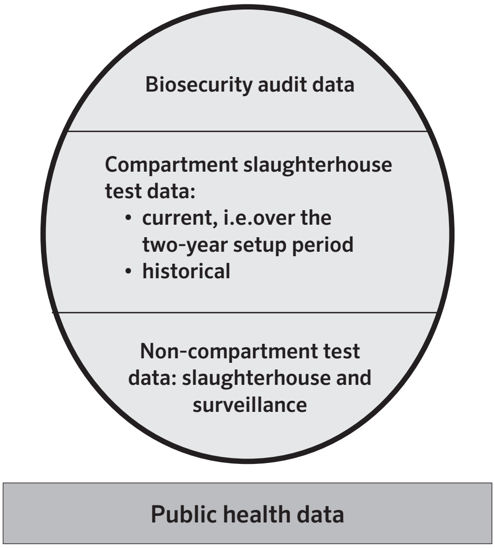

FIGURE 4. Sources of information for the establishment of a compartment with a "negligible risk" of *Trichinella* spp. infection in pigs

2.3.2.2 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 4) will likely vary in different country scenarios.

The public health authority will want assurance that 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 5. Trace-back information may be sought from any human illnesses that might occur to determine whether pigs housed under controlled housing conditions were involved.

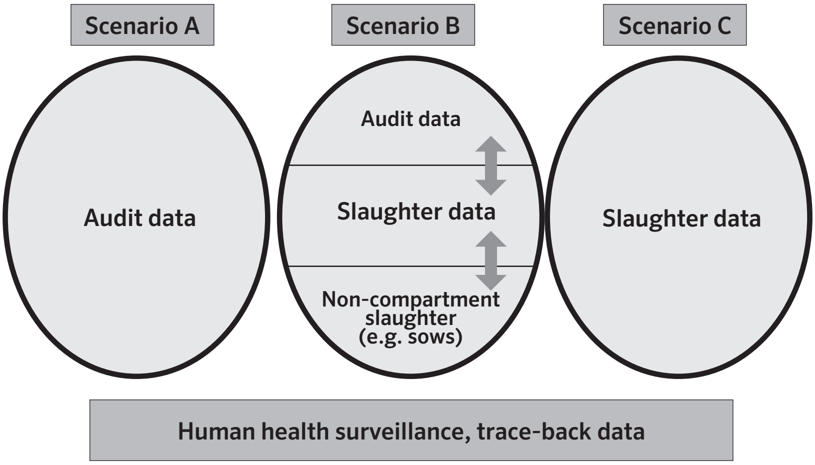

FIGURE 5. Different scenarios for sources of information used by the public health authority in assuring public health protection during the maintenance of a compartment with a "negligible risk" of *Trichinella* spp. infection in pigs.

2.3.2.3 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, 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 6. A detailed description of the model is provided in Annex 1.

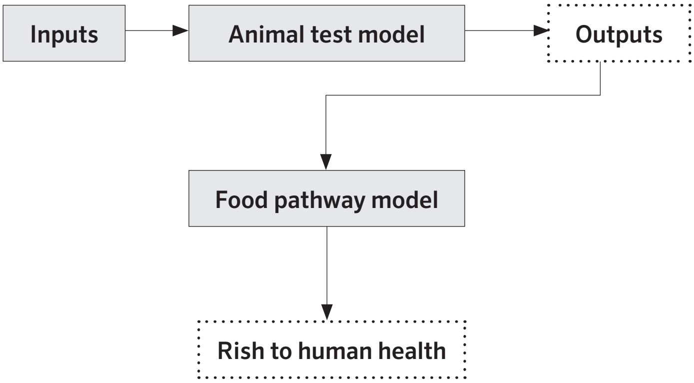

FIGURE 6. A simplified flow diagram of the model used to estimate risk to consumers

2.3.2.3.1 Animal test model

(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.[2] For the purposes of this modeling exercise, the test for which sensitivity and specificity characteristics were estimated is the digestion test

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[2] 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.

as described in Chapter 3.1.20 of the *OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (OIE, 2018). 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) Sampling inputs to the animal test model

The sampling inputs for the animal test model are shown in Table 7.

TABLE 7. Inputs for the animal test model*

Inputs	Values
Number of slaughter pigs in the compartment	10 000 to 100000000
Proportion of slaughter pigs tested	0.1% to 100%
Number of slaughter pigs testing positive	Maximum of 1
Sensitivity of the digestion test	40%–70% (expert opinion)
Specificity of the test	100%

* 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.

(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 percent (8/20 samples with 0.01-0.09 larvae per gram or LPG), 73 percent (49/67 samples with 1.0-1.4 LPG), and 67 percent (16/24 samples with1.5-1.9 LPG) (Forbes and Gajadhar, 1999). An earlier study using far fewer samples, with 0.88 and 1.5 LPG, reported positive results for 0/4 and 3/4 samples, respectively (Gamble, 1998). In both studies, up to 10 percent 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 percent 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 percent. The greatest limiting factor to achieving higher than the approximately 70 percent sensitivity for 1 g samples appears to be the natural, uneven distribution of larvae within tissues.

The risk model assumed 100 percent specificity, i.e. that the tests were done with adequate quality assurance as described by the ICT(Gamble *et al.*, 2000).

2.3.2.3.2 Food pathway model

(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) Food pathway inputs

The inputs for the food pathway model are shown in Table 8. 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 8. Inputs for the Food Pathway Model

Inputs	Values
Percentage of pig meat not subjected to any treatment by industry (including retail) that would inactivate larvae	20% to 80% (expert opinion)
Number of meal servings from a pig carcass	200 to 400 (expert opinion)
Percentage of pig meat not subjected to any treatment by the consumer that would inactivate larvae	0.5% to 5% (expert opinion)
Percentage of meal servings from an infected carcass that might contain sufficient larvae to infect a consumer	Unknown (conservative input of 100%)

- 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 that 15–17 percent of pork is sold as fresh product, 15–17 percent as frozen pork and 60–66 percent as processed pork, with processed pork sales represented by 30 percent cooked sausages, 20 percent cooked ham, 10 percent dried ham and 25 percent other (De Smet, pers. comm.). The National Pork Producers Council the United States of America reports that ham accounts for forty percent of processed pork products consumed in the United States of America, with sausages representing another 25 perecent of consumed product (National Pork Board, 2009).

- The number of meal servings per carcass is obviously highly variable and has been reported as being 371 in the United States of America (National Pork Board, 2009) 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; Forbes and Gajadhar, 1999; Ribicich *et al*., 2001). In the absence of published data to indicate otherwise, a conservative input to the model would be 100 percent.

(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 percent infectious dose was calculated to be 150 larvae. This paper also noted that a meal serving of 100 g 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, 1998, 2001). 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.

2.3.3 Modeling examples for establishing the level of consumer protection provided by a “negligible risk” compartment

2.3.3.1 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 9. 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 8. However, for illustration purposes only, the expert meeting agreed to use the set of point estimate inputs presented in Table 11.

TABLE 9. Model inputs for the development of examples to illustrate the establishment of a negligible risk compartment*

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

* 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.

2.3.3.2 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 percent, 50 percent and 100 percent are all test-negative is shown in Figure 7. (The sensitivity of the test

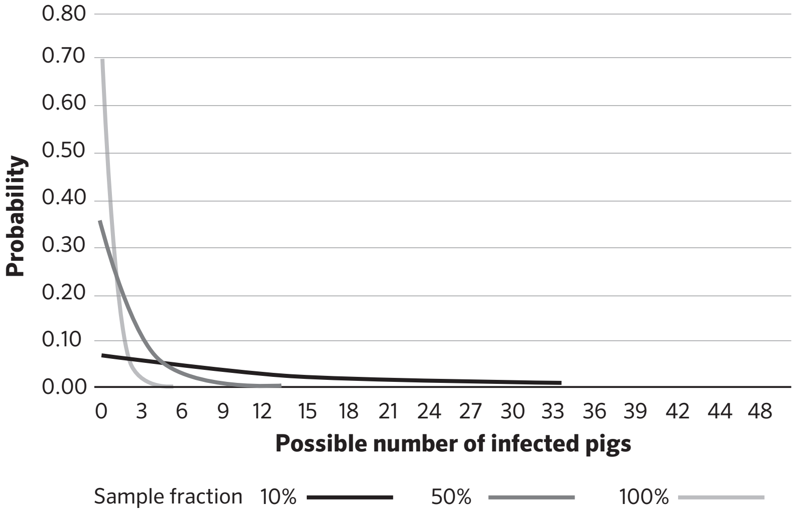


FIGURE 7. Probability distribution for the possible number of infected pigs in a slaughter population of 1 000 000 pigs when sample sizes of 10%, 50% and 100% are all test-negative

for this example is set at 70 percent). 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.

2.3.3.3 Changes in probabilities of possible number of infected pigs with different test sensitivities

Figure 8 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 percent. It can be seen that the impact of test sensitivity on the probability of identifying a possibly infected pig percentage are modest, and this is similar when other slaughter populations of different sizes and different sampling proportions are used.

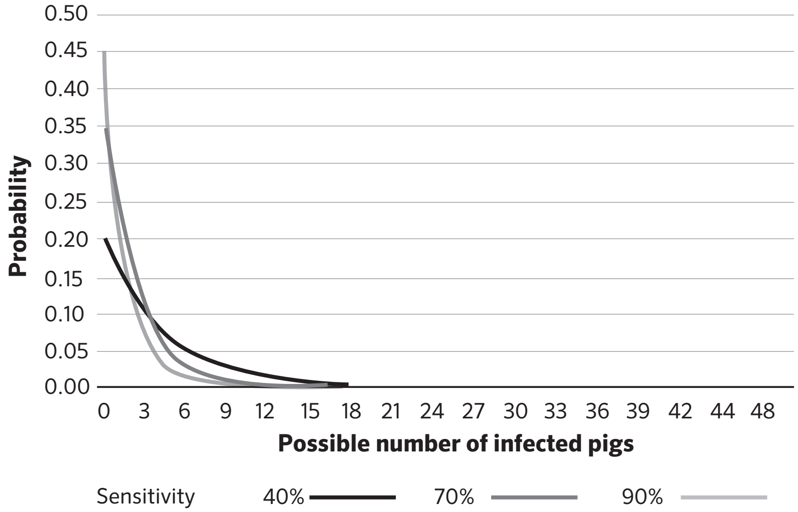


FIGURE 8. The effect of changes in sensitivity of the diagnostic test on the probability distribution of possible number of infected pigs in a slaughter population of 1 000 000 pigs with 50% of the pigs being sampled

2.3.3.4 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 percent to 100 percent of the population. The outcome is expressed as potentially infected pigs per 1 000 000 (Table 10). 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 10 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. 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.

