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Risk-Benefit Assessment of Hog Mandibular Lymph Node Incision at Slaughter in Canada

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Abstract

In the context of a risk-based meat inspection modernization, the change towards a visual only inspection of all hog mandibular lymph nodes (MLN) has been made in some countries and is considered in Canada. In fact, the current mandatory incision and visual inspection of all MLNs put in force a century ago to detect signs of infection by *Mycobacterium bovis* may no longer be relevant and may even generate cross-contamination by bacteria potentially pathogenic to humans. To support a science-based decision, a qualitative risk-benefit assessment following the European Food Safety Authority framework was undertaken for each inspection approach (with or without systematic incision). Both risk-benefit assessments led to similar results in concluding that the benefit of any MLN inspection for the detection of *M. bovis* infection in hogs is no longer existent. For the risk associated with this incision, data is lacking to differentiate the risk between both inspections on the qualitative scale chosen. In conclusion, the scientific opinion is that the replacement of the current systematic incision and visual inspection of all hog MLNs by a systematic visual-only inspection of all MLNs will not affect the food safety risks and in fact may reduce some of them.

Keywords: Carcass cross-contamination, food safety, meat inspection, *Mycobacterium bovis*, public health, risk-benefit analysis, swine

1. Introduction

The main purpose of meat inspection is to detect and prevent public health hazards such as food-borne pathogens and chemical contaminants in meat. It also assists in surveillance of zoonoses. In Canada, the systematic incision and visual inspection of mandibular lymph nodes (MLN) of all pigs slaughtered under the federal regulation is mandatory and is undertaken by trained veterinary inspectors from the Canadian Food Inspection Agency (CFIA). This specific inspection operation was put in force decades ago in order to detect potential signs (e.g. granulomatous lymphadenitis) of infection by *Mycobacterium bovis*, an agent of tuberculosis in man and animals, mainly in cattle. Over time, bovine and human tuberculosis cases have declined in Canada, therefore potentially reducing the extent of the benefits of this specific inspection operation. On the other hand, this repeated operation on all slaughtered pigs creates opportunities for cross-contamination (Alban et al., 2008; Hill et al., 2013). This cross-contamination has not been well studied or even described. It can occur between the lymph nodes manipulated, cut and inspected and other parts of the same carcass or between nodes of consecutive carcasses. When an inspector detects an abnormality in one MLN, the mesenteric lymph nodes are incised and inspected and, in the case of a lesion compatible with *M. bovis* infection, several carcass lymph nodes are incised and inspected. All those operations increase the likelihood of cross-contamination if basic hygiene procedures are not respected during the inspection. Therefore, there are risks of human infections with pathogens other than *M. bovis*, such as *Salmonella* spp., *Campylobacter* spp. or *Yersinia* spp., related to the MLN inspection. Hence, the current specific mandatory inspection of pig MLN encompasses both benefits and risks to food safety and human health.

Pressure exists towards modernizing meat inspection to optimize efficiency and resources based on a risk-based meat inspection approach (Alban et al., 2008; Scientific committee on veterinary measures relating to public health, 2000; Hamilton et al., 2002; TemaNord, 2006; Webber, 2012). In the European Union (EU), legislation was passed in 2004 (EC Regulation 854/2004) which allows for visual-only inspection of pigs, with palpation and incision only occurring where a lesion is suspected upon visual inspection. Since this 2004 risk-based legislation was passed, some EU member states and other countries have conducted country risk assessments on traditional versus visual meat inspection (Alban et al., 2008; Hill et al., 2013; Hiller, Heres, Althoff, Urlings, & Klein, 2012). The results of those risk assessments informed the decision made by several countries such as Denmark, Germany, the Netherlands, the United Kingdom, to modify their pig inspection at slaughter, including moving away from the palpate-and-incise practices of the past to a visual-only inspection of the carcass and incising the lymph nodes only where necessary.

In Canada, the CFIA has undertaken a general modernization process of the food safety rules and operations. Under this science-based modernization, the following specific question has been raised, whether the incision and visual inspection of all hog MLNs can be replaced by a visual-only inspection and incision in case of visual abnormalities without increasing risks for food safety and human health. This study details the qualitative risk-benefit assessment undertaken for both the current MLN inspection and the proposed visual-only inspection to answer the question.

