RISK-BASED EXAMPLES FOR CONTROL OF *TRICHINELLA* SPP. AND *TAENIA SAGINATA* IN MEAT

REPORT OF A JOINT FAO/WHO EXPERT MEETING,
22–25 OCTOBER 2013,
WHO HEADQUARTERS, GENEVA, SWITZERLAND

17th June 2014

Preliminary Report

This meeting report represents a first step taken to address ongoing discussions in this area. As such, it can only be considered as an interim or progress report, to be superseded as the work progresses to the next stage. This report is primarily to inform Codex of progress and to publicly recognise the efforts of the meeting and other contributors. Further considerations on this subject will be forthcoming in due course. The ultimate goal is to provide the scientific advice requested by Codex for the development of the Proposed Draft Guidelines for Control of Specific Zoonotic Parasites in Meat: *Trichinella* spp. and *Taenia saginata*.

Food and Agriculture Organization of the United Nations

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The preparatory work for and implementation of the expert meeting, and the preparation of this report were coordinated by the Secretariat of the Joint FAO/WHO Expert Meeting on Microbiological Risk Assessment (JEMRA). This included Sarah Cahill and Marisa Caipo in FAO and Mina Kojima in WHO. The work was supported and funded by the FAO Food Safety and Quality Unit and the WHO Department of Food Safety and Zoonoses.

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DECLARATIONS OF INTEREST

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

ABBREVIATIONS USED IN THE REPORT

APHIS	Animal and Plant Health Inspection Service [of the USDA]
CAC	Codex Alimentarius Commission
CCFH	Codex Committee on Food Hygiene
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]
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

A joint FAO/WHO expert meeting was convened following the request of the Codex Committee on Food Hygiene (CCFH) in its process of developing the Proposed Draft Guidelines for Control of Specific Zoonotic Parasites in Meat: *Trichinella* spp. and *Taenia saginata*. CCFH had requested 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.

The objectives of the meeting were:

(i) 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.

(ii) To analyse available data and information that contributes to establishing a risk-based approach to the control of these two zoonotic parasites.

(iii) To develop risk-based examples for *Trichinella* spp. and *Taenia saginata* describing the likely levels of residual risk for consumers with different pre- and/or post-harvest risk management options.

(iv) To provide an information resource for risk managers as an input to their risk management decisions.

TRICHINELLA SPP.

The expert meeting discussed how 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 used to develop the examples, which estimated the number of infected portions per million servings from pig populations in controlled housing compartments. The model applied an overarching assumption that every infected edible portion, independent of the number of larvae present in the meat, would cause human infection or illness. It also assumes that *Trichinella* larvae were uniformly distributed in an infected carcass, even though this was seldom the case in real life. Thus the model was very conservative in its outputs.

Seven hypothetical examples were developed to illustrate the different residual risks to consumers when different testing information was used to establish a negligible risk compartment by using model input parameters that included number of pigs slaughtered/tested/testing positive, diagnostic sensitivity of testing and percentage of undercooked or raw pork consumed. All tests results for pigs from controlled housing were assumed to be negative. Conservative estimates were taken for the percentage of a carcass reaching the consumer as fresh pork, and the percentage that was consumed raw or undercooked. The final output of the model was the average number of infected meals per million edible portions after cooking.

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

Once established, maintaining the controlled housing conditions, and thus the negligible risk status, was essential. Verification of the public health status resulting from maintenance could 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 (2013b).
- 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 will be the subject of an expert meeting planned for 2014.

TAENIA SAGINATA

The expert meeting used a model to illustrate differences in *relative* risks (RR) of beef to consumers when different intensities of postmortem meat inspection procedures were used, thereby informing decisions by risk managers on the most appropriate procedures to use in cattle populations with different levels of infection so that the outputs of the model were useful in modernization of meat inspection.

A simple spreadsheet model was used 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 could lead to one tapeworm infection in humans. Model inputs related to number of infected and detected animals, sensitivity of inspection, viability of cysts and the proportion of beef meat being subjected to a treatment that would inactivate cysts. These inputs were applied and the final output of the model was the number of human infections that would be expected to result from a slaughter population of known size.

