Source attribution at the food sub-product level for the development of the Canadian Food Inspection Agency risk assessment model

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ABSTRACT

Decreasing the health burden caused by foodborne pathogens is challenging and it depends on the identification of the most significant hazards and food sources causing illnesses, so adequate mitigation strategies can be implemented. In this regard, the Canadian Food Inspection Agency (CFIA) has developed the Establishment-based Risk Assessment (ERA) model, so that a more effective and efficient allocation of resources can be assigned to the highest food safety risk areas. To assess risk, the model considers the type of food sub-products being manufactured by establishments and its scope is limited to the 17 most important foodborne pathogens representing the highest level of food safety risk. However, the information on source attribution at the sub-product level based on a structured approach is limited. To overcome this challenge, an expert elicitation was conducted in 2016 to estimate the relative contribution and associated certainty of each sub-product for 31 pathogen-commodity combinations to the total Canadian health burden associated with foodborne illnesses (expressed in DALYs). These DALYs represent 78% of the total Canadian health burden associated with federally-regulated food commodities considered within the model. A total of 49 Canadian experts recruited using a "snow ball" sampling strategy participated in the study by completing an electronic survey. Results of the elicitation displayed variable levels of health burden allocation between the pathogens and the different commodity sub-products. Assessment of the certainty levels showed some combinations being evaluated with more confidence (e.g., *Campylobacter* and eggs/poultry sub-products) than others, where a bimodal distribution of certainty was observed (e.g., *Toxoplasma* in pork sub-products). Furthermore, no participant raised concerns on the food classification scheme, suggesting their agreement with the proposed sub-products categorization of the elicitation. Relative contribution estimates will be included in the CFIA ERA model and used to enhance its applicability for risk prioritization and effective resource allocation during food establishment inspections. While substantial uncertainty around the central tendency estimates was found, these estimates provide a good basis for regulatory oversight and public health policy.

1. Introduction

Foodborne illness source attribution is defined as the process of estimating the proportion of human cases caused by a specific pathogen and that is associated or can be attributed to the consumption of a specific food item or commodity (Greig and Ravel, 2009) or an animal reservoir such as pigs, cattle or pets (Pires et al., 2009). As such, it provides useful information for decision-making (e.g., targeted

sampling, surveillance), as it helps identify and prioritize food safety issues to better manage those risks and prevent foodborne illness outbreaks in the population.

Decreasing the health burden caused by foodborne pathogens is challenging and success depends on identifying the most significant hazards and food sources causing illnesses, so adequate mitigation strategies can be implemented. To decrease the incidence of foodborne disease, stakeholders advocate for the development of a science- and risk-based food safety system in which decision-makers prioritize hazards and interventions using the best available data on the distribution and reduction of risk (Batz et al., 2005).

Within this context, the Canadian Food Inspection Agency (CFIA) is developing a systematic risk-based approach to better manage and prioritize its inspection resources. This initiative proposes a streamlined approach to categorize food businesses according to the level of risk they represent to Canadian consumers. To achieve this, a quantitative CFIA Establishment-based Risk Assessment (ERA) model has been developed, which considers risk factors that are grouped based on their relationship to food safety assessment (Racicot et al., 2018). In brief, as a first step, the model allocates the risk taking into consideration the type of commodity and product distributed by the establishment, as well as the volume. Next, a series of risk factors found at the establishment level (i.e., inherent, mitigation, and compliance) are considered for the final risk result (Zanabria et al., 2017). Within the context of the CFIA ERA model, a food establishment is defined as any place, including a conveyance, where a commodity/food product is produced/manufactured, prepared, stored, transported, packaged or identified (including labelling). This definition does not include private homes or those facilities conducting operations that fall outside the scope of the CFIA (e.g., agricultural, retail, restaurants and/or food service practices). In Canada, "federally-regulated establishments" fall within CFIA's jurisdiction, and include those exporting to other countries and/or involved in inter-provincial trading.

To estimate the risk associated with food establishments, the CFIA ERA model utilizes the Disability Adjusted Life Years (DALYs) metric. To estimate the Canadian DALYs, the model takes into consideration the total number of domestically acquired foodborne illnesses per year in Canada (Thomas et al., 2013), the proportion of illnesses attributed to the foodborne pathway (Butler et al., 2015), the number of DALYs per case for each selected pathogen (Havelaar et al., 2012), and the attribution of DALYs at the commodity level (Butler et al., 2016; Davidson et al., 2011; Havelaar et al., 2008). With the aim of focusing on those hazards representing the highest level of food safety risk, the model scope is limited to the 17 most important foodborne pathogens, representing over 99.8% of the total Canadian health burden (estimated in DALYs) associated with all food commodities for which literature is available (Butler et al., 2015; Havelaar et al., 2012; Thomas et al., 2013). These pathogens include *Campylobacter* spp., *Salmonella* (nontyphoidal), norovirus, Shiga-toxin producing *E. coli* (STEC), *Toxoplasma gondii, Yersinia enterocolitica, Clostridium perfringens, Listeria monocytogenes, Bacillus cereus, Clostridium botulinum,* hepatitis A virus, rotavirus, *Shigella* spp., *Staphylococcus aureus, Trichinella* and *Vibrio parahaemolyticus*. The CFIA ERA model then distributes the burden of foodborne illnesses, considering not only the commodity and volume of production, but also the specific sub-product type manufactured by the federally-regulated establishments (e.g., ready-to-eat (RTE) cooked beef products, RTE dried fermented beef products, intact carcasses). Therefore, estimating the source attribution at the sub-product level is key to the model parametrization, to appropriately distribute the health burden among these regulated parties.