2. Risk-Benefit Assessment Framework

Risk-benefit assessment is part of the overall process of risk analysis. In particular, risk-benefit assessment is included in Health Canada's general risk analysis framework (Health Canada, 2000). Because most hazards pertaining to lymph nodes in slaughtered animals are microbiological, the *Codex Alimentarius* Principles and Guidelines for Conducting Microbial Risk Assessment (Codex Alimentarius Commission, 1999) should be the logical framework to guide our risk-benefit assessment. However, this document does not cover risk-benefit. Risk-benefit assessment with regards to food has only recently received more interest, specifically over the last decade. The output of a risk-benefit assessment is the probability of an adverse health effect or harm (both incidence and severity) as a consequence of exposure weighed against the probability of benefit, if both are known to be possible (European Food Safety Agency Scientific Committee, 2010). Risk-benefit assessment with regards to food usually focuses on the health risk as well as the benefit a particular food provides to the consumers at the same time. It also includes the comparison of the positive (health benefit) and negative (health risk) impact of a given food safety intervention (European Food Safety Agency Scientific Committee, 2010), which is the case for our risk-benefit assessment, namely discontinuing the systematic MLN incision.

Several frameworks have been developed or refined for the risk-benefit assessment related to food (see review by Berjia, 2013). Among them we chose the general approach proposed by the European Food Safety Authority (EFSA) (European Food Safety Agency Scientific Committee, 2010), which is more clearly aligned with the *Codex Alimentarius* risk assessment steps. The EFSA approach proposes the separate assessment of both the risk and the benefit of the food (or food safety intervention), and followed by the risk-benefit comparison weighing the risks against the benefits. Both risk and benefit assessments follow the usual four steps in risk or benefit assessment, i.e. the identification of the possible hazards or positive/reduced adverse health effects; the characterization of the identified hazards and positive/reduced adverse health effects; the exposure assessment to the hazardous product which has benefit at the same time; and finally the characterization of the risk and of the benefit.

Considering that the current as well as the proposed new hog MLN inspection operations encompass risks and benefits to food safety and human health, the following process was completed according to the EFSA's general approach. A qualitative risk-benefit assessment was undertaken for each inspection separately. A comparison of the risk-benefit assessment results was performed to conclude on the impact of the change from the current to the proposed MLN inspection. The qualitative risk assessment part of the risk-benefit was undertaken according to the risk characterization guidelines developed jointly by the Food and Agriculture Organization of the United Nations and the World Health Organization (Food and Agriculture Organization of the United Nations / World Health Organization, 2009). The scales used to define the hazard characterization as well as the exposure assessment are shown in Table 1, whereas Table 2 shows the risk or benefit assessment matrix.

Table 1. Scale to qualify the hazard characterization and the exposure assessment

Level	Hazard characterization		Exposure assessment	
	Descriptor	Meaning	Descriptor	Meaning
5	Major	Moderate to severe symptoms; difficult to treat; hospitalization, death or sequel possible; very low to low infectious dose	Almost certain	Is expected to occur in most circumstances
4	Minor	Moderate to severe symptoms; easy to difficult to treat; hospitalization, death or sequel possible; low to moderate infectious dose	Likely	Will probably occur in most circumstances
3	Low	Mild to moderate symptoms, easy to difficult to cure; unlikely hospitalization, death or sequel; moderate to high infectious dose	Possible	Might occur or should occur at some time
2	Very low	Mild to moderate symptoms, easy to cure; hospitalization, death or sequel rare; high infectious dose	Unlikely	Could occur at some time
1	Insignificant	Minor symptoms only; self-cure; no hospitalization, nor death, nor sequel; high infectious dose	Rare	May occur only in exceptional circumstances

Table 2. Qualitative risk assessment matrix

Exposure Assessment	Risk or Benefit Characterization				
	1 Insignificant	2 Very low	3 Low	4 Minor	5 Major
5 Almost certain	Moderate	High	High	Very high	Very high
4 Likely	Moderate	Moderate	High	High	Very high
3 Possible	Low	Moderate	Moderate	High	High
2 Unlikely	Low	Low	Moderate	Moderate	High
1 Rare	Low	Low	Low	Moderate	Moderate

3. Risk-Benefit Assessment of the Current Mandatory Hog MLN Inspection

3.1 Risk Assessment

3.1.1 Hazard Identification

Because the risks and the benefits of the specific MLN inspection operations are related to the microbiological contamination of the MLNs, a literature review was undertaken to build a listing of all pathogens reported found in pig MLNs worldwide (Table 3).