Examples of relative risks were developed for four countries (W, X, Y, Z) with high (W), medium (X), and low (Y and Z) number of cases of bovine cysticercosis as detected at abattoirs per year, respectively. Four model Scenarios sets (A, B1, B2, C) were used to derive the examples with different sensitivity of inspection or viability of cysts.

The spreadsheet model used to develop examples demonstrated the expected changes in residual human risks under different prevalence scenarios when different sets of meat inspection procedures were used at postmortem inspection. 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 use of simple spreadsheet models 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. The models, whose outcome was based on changes in relative risks rather than specific estimates of risk, 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.

The meeting agreed that this innovative approach would 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. between when establishing a negligible risk compartment and when 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

1. INTRODUCTION

1.1 BACKGROUND

Trichinella spp. cause human trichinellosis by consumption of raw or inadequately treated meat from domestic or game animals. *Taenia saginata* causes bovine cysticercosis, a parasitic disease of cattle, by the larval stage (*Cysticercus bovis*) of the human tapeworm *Taenia saginata*. Infection of humans with the adult tapeworm, known as taeniosis, occurs via the consumption of beef which has been insufficiently cooked or frozen to kill the cysticerci. Both are important for human and animal health and in 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 has been ongoing work for the Codex Committee on Food Hygiene (CCFH), with the elaboration of Draft Guidelines for Control of Specific Zoonotic Parasites. In parallel, OIE revised and recently adopted Chapter 8.14 on Infection with *Trichinella* spp. from the OIE Terrestrial Animal Health Code (2013a), recommending control measures at the farm level to prevent food borne illness 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, 2012).

Applying a risk-based approach to meat hygiene requires re-evaluation of traditional practices and a re-focusing 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 "new" (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.

This expert meeting was convened 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 CCFH reiterated 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*. A call for data was issued to member countries and a summary of the information was collated by FAO and WHO for use by the expert meeting. Risk profiles for these two parasites are available at http://www.fao.org/food/food-safety-quality/a-z-index/foodborne-parasites/en/ and http://www.who.int/foodsafety/micro/jemra/assessment/parasites/en/ .

1.2 OBJECTIVES

The objectives of the meeting were:

(i) 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.

(ii) To analyse available data and information that contributes to establishing a risk-based approach to the control of these two zoonotic parasites.

(iii) To develop risk-based examples for *Trichinella* spp. and *Taenia saginata* describing the likely levels of residual risk for consumers with different pre- and/or post-harvest risk management options.

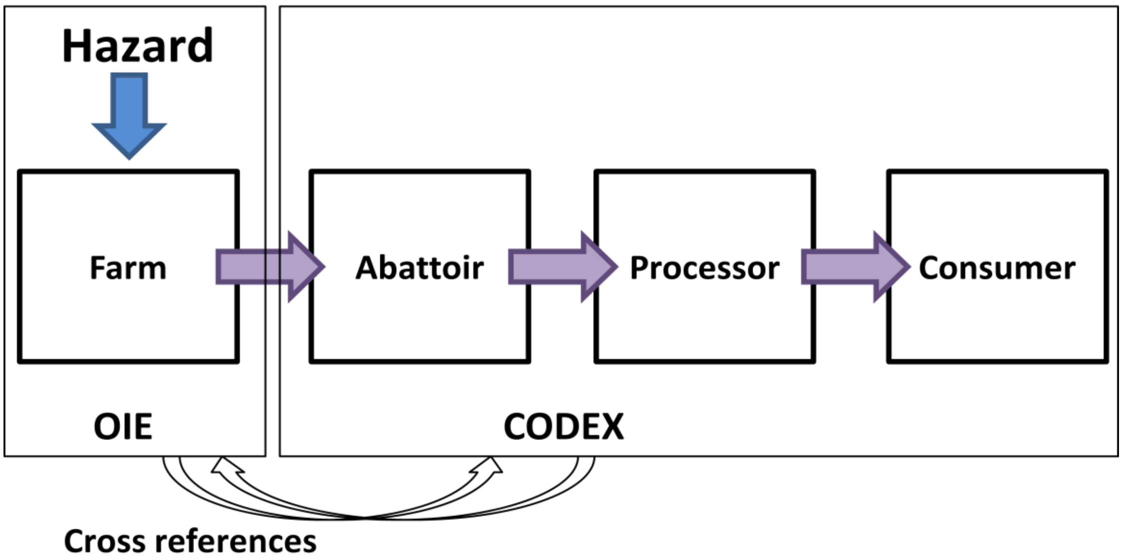
(iv) To provide an information resource for risk managers as an input to their risk management decisions.