TABLE 10. 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

	Population size				
Proportion sampled	**10 000**	**100 000**	**1 000 000**	**10 000 000**	**100 000 000**
0.1%	118 970	11 897	1190	119	12
1%	13 908	1 391	139	14	1
10%	1 326	133	13	1	0.1
20%	614	61	6	0.6	0.06
50%	186	19	2	0.2	0.02
90%	59	6	0.6	0.06	0.006
100%	43	4	0.4	0.04	0.004

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).

2.3.3.5 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 11, risk is described in terms of the possible number of human illness cases per 1 million meal servings. In Table 12, public health risks are described in terms of the number of human cases per 1 million 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 to 50 percent, (2) number of meal servings from a pig carcass, assuming a serving size is 150 g, (3) percentage of pig meat not subjected to any treatment by the consumer that would inactivate larvae –0.5 percent, and (4) probability that every meal serving from an infected pig will result in a human clinical case of trichinellosis -100 percent. The calculation: 400 servings x 50 percent, x 0.5 percent = 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 8, Tables 10 and Table 12 would have different risk descriptor values. This again highlights the illustrative nature of these examples.

TABLE 11. Mean estimates of possible human health risks using a risk descriptor of "human cases per 1 000 000 meal servings"

	Population size				
Proportion sampled	**10 000**	**100 000**	**1 000 000**	**10 000 000**	**100 000 000**
0.1%	297	30	3	0.3	0.03
1%	35	3	0.3	0.03	0.003
10%	3	0.3	0.03	0.003	0.0003
20%	2	0.2	0.02	0.002	0.0002
50%	0.5	0.05	0.005	0.0005	0.00005
90%	0.1	0.01	0.001	0.0001	0.00001
100%	0.1	0.01	0.001	0.0001	0.00001

*Using baseline inputs as per Table 9

TABLE 12. Mean estimates of possible human health risks using a risk descriptor of "human cases per 1 000 000 slaughtered pigs"

	Population size				
Proportion sampled	**10 000**	**100 000**	**1 000 000**	**10 000 000**	**100 000 000**
0.1%	118970	11897	1190	119	12
1%	13908	1391	139	14	1
10%	1326	133	13	1	0.1
20%	614	61	6	0.6	0.06
50%	186	19	2	0.2	0.02
90%	59	6	0.6	0.06	0.006
100%	43	4	0.4	0.04	0.004

*Using baseline inputs as per Table 9

Table 11 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 percent of a slaughter population of 1 million with test-negative results would mean that the potential number of human cases would be less than one per 1 million meal servings. For this example scenario, Table 12 shows that testing 90 percent of a slaughter population of 1 million pigs, 20 percent of a population of 10 million pigs, or 10 percent 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 percent 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 percent. 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.

2.3.3.6 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 fewer potential human cases per 1 000 000 slaughtered pigs. These options are represented in Table 13 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.

TABLE 13. Example of a "risk contour" of one or less human cases per 1 000 000 slaughtered pigs (Gray shaded area)

	Population Size				
Proportion sampled	**10 000**	**100 000**	**1 000 000**	**10 000 000**	**100 000 000**
0.1%	118 970	11 897	1190	119	12
1%	13 908	1 391	139	14	1
10%	1 326	133	13	1	0.1
20%	614	61	6	0.6	0.06
50%	186	19	2	0.2	0.02
90%	59	6	0.6	0.06	0.006
100%	43	4	0.4	0.04	0.004

*Using baseline inputs as per Table 9

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 fewer potential human cases per 1 million slaughtered pigs even if 100 percent of the slaughter population were sampled. It is important to reiterate 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 percent. 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 ten or more potential human cases per 1 million slaughtered pigs being deemed acceptable would result in more sampling options to demonstrate an equivalent level of public health protection.

2.3.3.7 *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 14.

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

TABLE 14. 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

	Population size									
	10 000		**100 000**		**1 000 000**		**10 000 000**		**100 000 000**	
Proportion sampled	Test negative	One test positive	Test negative	One test positive	Test negative	One test positive	Test negative	One test positive	Test negative	One test positive
0.1%	118 970	238 005	11 897	23 800	1 190	2 380	119	238	12	24
1%	13 908	27 916	1 391	2 792	139	279	14	28	1	3
10%	1 326	2 752	133	275	13	28	1	3	0.1	0.3
20%	614	1327	61	133	6	13	0.6	1	0.06	0.1
50%	186	471	19	47	2	5	0.2	0.5	0.02	0.05
90%	59	217	6	22	0.6	2	0.06	0.2	0.006	0.02
100%	43	186	4	18	0.4	2	0.04	0.2	0.004	0.02

*Using baseline inputs as per Table 9

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.

2.3.3.8 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 percent 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 *et al*., 2001; 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 9 aims to illustrate the impact of these uncertainties on the model outcome. It depicts 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 described above, when it is assumed that every serving from an infected pig will cause illness (Table 13) and the example risk contour is set at one or fewer human cases per 1 million slaughtered pigs (Contour A), smaller populations of slaughtered pigs (below 1 million) are visible to the left of the contour and could not statistically demonstrate achievement of that level of public health protection, even if 100 percent of the slaughter population were sampled.

However, if, for example, only 10 percent of meal servings from an infected pig had sufficient larvae to infect a human (Contour B), the risk contour would shift 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 fewer per 1 million 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.

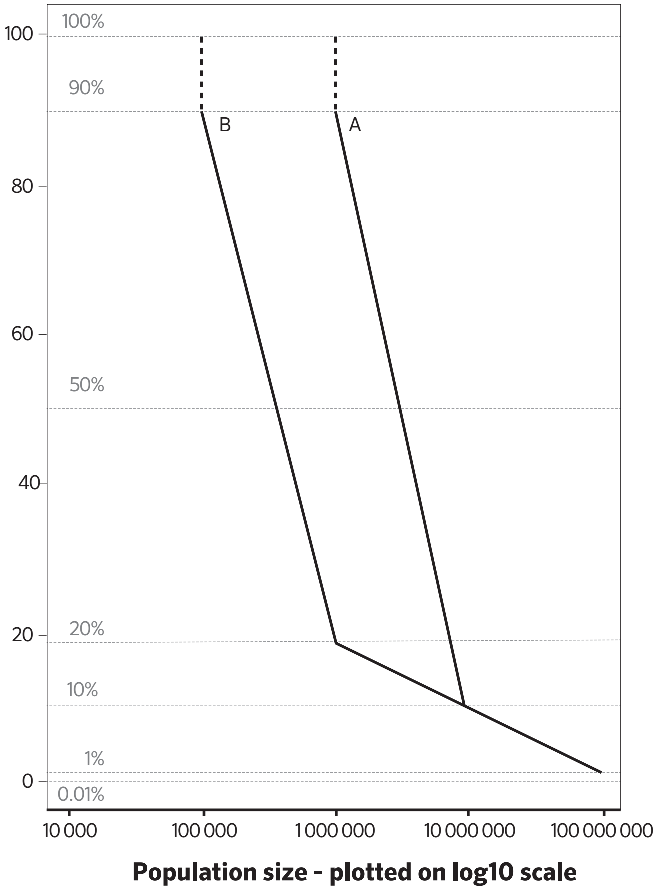


FIGURE 9. Impact of variations in potential exposure and dose response on illustrating the level of protection achieved through the establishment of a negligible risk compartment and the related control measures

Notes: Line A illustrates the contour of estimated risk (one or fewer human cases per 1 million 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 greater value of risk assessments may be in their use for comparative purposes, e.g. relative risk or changes to risk with implementation of different risk mitigations strategies by managers.

2.3.4 Modeling examples for the level of consumer protection provided by a "negligible risk" compartment once established

2.3.4.1 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 (Devleesschauwer *et al.*, 2015);
- 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 2013, 2014; 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.

2.3.4.2 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 two 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 lower 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 5. 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.

2.3.4.3 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; Van der Giessen *et al*., 2007; Pozio, 2014). Gamble *et al*. (1998) 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; 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.

2.3.4.4 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.

2.3.5 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 to illustrate 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.

2.3.5.1 *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 contour, 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 European Union, over 205 million pigs were tested for *Trichinella* spp. in 2018, and none of the 248 test-positive pigs were from fattening pigs raised under controlled housing conditions (EFSA, 2019). 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).

2.3.5.2 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 fewer positive pigs per 1 million slaughtered, at the 95 percent 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.

2.3.5.3 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 being considered rather than the actual risk of each scenario can help overcome this issue.