Table 3. Pathogens found in pig MLNs after slaughter (state of art)

Pathogen	Source
Mycobacterium spp.	(Ravel, Sidibé, Moreau, & Bisaillon, 2015)
Mycobacterium bovis	(Bailey, Crawshaw, Smith, & Palgrave, 2013)
Mycobacterium avium	(Bailey et al., 2013; van Ingen, Wisselink, van Solt-Smits, Boeree, & van Soolingen, 2010)
Mycobacterium other than *bovis* or *avium*	*Avium* subsp. *paratuberculosis* (Miranda et al., 2011); *malmoense, bohemicum, palustre* (van Ingen et al., 2010); Not specified (Bailey et al., 2013)
Salmonella enterica	(Oliveira et al., 2012; Pointon, Hamilton, Kolega, & Hathaway, 2000; Vieira-Pinto, Temudo, & Martins, 2005)
Campylobacter spp.	(Ravel, Sidibé, Moreau, & Bisaillon, 2015)
Yersinia spp.	(Nesbakken, Eckner, Hoidal, & Rotterud, 2003; Pointon et al., 2000; (Ravel, Sidibé, Moreau, & Bisaillon, 2015))
Rhodococcus equi	(Alban et al., 2008; Bailey et al., 2013)
Nocardia farcinica	(Alban et al., 2008)
Escherichia coli	(Ravel, Sidibé, Moreau, & Bisaillon, 2015)
Streptococcus suis	(Ravel, Sidibé, Moreau, & Bisaillon, 2015)
Staphylococcus aureus	(Ravel, Sidibé, Moreau, & Bisaillon, 2015)
Actinobacillus pleuropenumoniae	(Ohba et al., 2010)

The pathogens found in pig MLNs are of varying interest with regards to food safety and human health in Canada and thus are not equally relevant to the risk-benefit assessment. The relevance of those pathogens was qualified based on the incidence of the disease following infection by the pathogen, its burden, the importance of the foodborne transmission and the transmission through pork meat. The data collection for these four variables targeted sources covering Canada as a whole and, if not available, some parts of Canada (i.e. province). The pathogen was deemed relevant to the current risk-benefit assessment when more than 100 human cases have recently occurred in Canada and the transmission through pork was possible. In case of doubt about the transmission, the pathogen was considered relevant. According to these rules, five pathogens were no longer relevant to the risk-benefit assessment (*Actinobacillus pleuropneumoniae*, *Mycobacterium bovis*, *Nocardia farcinica*, *Rhodococcus equi*, *Streptococcus suis*), leaving six pathogens relevant for the next step of the risk-benefit assessment: *M. avium* and other non-tuberculosis *Mycobacterium spp.*, *Salmonella enterica*, *Campylobacter* spp., *Yersinia* spp., *Escherichia coli*, and *Staphylococcus aureus* (Table 4).