1.3 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.

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.

Figure 1. Steps in the food chain for application of control measures as described by OIE and Codex (De Smet, EU, pers. comm.; Hathaway, in prep.).



The OIE Terrestrial Animal Health Code 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 does not provide such guidance for *Taenia saginata.* The Codex Committee on Food Hygiene (CCFH) is currently developing guidance on the control of *Trichinella* spp. and *Taenia saginata* using a whole-food-chain approach (Proposed Draft Guidelines for Control of Specific Zoonotic Parasites in Meat: *Trichinella* spp. and *Taenia saginata*), 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, 2013a). This term, 'negligible risk 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, 2012).

1.4 RISK ASSESSMENT

In responding to the above objectives, the experts were tasked with quantitatively illustrating the risks associated with selection of different risk management options by risk managers. Two spreadsheet risk models were provided to the experts as a baseline resource (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.

1.5 NECESSARY INPUTS FOR MODELLING THE FOOD CHAIN FOR CONTROL OF *TRICHINELLA* SPP. AND *TAENIA SAGINATA* IN MEAT

1.5.1 TRICHINELLA SPP.

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 example 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, evidence of differences in current food safety systems.

The test method (digestion testing) was selected in accordance with the diagnostic techniques recommended in Chapter 2.1.16 of the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (2013b).

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 tests 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	USA, Fresh: 25% EU, (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 (USA) The model establishes between 50 and 150 meals/carcass
	Percentage of edible portions eaten raw or fresh	1–2%	USA, 1%; NZ, 1%; EU, 5% The model sets a range between 0 and 10% of meals not rendered safe by cooking (undercooked or raw)

1.5.2 TAENIA SAGINATA

A description of inputs required for modelling of the food chain for control of *Taenia saginata* in beef meat is shown in Table 2.

Table 2. 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	Prevalence positive at postmortem inspection	15%	From the scientific literature
	"Low prevalence" population or sub-population	Age of the animals at slaughter		
		Sex		Considered males and females
		Other risk factors such as type of breeding or management		
Abattoir		Prevalence positive at postmortem inspection	15%	From the scientific literature
		Designation of number of cysts constituting a lightly infected animal	4, 6 or 8	
		Performance characteristics of postmortem inspection (sensitivity and specificity)	2.0, 3.9, 4.7%	
		Regulatory action following positive test, e.g. 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%	NZ 10%; EU 90%; USA 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)

2. DEVELOPMENT OF THE RISK-BASED EXAMPLES

2.1 *TRICHINELLA* SPP.

2.1.1 ESTABLISHING A NEGLIGIBLE RISK STATUS

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 and illustrates relative risk, depending on the scenarios considered.

A negligible risk compartment refers to a compartment with a negligible risk of *Trichinella* infection (OIE, 2013a).

MODEL

A spreadsheet model (Annex 2) was used 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.

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.
- Number of edible portions per slaughtered pig.
- Percentage of undercooked or raw pork consumed.

OVERVIEW OF EXAMPLES

Seven hypothetical examples were developed that simulated a range of scenarios. All test results for pigs from controlled housing were assumed to be negative. Conservative estimates were 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 tests 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.

OUTCOMES

Seven examples with different scenarios and the results are presented in Table 3, and the model used for calculation of these outputs is presented in Annex 1.