Several methods have been used to attribute foodborne illness to different commodities including analysis of outbreak investigations, meta-analysis of case control studies, microbiological sub-typing combined with surveillance, and expert elicitation (Hoffmann et al., 2017). As far as we are aware, a structured/comprehensive study for estimating foodborne source attribution at the food sub-product level for multiple pathogen-commodity combinations has never been conducted, but rather study focus has been on isolated pathogens and limited to a specific number of sub-products (Opsteegh et al., 2011; Jones et al., 2009). Furthermore, the relative contribution of all sub-product categories within one specific commodity was not available; neither had such a study been applied in the Canadian context, which was essential for the successful application of the CFIA ERA model in Canada. Therefore, the main objective of this research was to estimate the relative contribution of each sub-product to the Canadian health burden for 31 specific pathogen-commodity combinations, and to provide a quantitative understanding of the risk associated with the different food categories.

2. Materials and methods

2.1. Selection and recruitment of experts for elicitation

A "snow ball" approach was used to identify experts for this process, by initially contacting the members of the CFIA Risk Assessment Scientific Advisory Committee (SAC), composed of 10 experts from academia (Université de Montréal, University of Manitoba, Dalhousie University, and the University of Guelph), the CFIA, Health Canada, and the Public Health Agency of Canada. SAC members along with representatives from the CFIA ERA Technical Committee were asked to nominate experts with direct and significant experience in food safety and/or risk analysis (risk assessment, risk management, risk communication, regulatory affairs in food), and who were involved in some aspect of the Canadian food industry and/or its regulation (academia, government or industry). To ensure consistency on the experts' nomination, the CFIA ERA Technical team developed the following definition: "*To be considered an expert, a person should have a university degree in food science, microbiology or any other related field OR a person should have a college diploma in an area related to quality assurance or any other field related to food safety, that displays strong and relevant knowledge and/ or skills derived from over 10 years training and/or working experience in the food industry as it relates to microbiological risk assessments associated with specific commodities in the food supply chain*". When contacted via e-mail for their voluntarily participation, experts were also asked to nominate others, taking into consideration the same criteria described above.

2.2. Classification of food sub-products

As far as could be determined, no officially recognised method of food categorization was available. Thus, a proposal was developed by grouping products based on similar expected levels of risk. For every commodity, each category was designed to be mutually exclusive and conjointly exhaustive (Table 1). The type of final product produced by the establishment was considered as the point for risk attribution because of its subsequent applicability into the CFIA ERA model, which estimates the level of risk at the establishment level. Also, the categorization included an "other" sub-product category as a residual group

Table 1

Type of Commodity and Sub-product categories used for the expert elicitation.

Commodity	Sub-product category	Definition
Beef, Pork, Poultry and Game (each species was assessed individually at the sub-product category)	Raw product - Ground, comminuted or mechanically separated (e.g. ground, textured meat products)	Any meat product that is ground, comminuted or mechanically separated (e.g., ground beef, textured meat products).
	Raw product – Non-intact (e.g. tenderized, injected, restructured)	Piece of meat whose internal structure has been modified (e.g., tenderized, injected, restructured).
	Raw product – Intact (e.g. carcasses) and/or commercial raw cuts	Piece of meat whose internal structure has not been modified. Non-comminuted meat products are considered to be intact meat products (e.g., carcasses and commercial raw cuts).
	Raw product – Offal and by-products (blood, brain, heart, kidney, liver)	Includes blood, brain, heart, kidney, liver, pancreas, spleen, thymus, tongue, tripe, and fat; but excludes meat flesh, bone and bone marrow.
	Ready-to-Eat (RTE) Cooked product	Meat products that have been subjected to a heating process sufficient to inactivate vegetative pathogenic microorganisms or their toxins and to control spores of foodborne pathogenic bacteria. These meat products do not require further preparation before consumption by the end-user, except from washing, thawing or exposing the product to sufficient heat to warm the product without cooking it (e.g., ham, hot dogs, pepperoni).
	RTE Dried Cured product	Meat products that have been subjected to a drying-curing process sufficient to inactivate vegetative pathogenic microorganisms or their toxins and to control spores of foodborne pathogenic bacteria. These meat products do not require further preparation before consumption by the end-user except from washing, thawing or exposing the product to sufficient heat to warm the product without cooking it (e.g., prosciutto, beef jerky).
	RTE Fermented product	Meat products that have been subjected to a drying fermentation process sufficient to inactivate vegetative pathogenic microorganisms or their toxins and to control spores of foodborne pathogenic bacteria. These meat products do not require further preparation before consumption by the end-user except from washing, thawing or exposing the product to sufficient heat to warm the product without cooking it, as per the Meat Inspection Regulations (Government of Canada, 1990).
	RTE Canned product	Meat products that have undergone a canning process (e.g., chicken and beef soup, canned poultry and beef).
	Other meat products	Any other meat product not included in the categories above
Dairy	Fermented dairy product	Dairy products made from pasteurized milk (phosphatase negative) and for which the main transformation process is fermentation (e.g., yogurt, kefir, sour cream, buttermilk, cultured butter, etc.). This definition does not include cheese.
	Cheese made from Pasteurized Milk (PM)	Coagulated milk curds separated from whey and made from pasteurized milk (phosphatase negative). (e.g., cheddar, mozzarella, cottage cheese, etc.). This definition excludes blue and surface ripened cheeses.
	Blue and Surface Ripened (SR) cheeses made from PM	Coagulated milk curds separated from whey and made from pasteurized milk, internally and/or surface ripened with a microbial culture (blue veined, mold ripened or washed rind).
	Blue or SR cheese aged for < 60 days and made from Unpasteurized Milk (UPM)	Coagulated milk curds separated from whey and made from unpasteurised milk (either raw or heat treated but phosphatase positive) that may or may not have been internally or surface ripened with a microbial culture and that have been aged for < 60 days.
	Blue or SR cheese aged for 60 days or more and made from UMP	Coagulated milk curds separated from whey and made from unpasteurised milk (either raw or heat treated but phosphatase positive) that may or may not have been internally or surface ripened with a microbial culture and that have been aged for 60 days or more.
	Thermally processed dairy products requiring refrigeration	Dairy products that have undergone a thermal process, either alone or in combination with other treatments, that is sufficient to render the dairy product phosphatase negative but not commercially sterile, so it will still require refrigeration in order to maintain product safety (e.g., fluid milk, butter, sweetened or flavored dairy products)
	Thermally processed dairy products that are shelf stable	Dairy products that have undergone a thermal process, either alone or in combination with other treatments, that is sufficient to render them commercially sterile. In addition, these products have been hermetically sealed in a container (canned dairy products).
	Dried, concentrated, or frozen dairy product	Dairy products that are subjected to drying, concentration or freezing (e.g., milk powder, protein concentrate, frozen yogurt, ice cream)
	Firm and hard cheese made from UPM, aged < 60 days	Coagulated milk curds separated from whey and made from unpasteurized milk (either raw or heat treated but phosphatase positive) that are either rinsed or not, and are generally packed into moulds under pressure and aged for < 60 days.
	Firm and hard cheese made from UPM, aged > 60 days	Coagulated milk curds separated from whey and made from unpasteurized milk (either raw or heat treated but phosphatase positive) that are either rinsed or not, and are generally packed into moulds under pressure and aged for 60 days or more.
	Soft and Semi Soft (SS) cheeses made from UPM, aged < 60 days	Coagulated milk curds separated from whey and made from unpasteurized milk (either raw or heat treated but phosphatase positive) that may or may not have been internally or surface ripened with a microbial culture and that has been aged for < 60 days