Table 4. Relevance of pathogens found in pig MLNs to the risk-benefit assessment

Pathogen	Incidence in Canada	Burden in Ontario* (Kwong JC, 2010)	Foodborne transmission: proportion of human cases	Transmission through pork	Relevance to the current risk-benefit assessment (yes or no)
Mycobacterium bovis	Null *M. bovis* infection is no longer an etiologic agent of human tuberculosis in Canada today but it was in the past (Public Health Agency of Canada, 2013)	Not reported	Yes, through unpasteurized milk and cheese Not documented in Canada nowadays	No The meat borne transmission has been ruled out (Scientific Panel on Biological Hazards of the European Food Safety Agency, 2003)	No
Mycobacterium avium	Incidence of infection by *M. avium* complex = 3.4 to 9.1/100,000 inhabitants in British Columbia, 1996-2006 Incidence of isolated non tuberculosis *Mycobacterium* (including *M. avium* complex)= 9.1/100,000 in 1997 up to 14.1/100,000 by 2003 in Ontario (http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/mycobacterium-eng.php)	Not reported	Possible for *M. avium* subspecies *paratuberculosis* in milk and beef meat (Mihajlovic, 2011)	No evidence documenting transmission through pork meat was found	**Yes** Because of uncertainty of its transmission through pork
Mycobacterium other than *bovis* or *avium*		Not reported	Claimed as not foodborne But large uncertainty	No evidence documenting transmission through pork meat was found	**Yes** Because of uncertainty of its transmission through pork
Salmonella enterica	Number of laboratory-confirmed non-typhoidal cases reported per year = 5,676 (Thomas et al., 2013) Estimated number of domestic cases per year = 109,384 (Thomas et al., 2013)	YLL= 66 YERF= 42 HALY= 108 % of total HALYs = 0.1	Yes : 80% (Thomas et al., 2013)	Yes : 8.1% (Davidson, Ravel, Nguyen, Fazil, & Ruzante, 2011) 7.2% (Davidson et al., 2011)	**Yes**
Campylobacter spp.	Number of laboratory-confirmed cases reported per year = 10,344 (Thomas et al., 2013) Estimated number of domestic	YLL= 2 YERF= 144 HALY= 146 % of total	Yes : 68% (Thomas et al., 2013) 18% (Ravel, Davidson, Ruzante,	Yes : 6.2% (Davidson et al., 2011) 4.7% (Davidson et al., 2011)	**Yes**

	cases per year = 213,749 (Thomas et al., 2013)	HALYs = 0.2	& Fazil, 2010) 68% (Ravel, Davidson, Ruzante, & Fazil, 2010)		
Yersinia spp.	Number of laboratory-confirmed cases reported per year = 975 (Thomas et al., 2013) Estimated number of domestic cases per year = 32,394 (Thomas et al., 2013)	YLL= 0 YERF= 1 HALY= 1 % of total HALYs < 0.1	Yes 80% (Thomas et al., 2013) 10% (Ravel, Davidson, Ruzante, & Fazil, 2010) 80% (Ravel, Davidson, Ruzante, & Fazil, 2010)	Yes : 45.9% (Davidson et al., 2011) 63.3% (Davidson et al., 2011)	**Yes**
Rhodococcus equi	No evidence documenting prevalence or incidence of human infection in Canada were found	No burden reported	Possible (large uncertainty) (Weinstock & Brown, 2002)	No evidence documenting transmission through pork meat was found	No
Nocardia farcinica	Nocardiosis : Reported incidence in the province of Quebec : 0.33 (1997–1998) to 0.87 (2007–2008) per 100,000 inhabitants (Tremblay, Thibert, Alarie, Valiquette, & Pepin, 2011)	No burden reported	No evidence documenting foodborne transmission were found	No evidence documenting transmission through pork meat was found	No
Escherichia coli	For VTEC O157: Number of laboratory-confirmed cases reported per year = 883 (Thomas et al., 2013) Estimated number of domestic cases per year = 6,968 (Thomas et al., 2013)	Including urinary infections: YLL= 6,430 YERF= 341 HALY= 6,771 % of total HALYs = 8.2	Yes 76% (Thomas et al., 2013) 14% (Ravel, Davidson, Ruzante, & Fazil, 2010) 76% (Ravel, Davidson, Ruzante, & Fazil, 2010)	Yes : 1.5% (Davidson et al., 2011) 1.4% (Davidson et al., 2011)	**Yes**
Streptococcus suis	5 cases reported in total until December 2013 (Goyette-Desjardins, Auger, Xu, Segura, & Gottschalk, 2014)	No burden reported	Yes	Yes (no quantitative figure found)	No
Staphylo-coccus aureus	Number of laboratory-confirmed cases reported per year = 0 (not reportable disease) (Thomas et al., 2013) Number of estimated number of domestic cases per year = 25,114 (Thomas et al., 2013)	Including the nosocomial methicillin-resistant *S. aureus* infections: YLL= 3,320 YERF= 400 HALY= 3,720 % of total HALYs = 4.5	100% (Thomas et al., 2013)	No evidence documenting transmission through pork meat were found	**Yes**
Actinobacillus pleuropneumoniae	No data were found: Human infection is not mentioned in the PHAC web page on *Actinobacillus* (http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/actinobacillus-eng.php)	No burden reported	No	Not applicable	No

*Years of life lost due to premature mortality (YLL), year-equivalents of reduced functioning (YERF), number and percentage of total annual health-adjusted life years (HALYs).