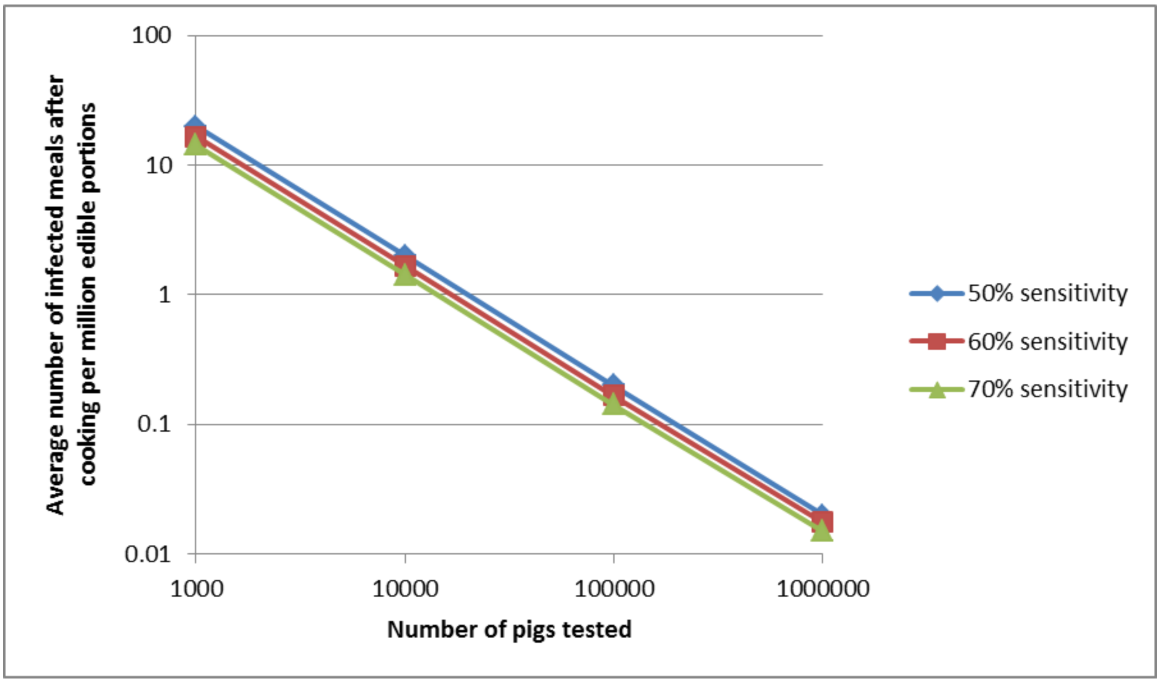
Table 3. Numbers of *Trichinella* spp. infected portions per million servings in seven examples

Example	No. of pigs slaughtered	No. of pigs tested	No. testing positive	% of fresh meat at retail	% of under-cooking 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	1000 to 1 million	0	50	2	66 600 – 67	16.7 – 0.017
3	1 million	1000 to 1 million	0	50	2	6 660 – 7	16.7 – 0.017
4	100 000	1000 to 100 000	0	50	2	666 – 7	16.7 – 0.017
Example with low percentages of fresh meat at retail and undercooking by consumers, respectively							
5	10 million	1 million	0	25	1	17	0.00425
Example with 1 pig testing positive for *Trichinella* spp.							
6	10 million	1000 to 1 million	1	50	2	133 200 – 133	33.3 – 0.033
Example from non-controlled housing, pigs testing positive for *Trichinella* spp.							
7	13 000	10 000	36	50	2	321	61.7

The results for Examples 1 to 4 are presented in Figure 2 and Table 4. The model shows that the average number of infected meals (i.e., infected portions served) 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% to 50%, using Examples 1 through 4, has little effect on the outcome for a given level of testing.

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 test sensitivity (50–70%) assuming no animals tested positive.*

Number of animals tested	Test sensitivity 50%	Test sensitivity 60%	Test sensitivity 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.