Table 1 (*continued*)

Commodity	Sub-product category	Definition
	Soft and SS cheeses made from UPM, aged > 60 days	Coagulated milk curds separated from whey and made from unpasteurized milk (either raw or heat treated but phosphatase positive) that may or may not have been internally or surface ripened with a microbial culture and that has been aged for 60 days or more.
	Other dairy products	Any other dairy product not included in the categories above
Produce	Intact fresh fruits and vegetables	Fresh fruits and/or vegetables that have not undergone any process other than cleaning, sanitation, classification and/or packaging (e.g., whole carrot, whole apples, whole potatoes)
	Minimally processed fresh fruits and vegetables	Refers to the raw fresh-cut fruits and/or vegetables that have been washed and peeled, sliced, chopped or shredded prior to being packaged for sale and that do not require further preparation prior to consumption, except for the potential addition of dressing or seasonings by the end-user. RTE minimally processed fresh fruits and vegetables are intended to be consumed raw (e.g., shredded lettuce and cabbage, sliced tomatoes, salad mixtures, raw fresh-cut vegetable salads, peeled baby carrots)
	Dehydrated fruits and vegetables	Fruits and vegetables that have undergone a dehydration process (e.g., dried plums, dried mango, dried mushrooms).
	Canned fruits and vegetables	Fruits and vegetables that have undergone a canning process (e.g., canned pears, canned pineapples, canned beans)
	Frozen fruits and vegetables	Fruits and/or vegetables that have undergone a freezing process (e.g., frozen blueberries, strawberries, cauliflower, green peas)
	Pickled fruits and vegetables	Fruits and/or vegetables that have either been anaerobically fermented in brine or immersed in vinegar in order to expand its shelf life (e.g., pickled olives, gherkin)
	Spices, herbs	Dried seeds, fruit, root, bark, or vegetable substance or leafy green parts of a plant (fresh or dried) primarily used for food flavoring, coloring or preserving.
	Other processed fruits and vegetables (jam, jelly, condiments, dressings, flavours etc.)	Refers to all other processed fruits and/or vegetables not included in the other processed fruits and vegetables sub-categories, e.g., jam, jellies, condiments, dressings, etc.
	Nuts, seeds, grains	Include almonds, Brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pine nuts, pistachios or walnuts, sesame seeds, soybeans, etc.
	Other produce products	Any other fruit and/or vegetable product not included in the categories above
Egg	Shell eggs	Eggs that have not undergone any process other than cleaning, sanitation, classification and/or packaging.
	Processed eggs - liquid pasteurized eggs	Liquid eggs that have been subjected to a pasteurization process sufficient to inactivate vegetative pathogenic microorganisms so that it does not require further preparation before consumption even though it is usually cooked prior to consumption.
	Processed eggs - dried	Liquid eggs that have been subjected to a drying process (e.g., egg powder)
	Other egg products	Any other egg product not included in the categories above

to provide experts with an opportunity to indicate if any significant food sub-product category had been omitted. Members of the CFIA ERA Technical team created the categorization system by grouping sub-products based on similar expected levels of risk. This list was then reviewed and approved by the SAC members prior to its inclusion in the expert elicitation survey.