3.1.2 Hazard Characterization

Table 5 summarizes the symptoms of the clinical infections, their severity in terms of hospitalization and sequel, and the infectious dose when documented. Those data were used to qualify the hazard characterization according to the scale defined in Table 1.

Table 5. Consequence assessment of various pathogens found in hog MLNs

Pathogen	Symptoms	Severity	Infectious dose in humans	Hazard characterization
Mycobacterium avium and other than *bovis*	Mostly pulmonary disease in immunosuppressed humans	Long treatment	Unknown	3 Low to 4 Minor
Salmonella enterica	Moderate gastroenteritis resolving in a few days to one week	Hospitalisation Death Chronic sequel	≈1000 organisms	4 Minor
Campylobacter spp.	Mild gastroenteritis resolving in a few days	Chronic sequel	≈500 organisms	3 Low
Yersinia spp.	Mild to moderate gastroenteritis	None	≈10^6 organisms	2 Very low
Escherichia coli	Moderate to severe gastroenteritis resolving in a few days to weeks	Hospitalisation Death	≈10^6-10^{10} organisms	4 Minor
Staphylococcus aureus	Acute mild to moderate toxic gastroenteritis resolving in 24 hours	None	>10^5 organisms	1 Insignificant

3.1.3 Exposure Assessment

First, a worldwide literature review was performed on the prevalence of the various pathogens found in pig MLNs after slaughter to understand the extent of the potential cross-contamination between MLNs and other lymph nodes and parts of the carcass due to faulty handling of pig heads and carcasses during the MLN inspection (Table 6).

Table 6. Prevalence of various pathogens found in pig MLNs after slaughtering

Pathogen	Reported prevalence	Country (reference)
Salmonella enterica	13/101 (12.9%); 40/101 (40%) non-culture method	Portugal (Oliveira et al., 2012)
	5/97 (5.2%)	Norway (Nesbakken et al., 2003)
	9/597 (0.9%)	Australia (Pointon et al., 2000)
	33/735 (4.5%)	Canada -(Ravel, Sidibé, Moreau, & Bisaillon, 2015)
Yersinia spp.	9/597 (*Y. enterocolitica*)	Australia (Pointon et al., 2000)
	44/735 (6.0%)	Canada (Ravel, Sidibé, Moreau, & Bisaillon, 2015)
Escherichia coli	168/735 (22.9%)	Canada (Ravel, Sidibé, Moreau, & Bisaillon, 2015)
Campylobacter spp.	0/97 (0%)	Norway (Nesbakken et al., 2003)
	8/735 (1.1%)	Canada (Ravel, Sidibé, Moreau, & Bisaillon, 2015)
Staphylococcus aureus	478/735 (65.0%)	Canada (Ravel, Sidibé, Moreau, & Bisaillon, 2015)
Mycobacterium avium	0/160 (0%)	The Netherlands (Komijn et al., 2007)

Other than occupational exposure to human pathogens during the carcass inspection and operation (e.g. evisceration, splitting, pluck removal), no people are directly in contact with pig MLNs, carcasses or offal. The main exposure for the general population is through pork meat at the end of the food chain, when the meat is bought, handled, prepared and consumed. The contamination of pork meat at retail provides a good sense of the probable exposure of human beings to human pathogens through the pig commodity. Obviously, the contamination at retail is the final result of the initial carcass contamination during the slaughtering process and the cross-contamination between carcasses, parts of pork meat, tools and human beings along the pork processing chain. The exact share of the cross-contamination potentially occurring during the whole MLN inspection process in the final pork contamination at retail is unknown but should overall be very limited compared to other sources or places of contamination such as the evisceration. Because of lack of data on this proportion, we use the prevalence of pathogens in retail pork meat as a proxy for estimating the human exposure to the selected pathogens through raw pork (Table 7). Pork is not eaten raw or purposely undercooked in Canada, therefore the actual exposure of the general Canadian population is the contact with raw pork.