2.3.5.4 Conclusions and recommendations

The expert meeting made the following conclusions:

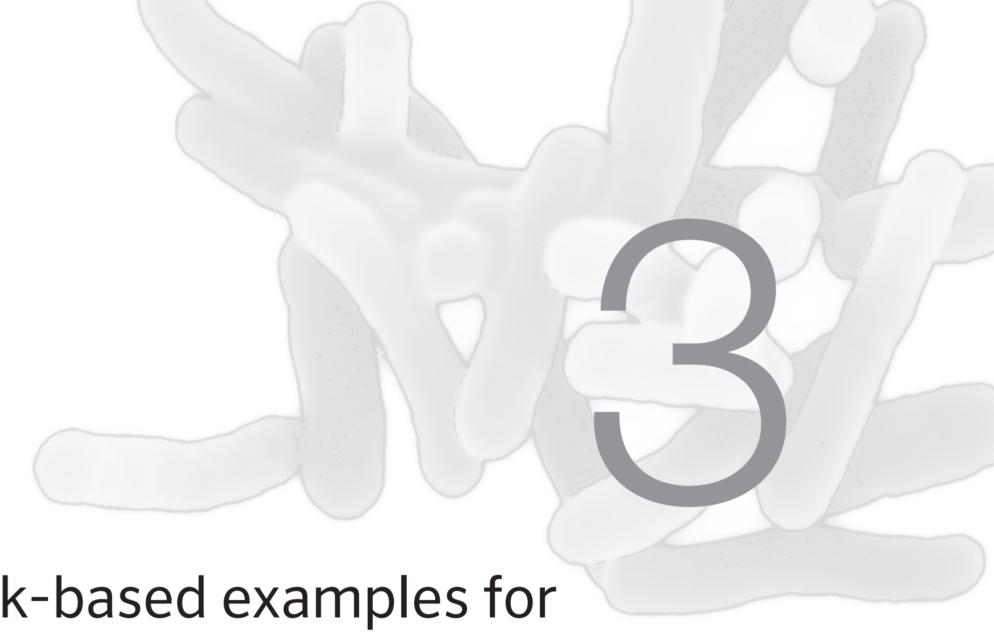
- Risk based models can be used to support the articulation of the level of consumer health protection that is achieved by the implementation of a defined set of control measures such as those included in the establishment of a negligible risk compartment.
- Risk models are only an attempt to model what 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 which 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 the model would be improved with the availability of better data in the areas of exposure and dose response.

The expert meeting made these recommendations:

- 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 the 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 continue.
- 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 and 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.



3

Risk-based examples for control of *Taenia saginata* in meat

3.1 NECESSARY INPUTS FOR MODELLING THE FOOD CHAIN FOR CONTROL OF *TAENIA SAGINATA* IN MEAT

A description of inputs required for modelling of the food chain for control of *Taenia saginata* in beef meat is shown in Table 15.

TABLE 15. Inputs required for modelling of the food chain for control of *Taenia saginata* in beef meat

Stage	Status (at farm level)	Factors	Values	Justification
Farm	"High prevalence" population "Low prevalence" population or sub-population	Prevalence positive at post-mortem inspection	15%	From the scientific literature
		Age of the animals at slaughter		
		Sex		Consider males and females
		Other risk factors such as type of breeding or management		

(cont.)

Stage	Status (at farm level)	Factors	Values	Justification
Abattoir		Prevalence positive at post-mortem inspection	15%	From the scientific literature
		Designation of number of cysts constituting a lightly infected animal	4, 6 or 8	
		Performance characteristics of post-mortem inspection (sensitivity and specificity)	2.0, 3.9, 4.7%	
		Regulatory action following positive test, require cooking of infected carcasses, trimming of lightly infected parts		
Processing		Distribution channels		
		Processing treatments		
		Percentage of carcass, fresh after processing and distribution	90%, 95%	New Zealand 10%; European Union 90%; United States of America 90%
Consumer		Number of edible portions from a carcass	1300 (150 g per portion)	
		Percentage of edible portions eaten raw or fresh	40%, 10%	
		Percentage of cysts viable/infective at point of consumption	100% infective	France: 1 infected and non-detected carcass could infect 10 people (estimate)

3.2 RISK-BASED EXAMPLES FOR CONTROL OF *TAENIA SAGINATA*

3.2.1 Purpose

The purpose of the model used was to illustrate differences in relative risks to consumers when different intensities of postmortem meat inspection procedures are used, thereby informing decisions by risk managers on the most appropriate procedures to use in populations with different levels of infection.

3.2.2 Model

This is a simple spreadsheet model that estimates the residual level of risk to consumers following the application of specified postmortem meat inspection procedures to a slaughter population of a known size. The model can be found in Annex 2.

For input parameters for which there is a paucity of available data, conservative point estimates were used. The model does not consider the human dose response but makes use of the assumption that ingestion of one viable cyst in an edible portion of meat can lead to one tapeworm infection.

Based on the risk assessment model by van der Logt, Hathaway and Vose (1997), the primary model parameters are the particular set of meat inspection procedures that are being evaluated and the number of infected and detected animals. Each set of procedures will have an estimated sensitivity for detecting infected animals. Those infected animals that are detected on inspection will be removed, and those infected animals that are not detected will remain in the food supply chain. The model applies estimates of the average number of cysts present in infected animals in the slaughter population (for example in one year), the percentage of viable cysts per infected animal, and the percentage of infected meat not processed or treated to inactivate the parasite, to generate an estimate of the total burden of cysts in fresh meat.

Subsequent steps in the model represent interventions that sequentially reduce the number of viable cysts. Each viable cyst that is ingested is assumed to result in infection (a conservative assumption) and the final output of the model is the number of human infections that is expected to result from a slaughter population of a specific size.

The primary value of the model is to illustrate the residual risk that results from "high prevalenc" compared with "low prevalence" slaughter populations (A low prevalence sub-population might also consist of specific animals within herds, such as calves or males). Model outputs demonstrate that when low intensity inspection procedures compared with high intensity procedures are used in "low prevalence" populations, there is negligible difference in residual risks.

3.2.3 Overview of examples

Countries W, X, Y and Z were chosen as examples to represent different prevalence situations (Table 16). For each of these examples, model parameters were based on available data or reasonable assumptions relevant to each scenario. Model parameters varied between countries to best reflect the "real-life" situation, including processing and consumption habits. Model outputs are shown in Table 16.

In scenario set A, the overall sensitivity of inspection is determined from published scientific information on the sensitivity of detecting a single cyst (Kyvsgaard *et al.*, 1990, 1996) and expert opinion on the average number of cysts likely to be present in a "lightly infected" population.

In scenario set B, overall sensitivity of inspection is determined from a theoretical stepwise increase in sensitivity according to the number of incisions performed. B1 and B2 scenario sets are based on seven and four cysts per infected animal, respectively, to assess the influence of varying, plausible cyst burdens.

In scenario set C, the effect of subjecting only the high-risk subpopulation to traditional meat inspection was assessed. In this scenario the probability of a cyst being viable was increased to 11 percent from 10 percent in the basic model.

3.2.4 Model inputs

3.2.4.1 Sensitivity of inspection

The prevalence of infected animals and the number of cysts present in an infected animal are known to be highly variable. There are several published sources of information that assign an average sensitivity of "traditional" postmortem inspection (a combination of visual inspection of all muscle surfaces and organs, palpation of predilection sites and a series of incisions of predilection sites) of 15 percent.

The sensitivity of detecting one *Taenia saginata* cyst in an infected animal is very low and Kyvsgaard *et al.* (1990) found this to be four percent in experimentally infected calves. As the number of cysts increases in an infected animal, the sensitivity of infection obviously increases. In heavily infected animals, the sensitivity is likely to be above 50 percent.

Scenario set A uses 4.7 percent as the sensitivity of detecting one cyst (Hathaway, 2013).

If the slaughter population is "lightly infected", the average number of cysts assigned in the model to infected animals is small. Model A assigns this point estimate as four and the average sensitivity of inspection for such a population is about 15 percent. Thus 85 percent of infected animals go undetected and enter the food chain.

When the set of procedures used for postmortem inspection is altered by the exclusion of the incisions of masseter and pterygoid, the sensitivity drops from

4.7 percent to 3.9 percent. Such changes in model inputs are the prime determinant in generating the relative risks that result from the different inspection packages.

Scenario set A can also be used to model “heavily infected” slaughter populations. In such a situation, the sensitivity assigned to inspection will be higher and the average number of cysts that is assigned to an infected animal will be higher than in the scenario described above.

In Scenario set B, overall sensitivity of inspection is determined from a theoretical stepwise increase in sensitivity according to the number of incisions performed (This model does not include the outcome of visual examination and palpation or the relative value of different types and sequences of incisions in different predilection sites). In Scenario set B, the average number of cysts in infected animals is assigned as four or seven, the latter assumption results in a more conservative estimate for the mitigation of residual risk.

This is combined with the sensitivity of meat inspection, the probability of a cyst being viable, and the proportion of beef meat being subjected to a treatment that would inactivate cysts.

3.2.4.2 Viability of cysts

The user of the model can assign a value appropriate to the baseline scenario. An estimate of 10 percent was used for the first three examples that are presented below (Scenario sets A, B1 and B2). This estimate of 10 percent cyst viability is based on studies entailing complete carcass dissection of naturally and experimentally infected cattle.

In Scenario set C, the parameter representing probability of a cyst being viable was increased from 10 percent in the basic model to 11 percent in this model, reflecting that in young, infected male cattle, cysts might have developed but not calcified to the same extent as in adult cattle. It would be of interest to study further to which degree the assumed higher proportion of viable cysts is compensated by a lower number of cysts in younger cattle compared with adult cattle which, through a longer life, have had a higher probability of getting infected not just once but several times.

3.2.4.3 Outcomes

The outcome of these models is shown in Table 16. Across all country and model scenarios, the increase in the annual number of human tapeworm carriers expressed in absolute numbers differed across countries depending on the baseline cysticercosis prevalence.

The model also provides the opportunity to compare the residual risk that results from "high prevalence" and "low prevalence" slaughtered populations using the same and/or different set of inspection procedures. The last scenario (Scenario set C) is an example of the above. This scenario was only run for a country with a low number of human cases. The input data were based on Calvo-Artavía *et al.* (2013a, b), who showed that male cattle could have a much lower prevalence than female cattle, probably as a result of being slaughtered at a younger age. Moreover, male cattle are most often raised indoors. Hence, only subjecting female cattle to traditional meat inspection only lowered the number of cattle identified at meat inspection from 44 to 36. When these figures were entered into the model, the estimated number of human cases increased from 36 to 42 – a very small increase in residual risk.