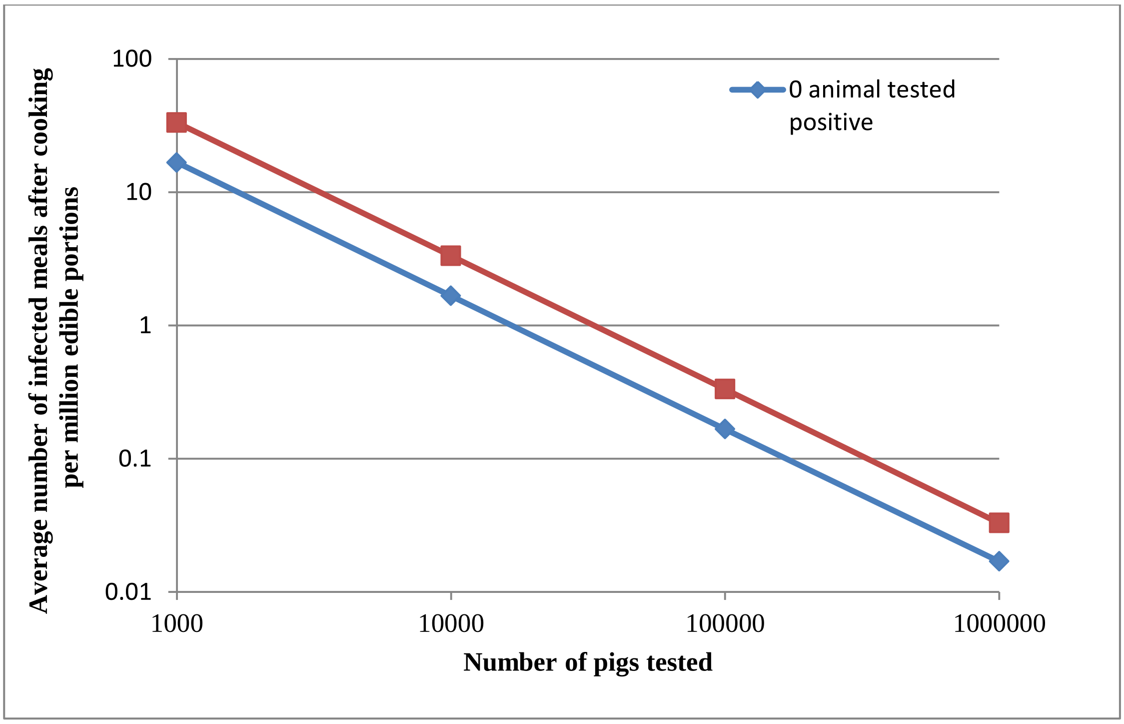
Table 5. Variation in the average number of infected meals after cooking depending on the number of animals tested, assuming one animal tested positive*

No. of animals tested	Test sensitivity 60%: 0 animal positive	Test sensitivity 60%: 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 5. 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 portions at 60% 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.

2.1.2 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:

- 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 (2013b).
- 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.

2.1.3 CONCLUSIONS

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

1. 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.

2. More work is needed to complement the outcomes of this expert meeting. The model is conservative in use of input parameters (e.g. one larva in an edible portion causes human illness), 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).

2.2 TAENIA SAGINATA

PURPOSE

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

MODEL

A simple spreadsheet model was used 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. 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 prevalence' 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.

OVERVIEW OF EXAMPLES

Countries W, X, and Y or Z with a high (W), medium (X) and low (Y and Z) number of cases of bovine cysticercosis detected in abattoirs per year, respectively, were chosen as example countries to represent different prevalence situations (Table 6). Y and Z differ in the proportion of meat traditionally eaten raw or undercooked. For each of these example countries, model parameters were based on available data or reasonable assumptions relevant to each scenario set below. Model parameters varied between countries to best reflect the 'real-life' situation, including processing and consumption habits. Model outputs are shown in Table 6.

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 7 and 4 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% from 10% in the basic model.