2.3. Survey design and supporting reference material

The expert elicitation survey was designed to collect information on the expert profile and the relative DALYs distribution at the sub-product level. The former covered 8 questions related to the participant's formal level of education, working experience and location, areas of expertise and past roles in the food industry. After completing the initial section, experts were offered the option to select between two versions of the questionnaire, depending on their expertise. The first version grouped questions by pathogen, while the second version grouped questions by

type of commodity (see Supplementary Material 1). To reduce the complexity of the expert's assessment during this elicitation, only 31 pathogen-commodity combinations were targeted based on their significant contribution to the total Canadian health burden (expressed as DALYs) (Fig. 1). Furthermore, even though the number of DALYs associated with the pathogen *L. monocytogenes* was smaller compared to others, this pathogen was included based on feedback from experts and considerations over the many recent events associated with this important hazard (Jackson et al., 2011; McCollum et al., 2013; Mead et al., 2006; WHO, 2018). Thereafter, combinations of interest included: *Campylobacter* spp. in beef, pork, poultry, game, eggs and produce; *Salmonella* (non-typhoidal) in beef, pork, poultry, dairy, eggs and produce; norovirus in beef, poultry and produce; STEC in beef, pork, poultry, dairy and produce; *Toxoplasma gondii* in beef, pork, poultry, game and produce; *Yersinia enterocolitica* in pork; *Clostridium perfringens* in beef; and L. *monocytogenes* in beef, pork, poultry and dairy. Then, for each type of commodity listed, experts were asked to estimate the
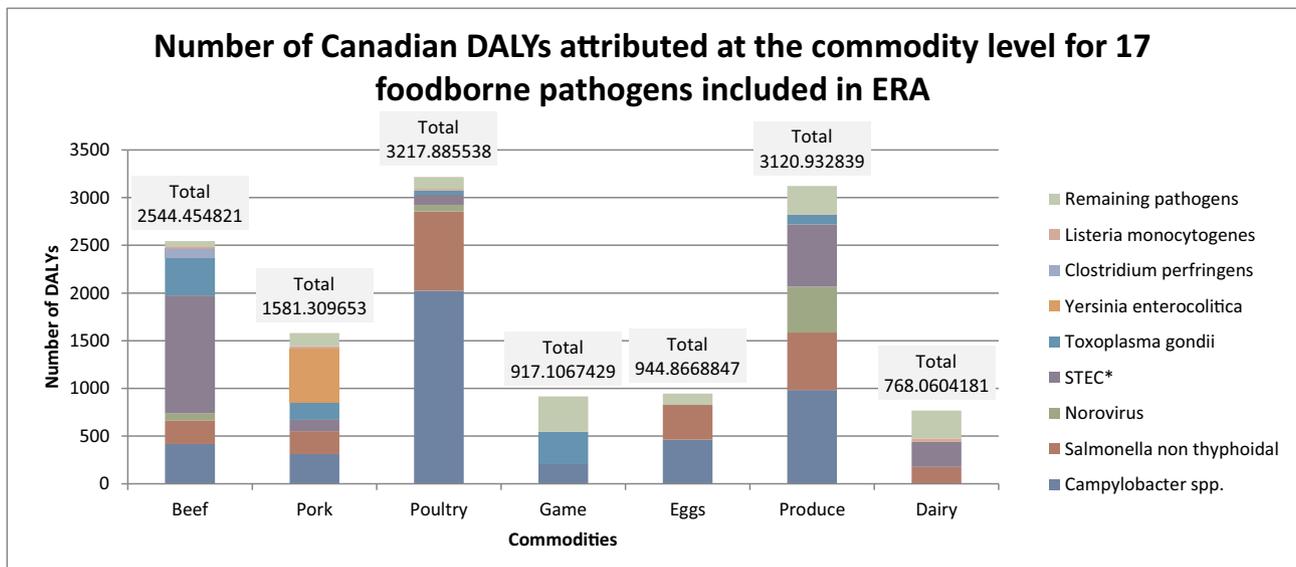
Fig. 1. Number of Canadian DALYs attributed at the commodity level for 17 foodborne pathogens included in the CFIA ERA model and the specific pathogen-commodity combinations investigated[1]

*Includes both STEC O157 and STEC non-O157.

[1] Based on Butler et al. (2015 and 2016), Davidson et al. (2011), Havelaar et al. (2008 and 2012), and Thomas et al. (2013).

relative contribution (%) of each sub-product to the total number of Canadian illnesses attributed to the pathogen-commodity combination. A rule was defined in the questionnaire to ensure that attribution estimates would add up to 100%. Also, for every pathogen-commodity combination, experts were asked to assign a level of certainty for their estimates, using a scale of 1 (low certainty) to 10 (high certainty) (see Supplementary Material 1).

The questionnaire was pre-tested by three food safety experts from the Université de Montréal, who provided feedback on the clarity of the questions and instructions, structure (flow), terminology, as well as on the time needed for its completion. Based on this initial feedback, the expected time to complete the questionnaire was 2 to 3 h.

As prior studies have shown that literature review/data summaries are useful when provided along with the questionnaire for elicitation (Vally et al., 2016), the CFIA ERA technical team prepared two supporting reference documents, i.e., a Food Safety Hazards Background document and a Glossary listing the pathogens and sub-product definitions respectively. Experts were invited to review them before the completion of the questionnaire if they considered it necessary. All reference documents, along with the expert survey, were available in English and French.

2.4. Completion of the survey

The survey took place between January and August 2016. The questionnaire was electronically provided via the Simple Survey web secure platform (Simple Survey, OutSideSoft Solutions Inc., Quebec, Canada). Experts were given 4–5 weeks to complete the questionnaire. Follow up emails were sent 3 weeks after the initial sharing of the survey, as reminders. Experts were also given the option to skip any

specific section or pathogen/commodity question, if they did not feel confident enough to provide responses for any of them.

2.5. Statistical analysis

Data were imported from the Simple Survey web secure account into an Excel file, and then processed using the R program version 3.4.0 (The R Foundation for Statistical Computing). Expert's estimates falling beyond the outer fences of the raw data were considered as outliers (Hogg and Tanis, 2010). Briefly, outer fences were constructed at a distance equal to 3 times the Inter Quantile Range (IQR), that was calculated as the difference between the third and first quartiles (IQR = Q3 - Q1). Data outside the ranges (Q1–3*IQR, Q3 + 3*IQR) were then removed prior to the statistical analysis.