Table 7. Prevalence of human pathogens in pork meat in Canada and exposure assessment

Pathogen	Prevalence	Exposure assessment
Salmonella enterica	2% in retail pork chop (Public Health Agency of Canada, 2014)	2 Unlikely
Yersinia spp.	82% (86/105) in retail pork chop but all were not pathogenic to humans (Public Health Agency of Canada, 2014)	1 Rare to 2 Unlikely
Campylobacter spp.	2% in retail pork chop (Public Health Agency of Canada, 2014)	2 Unlikely
Mycobacterium avium and other than *M. tuberculosis* complex	No evidence of the prevalence of *M. avium* complex or other than *M. tuberculosis* complex in pork in Canada were found	2 Unlikely (with great uncertainty because of lack of data)
Escherichia coli	VTEC: 0% (0/197) in retail pork chop (Public Health Agency of Canada, 2014)	1 Rare
Staphylococcus aureus	Methicillin-resistant *S. aureus*: 6.3% (8/127) in retail ground pork (Weese, Reid-Smith, Rousseau, & Avery, 2010) 13.6% (14/103) in retail pork chop (Weese, Reid-Smith, Rousseau, & Avery, 2010)	3 Possible to 4 Likely (with uncertainty about *S. aureus* other than the methicillin-resistant)

Obviously, other factors related to the specific food, it's processing and the consumers' behaviour and characteristics affect and define the actual exposure. Because the objective of the study is the comparison between the risk-benefit assessment of the proposed MLN inspection and the one of the current inspection, it was considered that all those factors would be the same independently of the type of MLN inspection. Therefore, the exposure assessment was based on the retail pork meat contamination with a downgrading of at least one level to take into account that not all retail pork contamination is a result of cross-contamination during the MLN inspection (see next section).

3.1.4 Risk Characterization

The risk characterization results from the cross-tabulation of the hazard characterization and the exposure assessment of selected pathogens according to the qualitative risk assessment matrix chosen (Table 8).

Table 8. Risk characterization on human health related to retail pork in Canada

Exposure assessment	Hazard characterization				
	1 Insignificant	2 Very low	3 Low	4 Minor	5 Major
5 Almost certain	Moderate : *S. aureus*	High	High	Very high	Very high
4 Likely	Moderate : *S. aureus*	Moderate	High	High	Very high
3 Possible	Low	Moderate	Moderate	High	High
2 Unlikely	Low	Low : *Yersinia* spp.	Moderate : *Campylobacter* spp. *M. avium and* other than *bovis* (and those of the tuberculosis complex)	Moderate : *Salmonella enterica*	High
1 Rare	Low	Low : *Yersinia* spp.	Low	Moderate : *Escherichia coli*	Moderate

The exact share of the potential cross-contamination related to the MLN inspection on pork contamination at retail is unknown; it is reasonable to claim that this share is small and might decrease the exposure assessment by at least one level if not two, hence putting infection with *Salmonella enterica* under moderate risk and all other infections (with *S. aureus*, *Yersinia* spp., *Campylobacter* spp., *M. avium* or other than of the *Mycobacterium tuberculosis,* and pathogenic *Escherichia coli*) under the low risk, if not no risk at all (for pathogenic *Escherichia coli* in particular) (Table 9).

Table 9. Risk characterization on human health related to the current hog MLN inspection in Canada

Exposure assessment	Hazard characterization				
	1 Insignificant	2 Very low	3 Low	4 Minor	5 Major
5 Almost certain	Moderate	High	High	Very high	Very high
4 Likely	Moderate	Moderate	High	High	Very high
3 Possible	Low : *S. aureus*	Moderate	Moderate	High	High
2 Unlikely	Low : *S. aureus*	Low :	Moderate	Moderate :	High
1 Rare	Low	Low : *Yersinia* spp.	Low : *Campylobacter* spp. *M. avium and* other than *bovis* (and those of the tuberculosis complex)	Moderate : *Salmonella enterica*	Moderate
0 Null		Null : *Yersinia* spp.		Null : *Escherichia coli*	

3.2 Benefit Assessment

3.2.1 Positive Health Effect/Reduced Adverse Effect Identification

The benefit of the current MLN inspection operation is its historical primary raison d'être, i.e. the prevention of the foodborne transmission of *M. bovis*, an agent of human tuberculosis, from pig to humans through the pork meat. It was the supposed reduction of an adverse effect related to the handling and consumption of pork meat.