MODEL INPUTS

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%.

The sensitivity of detecting one *Taenia saginata* cyst in an infected animal is very low and Kyvsgaard *et al.* (1990) found this to be 4% 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%.

Scenario set A uses 4.7% as the sensitivity of detecting one cyst (Hathaway, in prep.).

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 4 and the average sensitivity of inspection for such a population is about 15%. Thus 85% 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% to 3.9%. 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 'lightly infected' situation 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 4 or 7, 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.

VIABILITY OF CYSTS

The user of the model can assign a value appropriate to the baseline scenario. An estimate of 10 % was used for the first three scenarios that are presented below (Scenario sets A, B1 and B2). This estimate of 10% 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% in the basic model to 11% 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 that through a longer life have had more probability of getting infected not just once but several times.

OUTCOMES

The outcome of these models is shown in Table 6. 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 (Y) with a low number of detected cases of bovine cysticercosis. 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 6. Summary of various estimates of the residual risk of taeniosis in four example countries with different prevalences 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" (High no. of detected cases of bovine cysticercosis/year)							
A (14)	6633	4	4.70%	4	10%	95%	40%	100%	18%	4748		
	6633	4	3.90%	4	10%	95%	40%	100%	15%	5845	1097	23%
B1 (15)	6633	8	2.00%	4	10%	95%	40%	100%	15%	5748		
	6633	6	2.00%	4	10%	95%	40%	100%	11%	7824	2076	36%
B2 (15)	6633	8	2.00%	7	10%	95%	40%	100%	15%	10058		
	6633	6	2.00%	7	10%	95%	40%	100%	11%	13691	3633	36%
C (16)	—	—	—	—	—	—	—	—	—	—	—	—
	—	—	—	—	—	—	—	—	—	—	—	—
					Country "X" (Medium no. of detected cases of bovine cysticercosis/year)							
A (14)	1500	4	4.70%	4	10%	90%	40%	100%	18%	1017		
	1500	4	3.90%	4	10%	90%	40%	100%	15%	1252	235	23%
B1 (15)	1500	8	2.00%	4	10%	90%	40%	100%	15%	1231		
	1500	6	2.00%	4	10%	90%	40%	100%	11%	1676	445	36%
B2 (15)	1500	8	2.00%	7	10%	90%	40%	100%	15%	2155		
	1500	6	2.00%	7	10%	90%	40%	100%	11%	2933	778	36%
C (16)	—	—	—	—	—	—	—	—	—	—	—	—
	—	—	—	—	—	—	—	—	—	—	—	—
					Country "Y" (Low no. of detected cases of bovine cysticercosis/year)							
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" (Low no. of detected cases of bovine cysticercosis/year)							
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 *T. 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%

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% to 2%, implying a factor of close to 300. In fact, the country with the highest number of infected carcases (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 6 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.

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 (a.k.a. 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.

2.3 CONCLUSIONS

1. 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.

2. The output of the scenario sets 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 *T. 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 *T. 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.

3. OVERALL CONCLUSIONS AND RECOMMENDATIONS

3.1 CONCLUSIONS

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

2. 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.

3. The use of risk-based examples for *Trichinella* spp. and *Taenia saginata* demonstrated the value of a 'fit-for-purpose' risk modelling approach to support modernization of meat inspection.

4. The models, whose outcome was based on changes in relative risks rather than specific estimates of risk, 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.

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

3.2 RECOMMENDATIONS

1. 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. The model is conservative in the use of input parameters and additional modelling will provide clearer indications of the merits of an agreed level of testing relative to residual risk.

2. 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.