Frequency tables were used to describe response rates and respondents' profiles. For the analysis of experts' estimation of the relative contribution of each sub-product to the Canadian health burden by pathogen-commodity combination, data were weighted based on the experts' estimates of certainty as follows (Clemen and Winkler, 1999):

$$p_{j,k} = \sum_{i=1}^{n} w_{i,k} p_{i,j,k}$$

where:

n is the number of respondents for the jth sub-product and k^{th} pathogen-commodity combination,
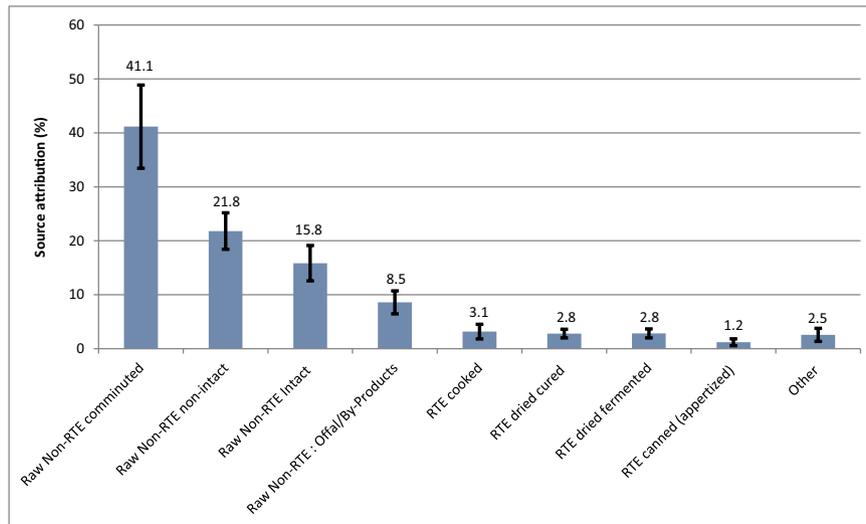
$p_{i,j,k}$ represents the expert i's estimate of the relative contribution for the jth sub-product and k^{th} pathogen-commodity combination,

$p_{j,k}$ represents the weighted average of the relative contribution for the jth sub-product and k^{th} pathogen-commodity combination across all n experts, and

a: Campylobacter spp.
(n = 30, C = 4.8)
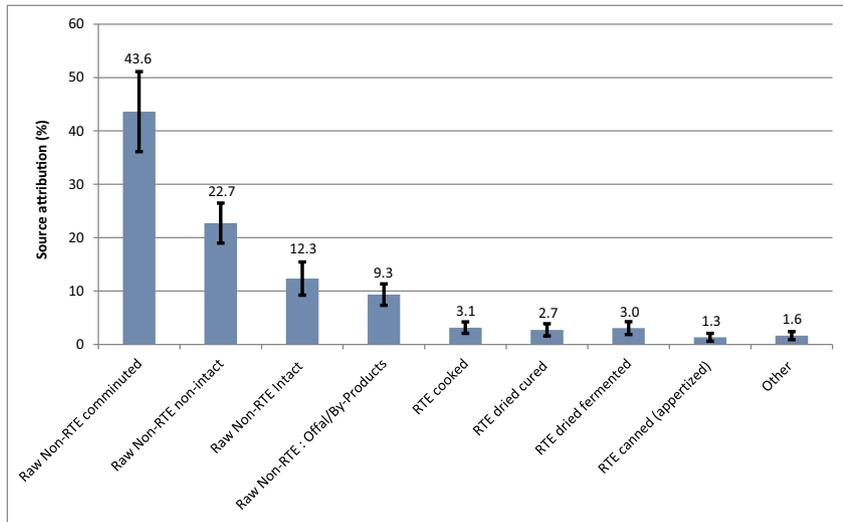
b: Salmonella non typhoidal
(n = 30, c = 5.2)

c: Norovirus
(n = 22, C = 4.6)
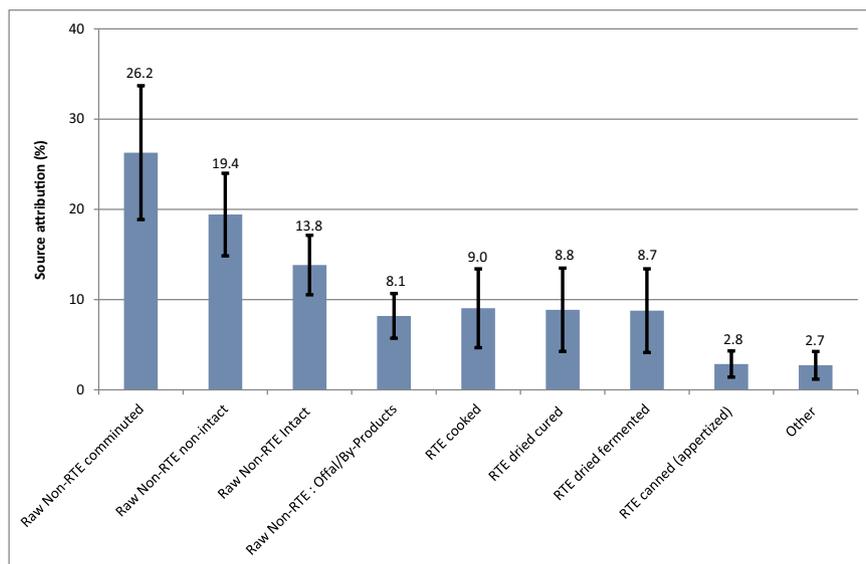

(caption on next page)

Fig. 2. a–g. Relative Contribution of individual Beef sub-products to the Total Number of Canadian Illnesses caused by different pathogens (n = number of participants, c = mean level of certainty).