3.2.2 Positive Health Effect/Reduced Adverse Effect Characterization

In Canada, the finding of grossly detectable abnormalities in MLNs as a result of the current mandatory MLN inspection triggers the further inspection with incision of mesenteric and then carcass lymph nodes to confirm the potential of gross signs of a *M. bovis* infection. In case of lesions compatible with *M. bovis* infection in several different lymph nodes, the carcass is marked with a large T at several places. The carcass is still considered fit for human consumption since *M. bovis* is not transmitted through meat (Scientific Panel on Biological Hazards of the European Food, 2003). Such T-marked carcasses are mostly sent to the domestic market. In the past, the carcass was removed from the human food chain, but this is no longer the case. As a result, the current MLN inspection has no positive effect on *M. bovis* infection in humans in Canada.

3.2.3 Exposure Assessment

The exposure assessment clearly concludes that the foodborne exposure of human to *M. bovis* through pork is null in the Canadian context, as it is in other countries (Table 10).

Table 10. Prevalence of *M. bovis* in pig MLNs and pork meat

	Prevalence	Country (source)
in pig MLNs	0/43 (0%)	Denmark (Alban et al., 2008)
	2 MLNs with lesion compatible with *M. bovis* infection but negative on bacteriological tests /9,697 (0.0002%)	Canada (Ravel, Sidibé, Moreau, & Bisaillon, 2015)
in retail pork	No evidence documenting presence or prevalence in pork meat in Canada were found	

3.2.4 Benefit Characterization

The benefit characterization is the cross-tabulation of the adverse effect reduction and the exposure assessment. It is null with regards to food safety and human health for the current MLN inspection.

From the animal health perspective, such inspection may help in monitoring the occurrence of *M. bovis* infection in pigs, but this infection is null according to the results of the current MLN inspection and this is consistent with the fact that domestic cattle herds are free of *M. bovis* in Canada and that cattle and pigs are raised in different premises, thus avoiding the transmission of *M. bovis* between the two species when present in one herd.

3.3 Risk-Benefit Assessment

Table 11 summarizes the risk-benefit matrix with regards to food safety and human health relative to the current mandatory hog MLN inspection in place in the CFIA-registered slaughterhouses in Canada.

Table 11. Qualitative risk-benefit assessment related to the specific hog MLN inspection currently mandatory in Canada (**benefits are in bold**; risks are in regular type)

Exposure assessment	**Benefit** / Hazard characterization					
	0 Null	1 Insignificant	2 Very low	3 Low	4 Minor	5 Major
5 Almost certain		Moderate	High	High	Very high	Very high
4 Likely		Moderate	Moderate	High	High	Very high
3 Possible		Low : *S. aureus*	Moderate	Moderate	High	High
2 Unlikely		Low : *S. aureus*	Low	Moderate	Moderate	High
1 Rare		Low	Low : *Yersinia* spp.	Low : *Campylobacter* spp. *M. avium* and other than *bovis* (and those of the tuberculosis complex)	Moderate : *Salmonella enterica*	Moderate
0 Null	**Null : *M. bovis* infection**		Null : *Yersinia* spp.		Null : *Escherichia coli*	

4. Risk-Benefit Assessment of the Proposed Hog MLN Inspection

The changes with the proposed visual-only MLN inspection compared to the incision and inspection of all MLNs are 1) that the cross-contamination during the lymph node inspection should be reduced down to an absence of cross-contamination and 2) that some MLNs with lesion compatible with *M. bovis* infection could be missed, thus resulting in the under detection and reporting of such lesions. The following sections explain the effects of those changes on the risk assessment and on the benefit assessment of the proposed MLN inspection.

4.1 Risk Assessment

Obviously, the microbial hazards are the same, and their characterization is the same. The exposure assessment is logically lower in virtue of the reduction in potential cross-contamination, which has been observed (Hiller et al., 2012). The actual reduction on human exposure through pork meat because of the absence of incision of all MLNs has been claimed (Alban et al., 2008) but has not been quantified. With the qualitative approach followed for this study, a prudent result is to consider that the exposures are qualitatively equal to the ones for the current MLN inspection, being quantitatively less to an unknown extent.