3. 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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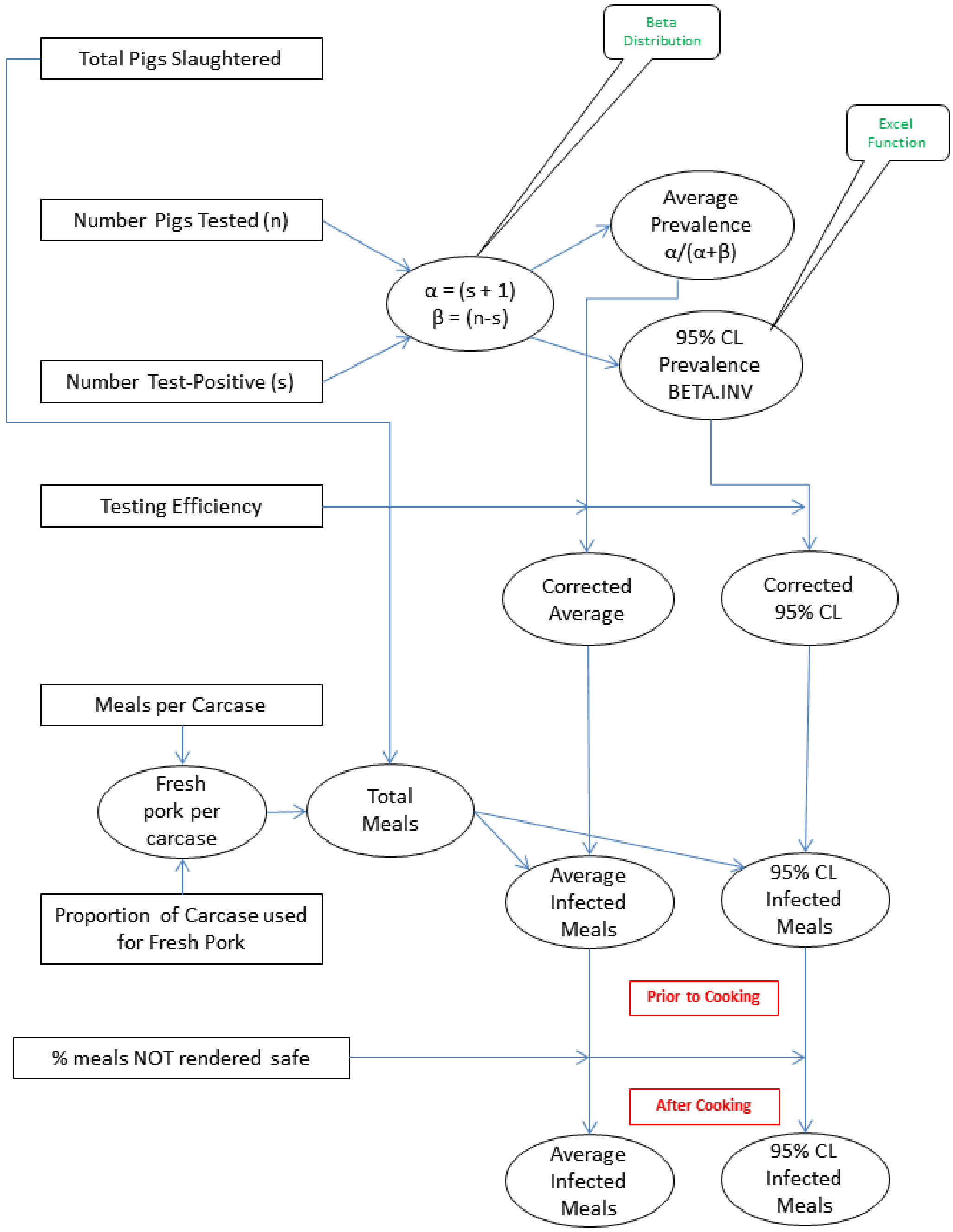
ANNEX 1. FLOW DIAGRAM FOR *TRICHINELLA* SPP. MODEL (BASE MODEL PROVIDED BY RYAN AND HATHAWAY, UNPUBL.).

Output: Number of infected portions per million servings



ANNEX 2. SPREADSHEET DIAGRAM FOR THE *TAENIA SAGINATA* MODEL (BASE MODEL PROVIDED BY VAN DER LOGT AND HATHAWAY, UNPUBL.).

Output: Number of people infected with *Taenia saginata* tapeworms