TABLE 16. Summary of various estimates of the residual risk of taeniosis in four example countries with different prevalence of *Taenia saginata* in slaughter populations according to current and alternative postmortem meat inspection regimes (the diagram for calculation is in Annex 2)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)
Country 'W'												
A(14)	6 633	4	4.70%	4	10%	95%	40%	100%	18%	4 748		
	6 633	4	3.90%	4	10%	95%	40%	100%	15%	5 845	1 097	23%
B1(15)	6 633	8	2.00%	4	10%	95%	40%	100%	15%	5 748		
	6 633	6	2.00%	4	10%	95%	40%	100%	11%	7 824	2 076	36%
B2(15)	6 633	8	2.00%	7	10%	95%	40%	100%	15%	10 058		
	6 633	6	2.00%	7	10%	95%	40%	100%	11%	13 691	3 633	36%
C(16)	—	—	—	—	—	—	—	—	—	—	—	—
	—	—	—	—	—	—	—	—	—	—	—	—
Country 'X'												
A(14)	1 500	4	4.70%	4	10%	90%	40%	100%	18%	1 017		
	1 500	4	3.90%	4	10%	90%	40%	100%	15%	1 252	235	23%
B1(15)	1 500	8	2.00%	4	10%	90%	40%	100%	15%	1 231		
	1 500	6	2.00%	4	10%	90%	40%	100%	11%	1 676	445	36%
B2(15)	1 500	8	2.00%	7	10%	90%	40%	100%	15%	2 155		
	1 500	6	2.00%	7	10%	90%	40%	100%	11%	2 933	778	36%
C(16)	—	—	—	—	—	—	—	—	—	—	—	—
	—	—	—	—	—	—	—	—	—	—	—	—

(cont.)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)
Country 'Y'												
A(14)	44	4	4.70%	4	10%	90%	40%	100%	18%	30		
	44	4	3.90%	4	10%	90%	40%	100%	15%	37	7	23%
B1(15)	44	8	2.00%	4	10%	90%	40%	100%	15%	36		
	44	6	2.00%	4	10%	90%	40%	100%	11%	49	13	36%
B2(15)	44	8	2.00%	7	10%	90%	40%	100%	15%	63		
	44	6	2.00%	7	10%	90%	40%	100%	11%	86	23	36%
C(16)	44	—	—	4	10%	90%	40%	100%	15%	36		
	36	—	—	4	11%	90%	40%	100%	12%	42	6	16%
Country 'Z'												
A(14)	44	4	4.70%	4	10%	90%	10%	100%	18%	7		
	44	4	3.90%	4	10%	90%	10%	100%	15%	9	2	23%
B1(15)	44	8	2.00%	4	10%	90%	10%	100%	15%	9		
	44	6	2.00%	4	10%	90%	10%	100%	11%	12	3	36%
B2(15)	44	8	2.00%	7	10%	90%	10%	100%	15%	16		
	44	6	2.00%	7	10%	90%	10%	100%	11%	22	6	36%
C(16)	—	—	—	—	—	—	—	—	—	—	—	—
	—	—	—	—	—	—	—	—	—	—	—	—

Key and Notes:
(1) Scenario (Overall sensitivity of inspection);
(2) Infected and detected animals;
(3) No. of cuts OR no. of cysts;
(4) Probability of detecting an infected animal per cut OR probability of detecting one cyst;
(5) Estimated no. of cysts in non-detected animals;
(6) Estimated probability of cyst viability;
(7) Proportion of meat not being subjected to cyst killing processes;
(8) Proportion of meat not cooked or undercooked;
(9) Probability of infection;
(10) Carcass-level sensitivity;
(11) People infected with *Taenia saginata* tapeworms;
(12) Risk difference = Difference in (11) due to (10);
(13) % Increase in risk associated with applying 15% vs 18% carcass level sensitivity;
(14) Scenario A = Detection of 1 cyst and average number of cysts in lightly infected population;
(15) Scenario B = No. of cysts or incisions performed; B1 = 4 cysts per infected animal, and B2 = 7 cysts per infected animal;
(16) Scenario C = Only high risk sub-populations will be subjected to traditional meat inspection; Viability of a cyst = 11%

3.2.4.4 Remarks

Initially, the case countries were compared based on the number of infected carcasses detected at meat inspection. Thereby the ranking of risk was made from high risk down to very low risk. However, the size of the slaughter population varied considerably between the four case countries: from 0.5 to 4.5 million. The true prevalence varied even more: from 0.007 percent to 2 percent, implying a factor of close to 300. In fact, the country with the highest number of infected carcasses (and expected human cases) turned out to have half as high a true prevalence as the case of the country believed to represent medium risk. To take this into account, the true prevalence and the human incidence calculated as human cases per 100 000 inhabitants or 1 million inhabitants should be calculated.

The model assumptions would benefit from investigating the parameters related to post-harvest processes (consumer habits in eating beef, whether raw or undercooked versus properly cooked) in order to improve confidence in the results. Therefore, the results presented in Table 16 should be interpreted with care. Attention should be paid to the difference in number of cases found when comparing the current scenarios with alternative scenarios.

The results from the model might be validated in some circumstances through a comparison with data representing recorded human cases in a particular country/region. Unfortunately, human prevalence data is not available for most countries, and where it is available it applies to a very small sample size. However, data indicating an approximate number exist in various countries. For example, in Denmark (6 million inhabitants), Statens Serum Institute reported 38 persons suspected to be infected by *Taenia saginata* in 2011, and between two and eight cases per year were diagnosed as *Taenia saginata* positives by examination of faecal material. Hence, the outcome of the model for Denmark was confirmed by this report.

The included models are merely examples to demonstrate the concept of "risk-based" control. These models are a first attempt to address this concept and as such, the models will undergo further improvements or changes. In general, any model should be accompanied by a clear and transparent narrative description. This description should include at least the assumptions behind the model and the rationale for the applied model parameter values or distributions. As far as possible, the model structure and parameter values should be based on scientific evidence. Reference should be made to the applied evidence base.

Uncertainty issues should be considered in the development and description of the model. At least two main sources of uncertainty can be distinguished: model uncertainty and parameter uncertainty. Model uncertainty relates to a lack of knowledge or controversy regarding the model structure. It can be dealt with through scenario analyses, in which different plausible model structures are implemented and compared. Parameter uncertainty relates to a lack of knowledge or controversy regarding the true value of model parameters. It can be dealt with through uncertainty analysis (as known as uncertainty propagation or probabilistic sensitivity analysis), in which model parameters are represented by probability distribution functions that reflect their uncertainty, and by repeatedly running the model starting from different randomly selected parameter values, a distribution of output values will be generated reflecting the uncertainty in each of the input parameters. Alternatively, parameter uncertainty can be dealt with through non-probabilistic approaches, such as one-way sensitivity analyses or the use of conservative estimates for each of the uncertain parameters.

There is model uncertainty regarding the estimation of the animal-level sensitivity (i.e. the probability of detecting a truly infected individual). Two approaches are implemented and compared in a scenario analysis: (1) the modelling of the animal-level sensitivity based on the number of cysts per animal and the probability of detecting one cyst, and (2) the modelling of the animal-level sensitivity based on the number of cuts performed on the carcass and the probability of detecting a truly infected animal per cut.

3.3 CONCLUSIONS

The spreadsheet model demonstrated the expected changes in residual human risks under different prevalence scenarios when different sets of meat inspection procedures were used at postmortem inspection. Thus, the model can be effectively used to provide examples to support public health decisions on "modernization" of meat inspection. If the difference in residual risk is very small when different sets of inspection procedures are used, then those that represent the best use of meat inspection resources and create the least contamination can be justifiably implemented.

The output of the examples showed that the relative increase in human taeniosis cases associated with less intensive meat inspection was only dependent on the evaluated change in inspection practices, and did not depend on the country-specific risk mitigation profiles. However, given the different baseline burdens, there was a marked difference in residual human risks between countries with a low versus high prevalence of *Taenia saginata* in their slaughter populations. In countries with a high prevalence of *Taenia saginata*, residual risks were relatively high irrespective of the inspection package used, with reduced inspection resulting in an expected increase in the number of human cases of the order of thousands. Conversely, countries with a low prevalence of *Taenia saginata* in their slaughter populations had a very low human residual risk, and changes to the inspection package had very little impact on model outputs.

4

Conclusions and recommendations

4.1 CONCLUSIONS

The application of simple spreadsheet models by the expert meeting resulted in effective generation of the quantitative information that is needed by public health officials when evaluating different postmortem meat hygiene programmes for *Trichinella* spp. and *Taenia saginata* in meat.

Notwithstanding differences in model inputs, the changes in relative risks in different risk management scenarios are important information for the risk managers in the design or review of their risk management activities.

The Expert Meeting showed, by using the risk-based examples for *Trichinella* spp. and *Taenia saginata*, the value of a "fit-for-purpose" risk modelling approach to support modernization of meat inspection.

The models enabled the development of science-based risk scenarios to assess the effect of various changes to digestion testing and meat inspection for *Trichinella* spp. and *Taenia saginata*, respectively, on the residual risk of human trichinellosis and taeniosis, respectively, whereby the outcome is based on changes in relative risks rather than specific estimates of risk.

The models used provide examples to demonstrate the concept of "risk-based" control. They are a first approach to this concept and will undergo further improvement.

4.2 RECOMMENDATIONS

More work is needed to further advance this innovative approach, e.g. when using a combination of risk management measures to assure maintenance of a negligible risk compartment. Therefore, further development of the spreadsheet model, such as using a Bayesian approach, might allow integration of other inputs to support public health decisions.

Further work could be undertaken to improve the spreadsheet model, e.g. to include other information, such as the dose-response model developed for *Trichinella* spp. (Teunis *et al*., 2012) and consumer behaviour.

Evidence-based data on consumer cooking habits in relation to beef/pork in a population or country will improve the confidence of the output from the model(s). Evidence-based data on meat treatments by food business operators are also necessary.