$w_{i,\,k}$ represents the weight of expert i's assessment which is the ratio between the expert i's level of certainty and the sum of all n experts level of certainties for the kth pathogen-commodity combination.

Weighted estimates with confidence intervals for weighted means were used to present the results (Kozak et al., 2008; Hogg and Tanis, 2010). The non-parametric Kruskal-Wallis test was used to evaluate whether there were any significant differences in the unweighted median of the experts' responses for each pathogen-commodity combination, considering the following respondent profile variables: (i) the years of training and/or working experience in food safety/risk analysis (i.e., 10 or less years vs. > 10 years); and (ii) the expert current work affiliation (i.e., industry vs. academia vs. government). This test was used because the data gathered were not normally distributed (Hollander & Wolfe, 1973). The Benjamini and Hochberg (1995) procedure was applied to help control the false discovery rate.

3. Results

3.1. Expert profiles

Three consecutive rounds of recruitment ("snow ball" approach) resulted in a list of 119 candidates that were invited (as names were received) to participate to the expert elicitation. Some experts were also contacted during external communications and meetings with industry associations (e.g., the Canadian Produce Marketing Association, the Canadian Poultry and Egg Processing Council), following the same inclusion criteria. Three of the authors of this paper were also experts who took part in the process as no conflict of interest was identified.

From those invited to participate, 49 (41%) agreed and completed the questionnaire. At the time of the expert elicitation, participants were employed in regulatory institutions/government (51%), university, college, academia and research institutions (20%), food/beverage and retail industry (12%), private consultation (6%), farm/agriculture-related firm (4%), food equipment, distribution and packaging industries (14%) and/or others (4%) (e.g., not for profit organizations, international agencies). The mean number of years of active work in food safety and/or risk analysis was 18.3 years (SD = 9.6), with 76% of the respondents having over 10 years of experience or more. All respondents had a university degree as the highest level of formal education: 13 (27%) held a Ph.D., 15 (31%) held an M.Sc. degree, 19 (39%) held a B.Sc. degree and 2 held other decrees (e.g., medical doctor). The most frequent university degree disciplines included food science (29%), biology (27%), microbiology (10%), animal science (10%), chemistry/biochemistry (6%) and epidemiology (6%). The remaining 12% of respondents had degrees in medicine, plant science, food/chemical/industrial or agricultural engineering and public health.

Experts were also asked to define the food product category to which his/her expertise was most related to, with produce (41%) and meat (37%) being selected among the most predominant ones (participants could make multiple selections). Other selected categories included fish and/or seafood products (25%), food ingredients/additives (20%), beverages (16%) and cereal/bakery and pasta products (10%).

The distribution of current and past roles in the food industry was as follows: scientist (67%), manager and quality control personnel (35% each), inspector/auditor and supervisor (29% each), risk assessor/manager (25%) and policy analyst (18%).

3.2. Source attribution at the sub-product level

None of the experts expressed concerns with the proposed food categorization scheme. Estimates with confidence intervals of the experts' responses for each pathogen-commodity combination (relative

contribution at sub-product level) are presented in Fig. 2a–g (beef), Fig. 3a–f (pork), Fig. 4a–f (poultry), Figs. 5a–e (eggs and dairy) and Fig. 6a–e (produce) along with the number of respondents per elicitation and mean certainty.

Results of the source attribution exercise show variable levels of risk between the pathogen and the different commodities' sub-groups, with mean levels of certainty varying from 4.0 to 6.1. For beef, 41 to 57% of the health burden was associated with raw ground beef comminuted products when considering the pathogens *Campylobacter, Salmonella* non typhoidal, and STEC (Fig. 2a, b and d). Adding the estimates for raw non-intact and intact beef products accounted for up to 82% of the total health burden for these pathogen-commodity combinations, with the remaining being associated with offal and ready-to-eat beef products. A similar trend was observed in pork, poultry and game commodities, where the raw sub-product categories accounted for approximately 75–87% of the total health burden (for all pathogens except L. *monocytogenes*) (Figs. 3a to f and 4a to f, game results not shown). Higher contributions to the health burden from contamination with L. *monocytogenes* were mainly associated with RTE cooked beef, pork and poultry products (37.8%, 36.9% and 41.8%, respectively). When considering the majority of the pathogens, most RTE meat product categories generally received a low level of health burden (< 5%) (Figs. 2a to 4f). Exceptions include combinations with norovirus (Figs. 2c, 4c), *Cl. perfringens* (Fig. 2f) and L. *monocytogenes* (Figs. 2g, 3e and 4f), which accounted in some cases for up to 25% of the total health burden. STEC and *Campylobacter* spp. attribution for beef and poultry products were mainly associated with raw ground products followed by raw non-intact, raw intact and raw offal (Fig. 2d and 4a, respectively). Similarly, RTE beef and poultry categories were assigned < 3.5% and 2.5%, respectively, for these two pathogens.

For egg products, most of the health burden was associated with shell eggs (81%) when the pathogens *Campylobacter* and *Salmonella* were considered, and < 8% was attributed to liquid pasteurized eggs (Fig. 5a and b). For dairy products, a trend was also observed across the attribution to different food pathogens including *Salmonella,* STEC, and L. *monocytogenes* (Fig. 5c to e). Sub-product categories associated with a higher risk perception level included those made from unpasteurized milk (independent of the ripening time, i.e., less or > 60 days, e.g., blue cheese, soft and semi-soft cheese) and firm and hard cheese made from unpasteurized milk aged < 60 days. According to experts, these categories overall represented between 61.6 and 68.3% of the total health burden associated with dairy sub-products. Specifically, 34.4% of the total health burden was associated with L. *monocytogenes* and soft and semi-soft cheeses made with unpasteurized milk, aged less or > 60 days (Fig. 5e).