4.2 Benefit Assessment

Given that *M. bovis* infection is not transmitted through meat, the benefit of the proposed visual-only MLN inspection is not different from the one associated with the current inspection, which is null with regards to food safety.

From the animal health standpoint, missing lesions in MLNs compatible with *M. bovis* infection would reduce the specificity of this inspection as a test for detecting probable cases of bovine tuberculosis in pigs. A recent survey in Canada quantifies the sensitivity of the visual-only inspection as a diagnosis of confirmed pathological lesion (of any kind) at 15% {Ravel, 2015 #54}. The sensitivity of the incision and visual inspection has not been measured. Both inspections yielded comparable very low apparent prevalence of grossly detectable abnormalities in hog MLNs: 0.54% (95% confidence interval: 0.40 - 0.72%) for the visual-only inspection and 0.17% (95% confidence interval: 0.16 - 0.19%) for the current incision and inspection. This comparability of prevalence means that both inspections perform relatively similarly. Considering the very low, if not null, prevalence of *M. bovis* infection in Canadian hogs, only a test close to 100% sensitivity would detect the very rare true case of *M. bovis* infection in hogs. It can be concluded that the reduced sensitivity of such detection with the proposed visual-only MLN inspection will have minimal impact on the detection of *M. bovis* infection in hogs compared to the current incision and visual inspection.

5. Risk-Benefit Assessment

As a result, the risk-benefit matrix (Table 12) is qualitatively similar to the one for the current MLN inspection (Table 11).

Table 12. Qualitative risk-benefit assessment related to the proposed specific hog MLN inspection (**benefits are in bold**; risks are in regular type)

Exposure assessment	**Benefit** /Hazard characterization					
	0 Null	1 Insignificant	2 Very low	3 Low	4 Minor	5 Major
5 Almost certain		Moderate	High	High	Very high	Very high
4 Likely		Moderate	Moderate	High	High	Very high
3 Possible		Low : *S. aureus*	Moderate	Moderate	High	High
2 Unlikely		Low : *S. aureus*	Low	Moderate	Moderate	High
1 Rare		Low	Low : *Yersinia* spp.	Low : *Campylobacter* spp. *M. avium* and other than *bovis* (and those of the tuberculosis complex)	Moderate : *Salmonella enterica*	Moderate
0 Null	**Null : *M. bovis* infection**		Null : *Yersinia* spp.		Null : *Escherichia coli*	

The scientific opinion focuses on the proposed change of the hog MLN inspection from the current incision and visual inspection of all MLNs to the visual-only inspection of all MLNs followed by incision in case a gross detectable abnormality is noted. The MLN inspection encompassing both risks and benefits with regards to food safety and human health, the question for the scientific opinion is the following : “Will the new MLN inspection (visual-only inspection) provide equal or less risks and equal or more benefits with regards to food safety and human health compared to the current inspection (incision and visual inspection) ?”.

The survey of the hog MLN condition and contamination shows that Canadian hogs are not infected with *M. bovis.* Furthermore, the current incision and inspection of all hog MLNs and the proposed visual-only inspection perform similarly in detecting gross detectable abnormalities in MLNs. Considering that *M. bovis* is no longer the agent found in patients with human tuberculosis in Canada, that *M. bovis* is very rare if not absent in domestic cattle, and that all pigs are raised indoors in facilities very rarely housing cattle, it can be concluded that the benefit of any MLN inspection for the detection of *M. bovis* infection in hogs is no longer existent.

The Canadian survey of the hog MLN condition and contamination shows that MLN can be contaminated with human pathogens other than *M. bovis*, raising the risk of cross-contamination during the inspection. The conclusions of qualitative risk-benefit assessment related to the current incision and inspection of all hog MLNs and to the proposed visual-only inspection are similar qualitatively. Data is lacking to quantitatively differentiate the risk between both inspections; nevertheless, it can be concluded that the food safety risk would be reduced with the proposed visual-only inspection compared to the current incision and visual inspection; while the food safety benefit is null for both inspections.

In conclusion, the replacement of the current incision and visual inspection of all hog MLNs by a visual-only inspection of all MLNs will, at a minimum, not affect food safety risks and, in fact, may reduce them.

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