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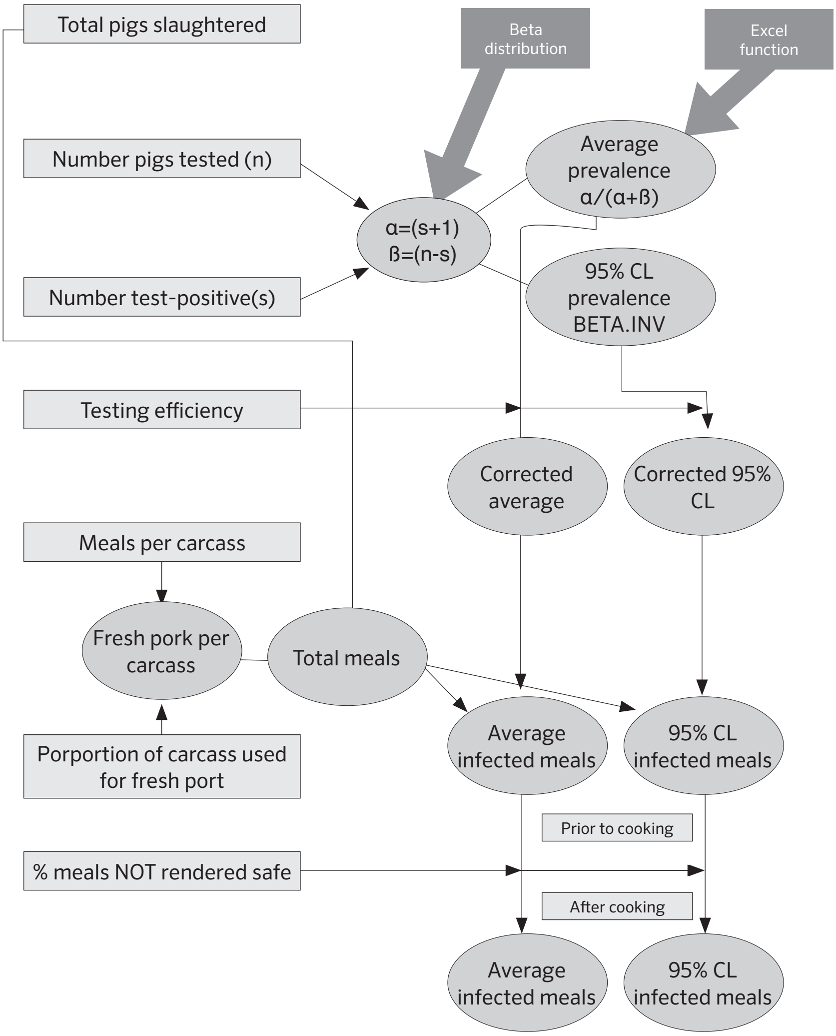
Annexes

Annex 1

Flow diagram for *Trichinella* spp. model

A1.1 MODEL STRUCTURE

Output: Number of infected portions per million servings (base model provided by Ryan and Hathaway, unpubl.).



A1.2 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, and (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 samples tested positive from a sample size of , the posterior distribution will be a . The mean of this distribution will be . The model further corrects this result for the test sensitivity () 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 ninety-fifth 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 ninety-fifth 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 ninety-fifth 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).

A1.3 MODEL ASSUMPTIONS AND LIMITATIONS

A1.3.1 Bayesian assessment of true prevalence

The model uses a *Beta*(1, 0) prior for the TP. This can be 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.

A1.3.2 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.

A1.3.3 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 percent) test specificity.

A1.4 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, and (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 percent first year, 50 percent second year, 100 percent 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.

A1.5 REFERENCES CITED IN ANNEX A1

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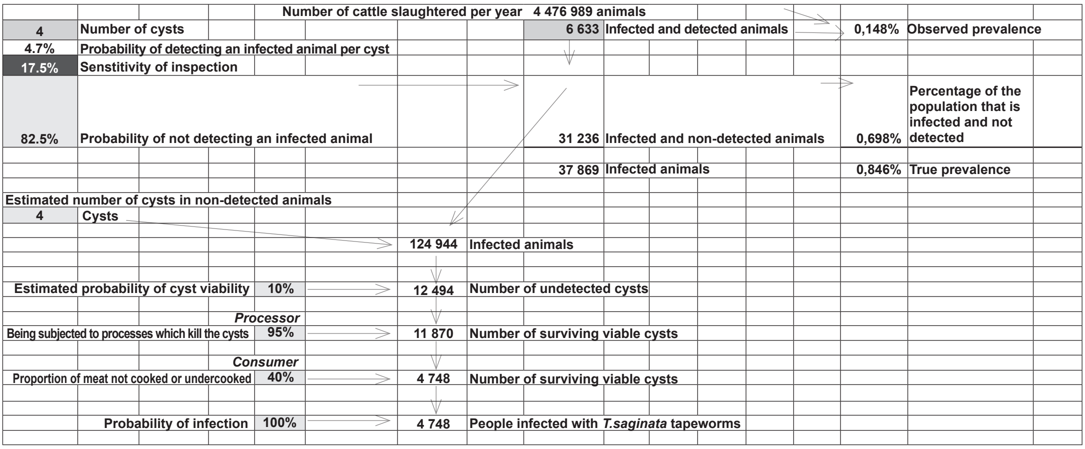
Annex 2

Spreadsheet diagram for the *Taenia saginata* model

Output: number of people infected with *Taenia saginata* tapeworms (base model provided by van Logt and Hathaway, unpubl.)



			Number of cattle slaughtered per year		4 476 989	animals		
4	Number of cysts				6 633	Infected and detected animals	0,148%	Observed prevalence
4.7%	Probability of detecting an infected animal per cyst							
17.5%	Senstitivity of inspection							
82.5%	Probability of not detecting an infected animal				31 236	Infected and non-detected animals	0,698%	Percentage of the population that is infected and not detected
					37 869	Infected animals	0,846%	True prevalence
Estimated number of cysts in non-detected animals								
4	Cysts							
			124 944	Infected animals				
	Estimated probability of cyst viability	10%	12 494	Number of undetected cysts				
	Processor							
	Being subjected to processes which kill the cysts	95%	11 870	Number of surviving viable cysts				
	Consumer							
	Proportion of meat not cooked or undercooked	40%	4 748	Number of surviving viable cysts				
	Probability of infection	100%	4 748	People infected with *T.saginata* tapeworms				

Annex 3

Summary of the Call for Data on the Control of *Trichinella* spp. and *Taenia saginata* in meat

A3.1 BACKGROUND

The 44th session of CCFH held in November 2012 refined its earlier request at the 43rd CCFH to FAO/WHO to develop risk-based examples for *Trichinella* spp. and *Taenia saginata* to illustrate the level of consumer protection likely to be achieved with different post-harvest risk management options. With regard to addressing this work, the CCFH also requested FAO/WHO to focus on the collection and review of existing information and examples and use this to guide further work. According to the request, FAO/WHO issued the call for data in January 2013 to collect relevant information.

A3.2 RESPONSE TO CALL FOR DATA

There were ten countries (Argentina, Australia, Croatia, Cyprus, Dominican Republic, the Netherlands, New Zealand, Peru, Sweden and the United States of America), one region (European Union) and one international organization (the Center for Science in the Public Interest(CSPI)) that responded to the call for data for *Trichinella* spp., and eleven countries (Australia, Cyprus, Denmark, Dominican Republic, the Netherlands, New Zealand, Peru, Eswatini, Sweden, the Sudan and the United States of America) and one region (European Union) for *Taenia saginata*.

A3.3 RESULTS

A3.3.1 *Trichinella* spp.

A3.3.1.1 Public health data on the burden of disease in a country or region

(i) Prevalence of human cases

Eight of the 12 respondents reported the prevalence of human trichinellosis. Argentina reported a higher prevalence compared with Europe. No occurrences were reported for Australia, Dominican Republic, New Zealand (as of 2011) and Peru. (Cyprus: no information provided.)

TABLE A3.1. Summary of cases reported in responses to Call for Data

Argentina (cases per 100 000 people)	Croatia[(1)] (cases)	European Union[(2)] (case-reporting countries)	Netherlands (cases)	New Zealand (cases)	Sweden[(3)] (cases)	CSPI[(4)] (case from database)	United States of America (cases)
0.98 (2012) 1.17 (2011) 1.63 (2010)	8 (2011) 7 (2010)	363-26 (2011) (confirmed: 268) 394-25 (2010) (confirmed: 223) 1073-25 (2009) (confirmed: 748)	1 (2009) without travel history reported	1 (1992), suspected overseas source of infection 2 (2001), endemic source 0 (2011)	2 (since 1997)	258 of 26 outbreaks	17 (2011) (median of 11 cases per year reported during 2002-2011)

Notes: (1) Population: approximately 4.5 million. (2) Population of 27 countries (excluding Croatia, including Sweden): 50.25 million. (3) Population: 9.5 million. (4) Center for Science in the Public Interest (CSPI).

(ii) Notification status

Argentina, Croatia, the European Union, the Netherlands, Sweden and the United States of America dealt with trichinellosis as a notifiable disease. In New Zealand, organisms in pigs are also notifiable to the Ministry for Primary Industries.

(iii) Source attribution

Argentina, the European Union and New Zealand reported that the major source of the hazard related to human cases was pig meat. At the same time, data from CSPI showed that 20 of 26 outbreaks were associated with game meat (bear, walrus and cougar). The United States of America reported game meat, such as bear, boar, deer, pork and beef meat as sources of infection.

Figure A3.1 demonstrates the decline in total number of cases of human trichinellosis attributed to pork or pork products over the past 35 years in the United States of America. As can be seen, pork is no longer a significant source of human infection in the United States of America. In the period since 2002, an average of 1.7 cases per year were reported with pork as the source. Of these only one case per year, on average, has been linked to commercial pork. Thus, the risk of acquiring human trichinellosis from commercial pork in the United States of America in the years between 2002 and 2007 was 1 in 285 million.