With respect to produce, the majority of the health burden was associated with intact and minimally-processed fresh fruits and vegetables (81%, 55%, 70% and 70% for *Campylobacter, Salmonella* (non-typhoidal), STEC and *T. gondii,* respectively) (Fig. 6a to e). When norovirus was listed as the causative agent, experts associated intact (34%) and minimally-processed fruits and vegetables (32%) as the main sub-product categories responsible for the health burden, while frozen fruits and vegetables were ranked in third place (12%) (Fig. 6c). Spices/herbs, and nuts/seeds/grains were the third and fourth sub-product categories of higher risk associated with *Salmonella* (16 and 14%, respectively) (Fig. 6b).

In addition, the category "other" sub-product was included in all commodities to test for omission of any that might be significant. From the 31 pathogen-commodity combinations elicited, 11 (34%) "other" cases were estimated to be responsible for < 2% of the health burden, while 16 (50%) cases were responsible for 2–4% of the health burden. The largest estimates under this category were found in the egg-

d: STEC
(n = 29, C = 5.8)
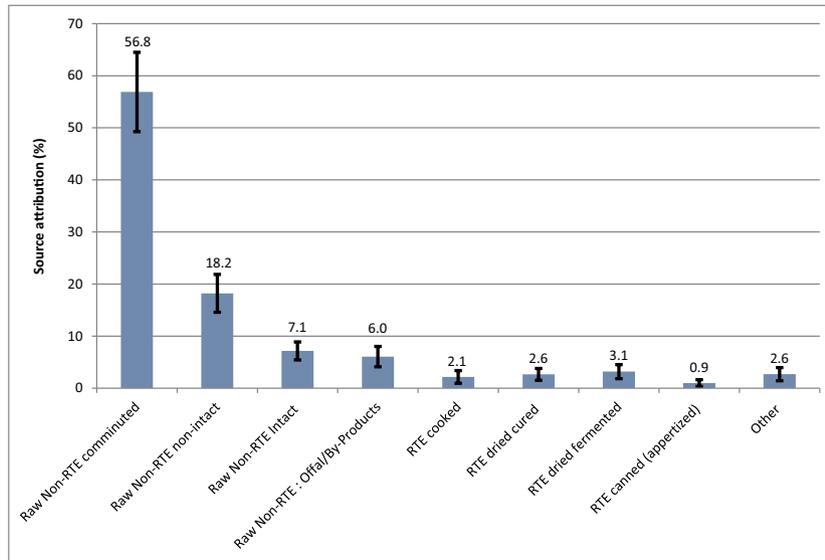
e: Toxoplama gondii
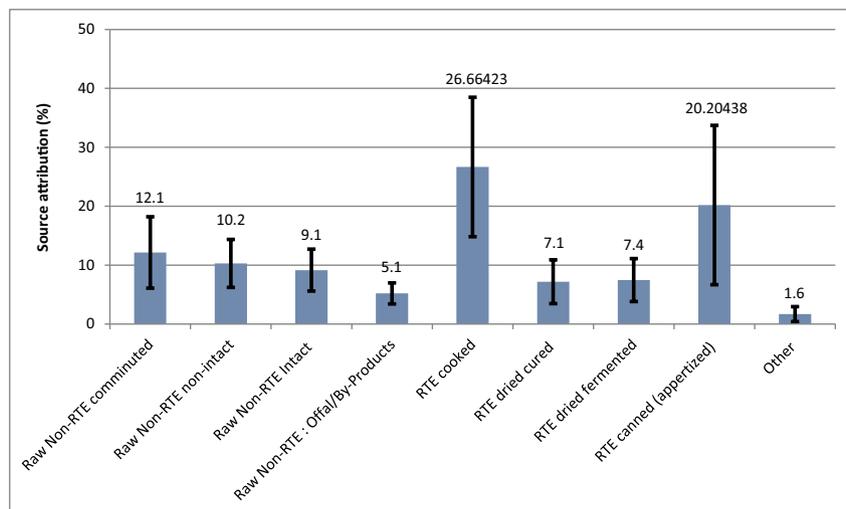(n = 20, C = 4.1)
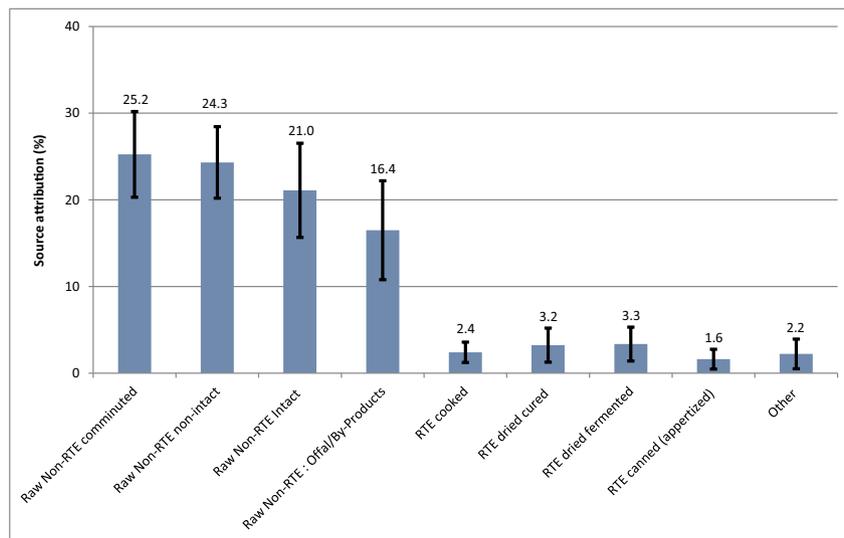
f: Clostridium perfringens
(n = 26, C = 5.3)