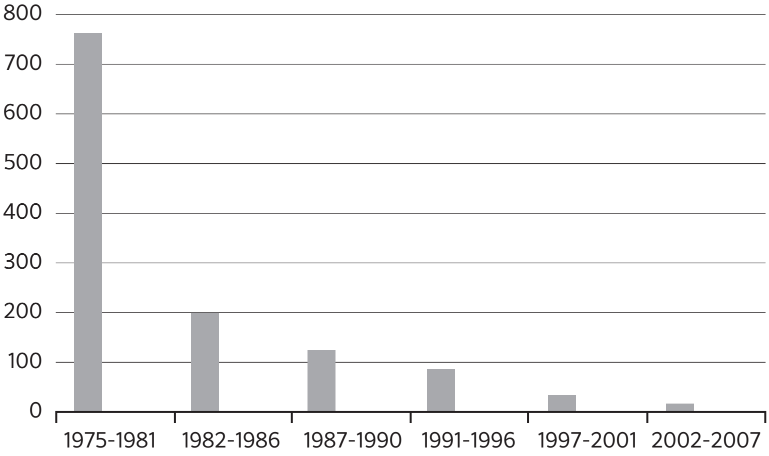


FIGURE A3.1. Human trichinellosis caused by pork (all sources) from 1975 to 2007 in the United States of America

(iv) Types of human illness or clinical symptoms

Argentina reported that symptoms might range from very mild to severe, with gastrointestinal disorders (firstly) and muscle pain, fever, etc. (secondly). The European Union evaluated that (1) case fatality of confirmed cases associated with pig was <0.1%, (2) incidence associated with soliped meat was 0.05–0.15 cases per 100 000 European Union population, and (3) result of evaluation of severity in humans was low. New Zealand reported patients' symptoms, including myalgia, fever, periorbital oedema, and photophobia. In the United States of America, eosinophilia, fever, periorbital oedema and myalgia have been observed. The number of reports of human trichinellosis in the United States of America have declined from approximately 500 cases annually in the 1940s and 1950s to an average of 14.2 cases annually in the period 2000–2009.

A3.3.1.2 Trade-related information

(i) Detections at port-of-entry inspection

There was no country reporting the detection of *Trichinella* spp. at port-of-entry point (including no testing conducted). Argentina reported that it has not been subjected to product rejection caused by *Trichinella spiralis* from countries which import livestock-derived products from Argentina. The United States of America reports that *Trichinella* control in the foreign producing country is addressed during United States Department of Agriculture Food Safety Inspection Service (USDA FSIS) equivalence determinations and verified in the audit process. FSIS does not perform re-inspections for trichinae at port of entry. New Zealand also mentioned that most of the risk mitigation measures are applied and certified offshore due to New Zealand's geographic isolation and that most imported meat is frozen.

(ii) Risk management response to detection

The European Union applies the relevant regulation (Articles 18 and 19 of EC No 882/2004) to every detection. Peru reported that in the event of finding a product with deficiencies, the respective lot was destroyed.

A3.3.1.3 Performance of post-harvest control measures

(i) Prevalence of detection in domestic pigs

Argentina, Croatia, the European Union, New Zealand and the United States of America reported the prevalence of detection of *Trichinella* (see Tables A3.2A & B). There is no report or detection in Australia, Cyprus, Dominican Republic, Peru and Sweden. New Zealand reports that routine monitoring of domestic pigs continued until 2007, but all samples tested were negative.

TABLE A3.2A. Reported prevalence of *Trichinella* spp. in domestic swine

Argentina	European Union	New Zealand
52 positive out of 3 643 538 slaughtered swine (2012)	Frequency of detection in pork carcasses after chilling: <0.1% For solipeds: 3 per 775 762 single samples (2007–2011)	Summary of recorded porcine and equine *Trichinella spiralis* infections in New Zealand: 1965 – 4 pigs; 1968 – 3 pigs; 1997 – 4 pigs; 2001 – 16 pigs; 2004 – 1 horse.

TABLE A3.2B. Reported prevalence of *Trichinella* spp. in swine and game in Croatia, 2010–2012

	No. of positive cases in domestic pigs and game					
	Tested in approved slaughterhouses			Tested in authorized veterinary establishments		
	Domestic	Wild boar	Other species	Domestic	Wild boar	Bear
2010	2	2	–	66	53	2
2011	4	4	–	39	41	–
2012	4	7	–	34	28	2

The United States of America reports that sera collected for the USDA's National Swine Survey in 1990 and 1995 demonstrated a continued decline in prevalence on a national basis (0.16 percent and 0.013 percent positive, respectively). Positive animals identified in the 1990 and 1995 NAHMS were sows; no market hogs were found positive in the 1990, 1995, 2000 or 2006 National Animal Health Monitoring System (NAHMS) Swine Surveys.

By far the largest data set of testing for *Trichinella* in pigs comes from hog slaughter plants that test for export under the Agricultural Marketing Service (AMS) Trichinae Export Program (unpublished data, AMS).

All testing performed in the AMS programme was by digestion and was performed as described in European Union Regulations and OIE guidelines. Some participating slaughter plants have been in the programme since 1996, while others came and went as the market changed. Nevertheless, the numbers of tests conducted from slaughter plants in the Midwestern United States of America (n = 38 755 374, with all negative results since 1996) comprise a data set that clearly demonstrates the lack of *Trichinella* infection in commercial pigs from this region.

(ii) Prevalence of detection in game

Argentina, Croatia, the European Union and New Zealand reported the prevalence of detection of *Trichinella* as below. There is no report or detection in Australia, Cyprus, Dominican Republic, New Zealand, Peru, Sweden and the United States of America.

TABLE A3.3. Reported prevalence of *Trichinella* spp. in game

Argentina	European Union
13 from wild boars (2008–2012)	**2011:** farmed boars (115/25 996 (0.4%)), wild boars (EU 831/700 289 (0.12%), Non-EU 0/1919)
	2010: farmed boars (26/36 871 (0.07%)), wild boars (EU 988/72 4640 (0.14%), Non-EU 0/2448)
	2009: farmed boars (8/27 591 (0.03%)), wild boars (EU 959/580 841 (0.2%), Non-EU 0/2558)

For Croatia, see Table A3.2B.

For New Zealand, Clear and Morris (2004) stated:

> Since 1990, more than 17 500 feral pigs have been processed. Many have come from the wilderness areas of the South Island. The last testing of feral pigs for export was in April 2002, as none have been exported since then. Feral pigs heavier than 68 kg continue to be tested for the local market, but as few reach this size most are not tested. There have been no positive *Trichinella spiralis* findings in feral pig samples tested (page 3).

As of 12 April 2013, no infections had been detected in pigs since that article was published.

(iii) Test methodology applied

The European Union, including Croatia, Cyprus, the Netherlands and Sweden, reported that testing according to Commission Regulation (EC) No 2075/2005 was conducted, which recommends the magnetic stirrer method for pooled-sample digestion. Argentina and Australia also apply a digestion method, which is described in their own regulations. New Zealand also applies this method, set by OIE. All testing in the United States of America is done according to US test licensure, OIE guidelines and EU regulations.

A3.3.1.4 Availability of risk models

Table A3.4 shows the results of qualitative risk ranking for pork and horsemeat for *Trichinella* spp. for the European Union.

TABLE A3.4. EU qualitative risk ranking (Source: EFSA)

Pork	Horsemeat
• Frequency of detection: low • Severity: low • Source attribution: high • Final medium risk	• Human incidence: low • Severity: low • Prioritization: low

The Netherlands reported models based on the risk of transmission, and development of a dose response model in rats, swine and humans. A scenario analysis of a risk-based approach has also been published (van der Giessen *et al*., 2013). See also Teunis *et al*. (2012) and Takumi *et al*. (2009, 2010).

New Zealand provided a *Trichinella* model used for the expert meeting as the basis for the development of risk-based examples.

The United States of America provided a reference for *Trichinella* (Gamble, 2011).

A3.3.2 *Taenia saginata*

A3.3.2.1 Public health data on the burden of disease in a country or region

(i) Prevalence of human cases

Australia reported 12 human cases of *Taenia saginata* in 2000, of which ten were imported (two were unknown). In the Sudan, 6 932 cases

(0.018 percent of the population) were reported in 2011. In New Zealand, ten cases of taeniasis were notified in 2011 (0.2 per 100 000 population). United States of America reports about 2 000 cases/year. There was no information from the other responding countries.

(ii) Notification status

All countries reported that human taeniasis is not notifiable (or reported "no information"), except New Zealand, where it is notifiable under human health legislation.

(iii) Types of human illness and clinical symptoms

The European Union, including Denmark, reported that severity of disease was unknown from EU-wide data, and considered to be "low".

A3.3.2.2 Trade-related information

All countries reported that either that there was no detection of the parasite at port-of-entry or that no information was available.

A3.3.3.3 Performance of post-harvest control measures

(i) Prevalence of detection in cattle

Australia, Denmark, the European Union, New Zealand, Sweden, the Sudan and Eswatini reported the prevalence of detection of *Taenia saginata* (Tables A3.5A & B). Eswatini reported 482 cases for the year 2012. There was no report or detection reported from the rest of countries. In the United States of America, the Animal and Plant Health Inspection Service (APHIS) has not recorded or compiled national-level information on *Taenia saginata* since 2005, when OIE removed it from the OIE list of diseases.

TABLE A3.5A. Reported prevalence of detection of *Taenia saginata*

Australia	Denmark	EU	Sweden	Sudan	Eswatini
Taenia saginata is present in the cattle population at a very low prevalence (Pearse *et al*., 2010).	348/4 090 661 (2004–2011) The true animal level prevalence was estimated to be 0.06%	Between 0.007% and 6.8% (Dorny and Praet, 2007; SCVMPH, 2000)	Approx. 1/ year for the last three years. (Total slaughter of cattle ca. 400 000/ year.)	Infection rate in different parts of the Sudan: 0.06-2.7% by region (6 regions)	482 cases (2012)

TABLE A3.5B. New Zealand – Number and prevalence of cases of *Taenia saginata* per year from 2000 to 2012

Year	*Taenia saginata* confirmed	Possible *Taenia saginata*	Total	Annual kill (1 000s)	Prevalence %
2000	1	5	6	2 206	0.000272
2001	4	6	10	2 146	0.000466
2002	19	22	41	2 226	0.001842
2003	13	16	29	2 556	0.001135
2004	6	5	11	2 632	0.000418
2005	1	5	6	2 443	0.000246
2006	1	3	4	2 373	0.000169
2007	0	4	4	2 232	0.000179
2008	1	4	5	2 429	0.000206
2009	8	8	16	2 373	0.000674
2010	11	4	15	2 432	0.000617
2011	7	8	15	2 275	0.000659
2012	4	0	4	2 263	0.000177
Total	76	90	166	30 586	Av. 0.000543

(ii) Inspection methodology in national legislation

Australia, Denmark, Dominican Republic, the European Union, New Zealand, Peru, the Sudan and Eswatini reported routine meat inspection associated with *Taenia saginata*, including EC No 854/2004 applied by European Union Member States. In the United States of America, APHIS does not have national legislation regarding beef cysticercosis, but FSIS legislation exists (9CFR 311.23 Tapeworm cysts in cattle; 9CFR 325.7, FSIS directive 6100.2; FSIS training materials). In Eswatini, postmortem inspection includes palpation, incision of parts of the carcass and offal, with laboratory tests to reach a definitive diagnosis.

(iii) Epidemiological information on the level of infection

Australia reported a sporadic case, which was probably caused by imported copra meal contaminated with human faeces. Denmark also reported that the level of infection was low, and infected cases were only observed sporadically. The European Union estimated 0.17 percent (0-0.29) in fresh bovine meat out of 1 386 366 samples. New Zealand reported that generally a low level of infection exists where one cyst from one animal from one farm is detected, but that over the last ten years three instances of clustering have occurred. The Sudan regarded the level of infection as medium. The Netherlands reported low to very sporadic levels of infection, high in veal calves mostly due to contamination of food. In the United States of America, state-level information on clusters and sporadic outbreaks is held by the State.

A3.3.2.4. Availability of risk models

Denmark reported two studies, namely Calvo-Artavia *et al.* (2013) and Calvo-Artavia, Nielsen and Alban (2013). The EU-provided qualitative risk ranking based on notification rate in humans and severity was given as “low”.

New Zealand reported that various unpublished *Taenia saginata* models have been developed by MPI. Relevant references are van der Logt, Hathaway and Vose (1997), and Richardson *et al.* (2009).

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Annex 4

Trichinella spp. infections in domestic pigs of Europe and America

TABLE A4.1. *Trichinella* spp. Infections in domestic pigs of Europe and America (derived from Pozio, 2014)

Country	Controlled systems[a]	Non-controlled systems[b]	Reference period
Belarus	No data	0.00%	1980–1989
Bosnia and Herzegovina	No data	~300/unknown	1997–2000
Bulgaria	0.0/0.36 million	~40/unknown	2006–2012
Estonia	0.0/0.48 million	1 in 1994, 1 in 1999	1994–2012
Finland	0.0/4.8 million	343/unknown	1995–2004
France	0.0/16 million	19/unknown Corsica island	2004–2012
Germany	0.0/49 million	8/unknown	2003–2012
Greece	0.0/4.5 million	36/12,717	2009–2012
Hungary	0.0/4 million	2 in 2000, 6 in 2003, 4 in 2009	2000–2012
Italy	0.0/9 million	17/unknown	2006–2012
Latvia	0.0/0.3 million	2/unknown	2011
Lithuania	0.0/0.8 million	84/unknown	2006–2011
Poland	0.0/20 million	342/unknown	2001–2011
Macedonia	0.0/0.1 million	Not available	2000–2003
Montenegro	0.0/0.05 million	26–42/unknown	2000–2003
Romania	0.0/3.0 million	404/unknown	2007–2011
Serbia	0.0/1.7 million	416–2875/unknown	2001–2010
Slovakia	0.0/0.8 million	Sporadic reports	2000–2011
Spain	0.0/38 million	160/9,000	2004–2008
Argentina	0.0/1.5 million	100/1 million	2008–2012
Canada	0.0/30,000	0.0/30,000	1998–2012
Mexico	0.0/10 million	~10/150,000	2009–2012
United States of America	0.0/85 million	10–20/15 million	2003–2012

[a] Prevalence or number of infected pigs per number of tested pigs in controlled systems per year
[b] Prevalence or number of infected pigs per number of tested pigs in non-controlled systems per year

Annex 5

Application of a Bayesian approach to consideration of pre-existing data in defining testing requirements for ongoing assurance of consumer protection

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 A5.1 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 A5.1. A Bayesian approach to estimate the mean prevalence of possibly infected pigs

Year	Prior	Test data	Posterior	Mean prevalence of possibly infected pigs
Establishment phase (2 years)	*Beta*(1:0)	0:500 000 positive	*Beta*(1:500000)	1/500 001
Maintenance – year 1	*Beta*(1:500 000)	0:50 000 positive	*Beta*(1:550000)	1/550 001
Maintenance – year 2	*Beta*(1:550 000)	0:50 000 positive	*Beta*(1:350000)	1/350 001
Maintenance – year 3	*Beta*(1:350 000)	0:50 000 positive	*Beta*(1:150000)	1/150 001

Annex 6

Summary risk profiles on *Trichinella* spp. and *Taenia saginata/Cysticercus bovis*

6.1 ACKNOWLEDGMENTS

The work on the proposed Draft Guidelines for Control of *Trichinella* spiralis and Cysticercus bovis in meat (CX/FH11/43/6) required the preparation of two risk profiles to assist the Committee members. During its 43rd Session of CCFH, the Committee requested that FAO and WHO conduct a peer review of two summary risk profile documents, one for *Trichinella* spp. and a second one for Cysticercus bovis. The Committee considered that the information presented in the risk profiles was useful for other stakeholders and had to be peer reviewed before making the risk profiles available to the public.

Although these risk profiles were developed independently from this report, we still include them here to provide a comprehensive compilation of the work that FAO and WHO have supported on *Trichinella* spp. and *Taenia saginata*, to support the risk management of these foodborne parasites.

FAO and WHO would like to express their appreciation to all those who contributed to the preparation of these risk profiles through their participation in the initial drafting, peer review process and the provision of their time, expertise, data and other relevant information.

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6.2 SUMMARY RISK PROFILE ON *TRICHINELLA* SPP.

A6.2.1 Hazard-food commodity of concern

Trichinellosis is a parasitic disease of humans caused by eating raw or inadequately treated meat from domestic or game animals infected by *Trichinella* spp. Infective first stage larvae live in muscle cells of a wide range of meat-eating mammals, and some birds and reptiles (OIE, 2018). Human trichinellosis contracted from commercial supplies of meat have been most often linked to infected pigs, wild boar, or horses. Human cases have been also linked to the consumption of infected meat from game animals including bears and walruses. The parasite is a nematode which has an atypical direct life cycle that does not involve stages developing outside of the host. Muscle larvae are released from infected meat in the stomach of suitable host species, develop to adult worms in the intestine, and produce pre-encapsulated larvae which migrate preferentially to certain muscle sites in the host to complete the life cycle within several weeks. Within the muscle cells the larvae of some *Trichinella* species are encapsulated in a thick collagen layer. Within the host muscle larvae remain infective for up to several years. All genotypes of *Trichinella* are pathogenic for humans, but in animals the infection appears clinically unapparent. Some animal species serve as reservoir hosts. Domestic pigs and rats have been reported to harbour *T. spiralis* within the domestic cycle mostly in temperate regions of the world (Dupouy-Camet, 2000). Wild carnivores and other meat-eating species such as wild boar and bears maintain the sylvatic *Trichinella* cycle which involves other species of *Trichinella*. Feeding behaviours such as predation, scavenging and cannibalism facilitate transmission. Encapsulated species of *Trichinella* infect only mammals, and include *T. spiralis* (T1), *T. nativa* (T2), *T. britovi* (T3), *T. murrelli* (T5), *T. nelsoni* (T7), and T6, T8, T9, T12 (OIE, 2018). The non-encapsulated species infect mammals as well as birds (*T. pseudospiralis*) or crocodiles (*T. papuae* and *T. zimbabwensis*). *Trichinella*'s geographical distribution and biological characteristics such as freeze tolerance and reproductive capacity for host species vary according to the species of parasite and host. Species which thrive in pigs and represent a potentially high level of food safety risk for consumers of pork and pork products include *T. spiralis, T. britovi, T. pseudospiralis, T. papuae,* and *T. zimbabwensis*. Historically, most outbreaks of human trichinellosis have been associated with *Trichinella*-infected swine (Murrell and Pozio, 2011, Dupouy-Camet, 2000). Regulations for the inspection and control of *Trichinella* have been applied in many countries for over a century. Consequently, in countries with effective inspection and regulatory systems, human trichinellosis from commercial meat is rare.

A6.2.2 Description of the public health concern

It is estimated that approximately 11 million people are infected with *Trichinella* worldwide, with significant under-reporting likely in many parts of the world (Dupouy-Camet, 2000). An analysis of outbreak data reports 65,818 human cases from 41 countries worldwide from 1986-2009 (Murrell and Pozio, 2011). Even when mandatory testing for *Trichinella* is performed at slaughter, in some countries human outbreaks linked to imported meat or consumption of wild game have been reported. Although *Trichinella* has a global distribution, most species are geographically limited. Trichinellosis in humans can be a debilitating, occasionally fatal, disease. Food safety experts extrapolate that ingestion of 100 larvae is sufficient to cause clinical disease. In early infection, the adult worms in the intestine can cause a transient gastroenteritis, but the most severe symptoms are associated with the migration and establishment of the larvae in muscle. These include periorbital and facial oedema, myalgia, fever, conjunctivitis, photophobia, and skin rash. Myocarditis, endocarditis, encephalitis and meningitis have been observed in severe cases with poor prognoses. Most symptoms diminish approximately one to two months post-infection, but chronic myalgia and fatigue can persist. In addition to supportive therapy, anthelmintics are most effective for treatment of infection involving pre-muscle stages (Kociecka, 2000). However, most infected patients are not diagnosed until two or more weeks after exposure, when larvae have already become established in the muscles, where drug bioavailability may be limited.

A6.2.3 Food production, processing, distribution and consumption

Important risk factors for farmed swine and other susceptible livestock include feeding of infected food waste, and exposure to swine carcasses, rats and other wildlife species (OIE, 2018). Mitigation of these risks in free-range pasturing and back-yard rearing practices can be challenging. Education, regulations and compliance to prevent access to infected food waste, carcasses, rats, wild animals, and birds can be effective. Standard biosecurity measures implemented in modern swine production facilitate the certification of *Trichinella*–free farms and herds in non-endemic areas (Pyburn *et al.*, 2005). Serological testing of pre- or post-mortem samples for *Trichinella* can be a valuable tool for surveillance programmes and disease outbreak investigations at the herd or population level but cannot reliably determine individual animal status for food safety purposes, as recommended by the OIE (OIE, 2018). Artificial digestion incorporating adequate quality assurance is currently the only method recommended for food safety purposes (OIE, 2018). This method is capable of testing up to 100 g of pooled meat samples with a detection sensitivity of ≥ 1 larva per gram (LPG) for individual samples ≥ 3g. An infection intensity of 1 LPG is considered sufficient to cause clinical disease in humans (Gajadhar *et al.*, 2009). Sensitivity of the digestion assay is enhanced when samples from sites of predilection are tested. Although these vary according to host species, tongue and diaphragm are often amongst the preferred sites. Trichinoscopy, another direct method based on the detection of larvae in-situ in grain-size meat samples compressed between two glass plates and observed under magnification is less sensitive than digestion and is not recommended for reliable testing (OIE, 2018).

Three treatment methods have been shown to reliably inactivate *Trichinella* larvae in meat, namely cooking and irradiation, and freezing for some *Trichinella* genotypes.

Heat treatment is a suitable method for killing *T. spiralis* in meat from domestic swine. Different time/temperature/meat thickness combinations can be applied to infected pork to ensure destruction of the parasite. The thermal death point for *T. spiralis* is 54-57 °C. Data related to other host species and *Trichinella* genotypes are not available. However, it is likely that thorough cooking will effectively inactivate all *Trichinella*, and so this is currently the most widely recommended method to ensure food safety. No curing or smoking processes are recommended to reliably inactivate *Trichinella* larvae in pork, horse, or game meat (Gamble *et al.*, 2000).

Freezing, at -15°C for no less than three weeks for meat up to 15 cm thickness and for no less than four weeks for meat up to 50 cm thickness, can kill *T. spiralis* in pig meat. However, other *Trichinella* genotypes, such as *T. nativa, T. murrelli* and *T. britovi* occurring in game, horses, etc. are freeze tolerant (OIE, 2018). It is therefore recommended that meat from game or other potential hosts of these genotypes be thoroughly cooked to mitigate risk of infection for consumers. Irradiation, where permitted, can also be an acceptable method for rendering meat safe for human consumption, since levels of at least 0.3 kGy have been proven to inactivate *Trichinella*.

A6.2.4 International trade

The movement of domestic pigs and farmed wild boar represents a significant risk for the control of *Trichinella* and trichinellosis in the domestic cycle. Commercial movements of these animals and their meat and meat products have been implicated in the spread of the parasite to farms and countries. The amount of such meat involved in international trade is enormous, where, on 2017, the largest exporters of pig meat are the European Union, the United States of America, Canada and China (FAO, 2020). Globally, over 5 million tonnes of pork and 132 000 tonnes of horsemeat were exported in 2017 (FAO, 2020). Guidelines and control recommendations to reduce the risk of *Trichinella* in food animals and their products exist (Dupouy-Camet and Murrell, 2007). Nonetheless, meat and meat products from susceptible host species such as pigs and horses continue to be a potential source of infection for consumers.

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6.4 SUMMARY RISK PROFILE ON *TAENIA SAGINATA*

A6.4.1 Hazard-food commodity of concern

Bovine cysticercosis is a parasitic disease of cattle caused by the larval stage (*Cysticercus bovis*) of the human tapeworm *Taenia saginata*. The indirect life cycle of this taeniid involves only humans as the primary host and bovines as the intermediate host. Taeniosis, infection of humans with the adult tapeworm, ocurrs following consumption of beef with cysticerci that has not been sufficiently heated or frozen to kill the parasite. Although multiple infections in humans can occur, most cases of taeniosis involve a single tapeworm, which can persist for years. The adult tapeworm develops to reproductive maturity as early as ten to twelve weeks after infection. The adult tapeworm regularly sheds its most posterior and mature segments, called gravid proglottids, which are discharged from infected humans spontaneously or with defecation. Upon release, these proglottids contain thousands of infective eggs that can remain in the proglottid or be expelled into the surrounding fecal matrix or environment.

Eggs can remain infective for several months under cool and moist environmental conditions and can be disseminated by water and other fomites. Upon ingestion of contaminated feed or water by a bovine intermediate host, a hexacanth embryo, or oncosphere, hatches from the egg and penetrates the intestinal mucosa within a few hours to enter the cardiovascular or lymphatic system. Once it reaches a suitable muscle or other tissue site it develops into a cysticercus and becomes infective for a human host after about ten to twelve weeks. In cattle, cysticerci are found predominantly in cardiac and skeletal musculature, and occasionally in other sites including liver, lungs, kidneys and lymph nodes. Cysticerci remain infective for several months to a year or more (OIE, 2005; OIE, 2018).

Taenia saginata occurs worldwide, with the highest prevalence in developing regions where poor sanitation and poor animal husbandry practices, and habits of eating inadequately prepared beef, facilitate parasite transmission. In non-endemic areas, sporadic cases of human taeniosis and of epizootic outbreaks of bovine cysticercosis do occur in spite of better public health and veterinary infrastructure, including regulated inspection of cattle carcasses at slaughter.

A6.4.2 Description of the public health concern

Taenia saginata is most prevalent in sub-Saharan Africa, Latin America, Asia, and some Mediterranean countries. Tens of millions of persons are likely infected with *T. saginata* taeniosis worldwide, but reliable estimates are lacking due to the low pathogenicity and under-reporting of this infection. For many otherwise healthy humans infected with *T. saginata*, the symptoms are mild and unrecognized for many years until the parasite dies or is eliminated. The most common manifestation is mild non-specific gastrointestinal illness with symptoms such as pruritus ani, nausea, weight loss, abdominal pain, diarrhea, and anorexia, although more serious complications such as appendicitis have been reported. Cattle with cysticercosis typically do not exhibit any clinical signs. Human taeniosis can be safely and effectively treated with a single oral dose of praziquantel or niclosamide (Craig and Ito, 2007)

Globalization poses an increased threat of incursions of cysticercosis and taeniosis via the international movement of people and animals, their products, and potentially contaminated produce or other fomites from endemic regions. Since humans as the definitive host are key to maintaining the parasite cycle, accurate prevalence data on *T. saginata* taeniosis are needed; this can be acquired by effective surveillance and mandatory reporting by public health agencies. Practical and effective control programs are also needed, including education regarding the parasite life cycle, mitigating measures such as proper hygiene to prevent access of cattle to human faeces, thorough cooking of meat, and taeniacidal treatment (Gajadhar *et al.*, 2006).

A6.4.3 Food production, processing, distribution and consumption

Risk factors for bovine cysticercosis include any that increases the chance of exposure of cattle to infective eggs from human faeces/sewage, such as close proximity to public areas, flooding, use of fertilizer that may contain human sewage, use of potentially contaminated feed or water, and employing labour potentially infected with *T. saginata*. The control measures most commonly implemented are based on the organoleptic detection of cysticerci in bovine carcass “predilection” sites during postslaughter inspection. These sites typically include the heart, masseters, tongue, oesophagus, diaphragm, and the superficial and cut surfaces of the carcass; the triceps brachii muscle of the forelimb may also be examined in some regions. The heart and masseters consistently rank amongst the most likely sites to detect infection (Scandrett *et al.*, 2009). Degenerating cysticerci are more easily detected than viable cysticerci, which are translucent and difficult to differentiate from surrounding host tissue. Since both viable and degenerating cysticerci can co-exist in the same carcass, detection of degenerated cysts does not ensure that viable cysticerci are not present at other sites (Gajadhar *et al.*, 2006). The sensitivity of post-slaughter organoleptic inspection is low, particularly for lightly infected animals. Serological assays for bovine cysticercosis are not yet reliable for determining the status of individual animals but may be of some value as screening tests in herds and for epidemiological investigations. There are no commercial vaccines yet available, and anthelminthic treatment of infected animals is not cost-effective. However, methods are available for the effective treatment of carcasses to render cysticerci non-infective.

Freezing meat and viscera at a minimum of -10 ° C for no less than ten days should render any cysticerci non-viable. Those establishments that use freezing rather than chilling for cold storage of carcass meat and viscera, especially heart and head meat, can reduce the likelihood of products being infective to consumers. Also, cooking to attain a core temperature of at least 60 °C is considered sufficient to kill cysticerci, which can also be inactivated with low dose irradiation of 0.5 kGy (WHO, 1995). Beef produced in endemic regions and distributed for local consumption is often not subjected to any cold or heat treatments and thus is more likely to be infective than products which are frozen for broader distribution.

Consumers are generally unaware of this parasite and the potential for beef to transmit taeniosis. Education of the public on the risks posed by consuming inadequately cooked or frozen beef will contribute to better overall control of this zoonosis.

A6.4.4 International trade

Due to the public health and aesthetic implications of cysticercosis, this parasite causes substantial economic loss through condemnation of infected meat and offal, and trade restrictions for endemic regions. The international trade of beef and beef products is the largest of the red meat trade sector. Close to 5 million tonnes of beef and veal were exported globally in 2011 (FAO, 2020). Much of the global trade in beef is destined for the fast food market, and such products are usually frozen, cooked or otherwise processed, which reduces the likelihood of consumers being infected with *T. saginata*. However, the international trade in chilled beef poses a higher risk, especially to those markets where raw or poorly cooked meat is consumed.

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Human trichinellosis is caused by the consumption of raw or inadequately treated meat from domestic or game animals containing the larvae of parasites of the *Trichinella* species. Taeniosis occurs when people consume beef with cysticerci that have not been sufficiently heated or frozen to kill the parasite.

This report provides the spreadsheet models that resulted in effective generation of the quantitative information needed by public health officials when evaluating different postmortem meat hygiene programmes for *Trichinella* spp. and *Taenia saginata* in meat.

The models enable the development of science-based risk scenarios to assess the effect of various changes to digestion testing and meat inspection for *Trichinella* spp. and *Taenia saginata*, respectively, on the residual risk of human trichinellosis and taeniosis.

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