Fig. 2. (*continued*)
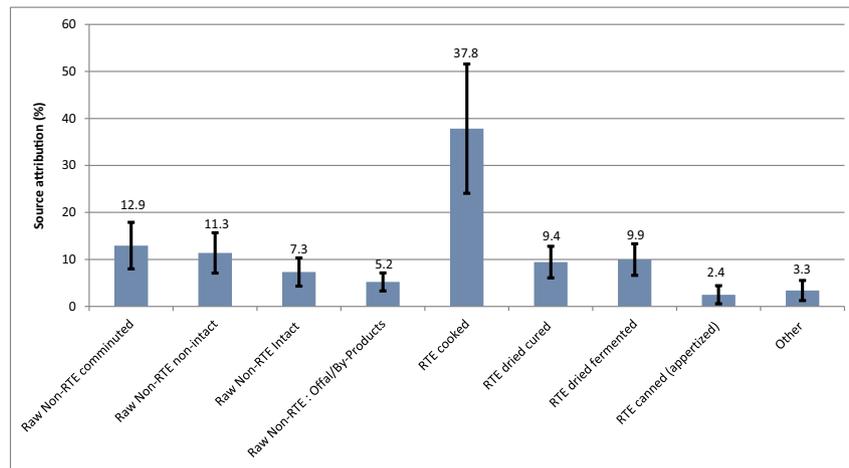
g: L. monocytogenes
(n = 25, C = 5.3)

Fig. 2. (*continued*)

Campylobacter and egg-*Salmonella* (non-typhoidal) categories, with 5.9% and 5.3% contributions, respectively. However, none of the participants indicated concerns with the proposed classification scheme, indicating that experts generally agreed with the selection of food sub-products categories included in the elicitation.

Results for the Kruskal-Wallis tests showed that there were no significant differences in the experts' responses for each pathogen-sub-product combination based on their years of experience in food safety/risk analysis ($\leq$ 10 vs. > 10 years of experience) or the expert's current affiliation (academia, industry or government) after adjustment for multiple comparisons (Benjamini and Hochberg, 1995). In addition, looking at the standard deviations across experts' individual attribution estimates for each pathogen-sub-product combination as an indicator of agreement on the food contribution to the burden of illness for a particular pathogen, it was found that this measure varied significantly across pathogens, from 1.0 for *Toxoplasma* in RTE canned pork products to 36.6 for L. *monocytogenes* in RTE cooked poultry products. When the level of certainty provided by experts for each pathogen-commodity assessed were evaluated, most combinations showed a fairly symmetrical distribution of the experts' certainty, with the exception of the bimodal distribution shown for *Toxoplasma* and norovirus, as well as 8 combinations that showed a moderately skewed distribution to the left (*Salmonella* in poultry/eggs, STEC in beef/pork, *Campylobacter* in poultry/eggs, *L. monocytogenes* in poultry and norovirus in poultry), which can be interpreted as a general trend to better certainty (Bulmer, 1979) (see Appendix A). Also, there was considerable individual variation in the mean certainty across experts for individual pathogen-commodity combinations, varying from 4.0 for *Yersinia* in pork [3.1, 4.9] and *Campylobacter* in game [3.1, 4.9] to 6.1 for *Campylobacter* in eggs [5.5, 6.8].

4. Discussion

An expert elicitation approach was chosen as this has been successfully used in a wide range of applications where primary data are absent, including foodborne disease source attribution (Hoffmann et al.,

2017). Also, this method has been used to characterize uncertainty about existing scientific knowledge and to provide alternative parameter estimates when there are meaningful gaps in available data (Batz et al., 2012).

Understanding the relative public health impact of major biological hazards in the food supply is critical for risk-based decision making, but adding a level of specificity by determining the particular pathogen-sub-product combination that contributes most significantly to the total health burden could further enhance the risk assessment and management processes. For the purposes of this study, and to reduce the burden on experts, this research group focused on estimating the health burden of 31 major pathogen-commodity combinations which account for almost 80% of the Canadian health burden related to foodborne pathogens (Butler et al., 2015; Havelaar et al., 2012; Thomas et al., 2013).

Results from this study generally agree with previous findings cited in the literature. For example, higher levels of health burden associated with L. *monocytogenes* and RTE meat product categories agree with results from risk-ranking models for listeriosis, where delicatessen and RTE meat products were identified as the highest risk food (Bohaychuk et al., 2006; FDA, 2003). Estimates provided by experts during this study (10%, 11.5% and 8.2% for RTE fermented beef, pork and poultry products, respectively) (Figs. 2g, 3e and 4f) also agree with the frequent contamination of fermented sausages with L. *monocytogenes* previously reported in Belgium and Switzerland (Jemmi et al., 2002; Uyttendaele et al., 1999). Similarly, results for STEC attribution to beef products agree with reports of frequent contamination with *E. coli* O157 ranging from: 0.1% to 54.2% in ground beef, 0.1% to 4.4% in sausage, 1.1% to 36.0% in various retail cuts, and 0.01% to 43.4% in whole carcasses (Hussein, 2014). Bohaychuk et al. (2006) also reported that STEC was not detected in fermented sausages, beef wieners or chicken wieners, while Rangel et al. (2005) reported that the food vehicle for 41% of the foodborne outbreaks in the United States (U.S.) between 1982 and 2002 was ground beef.

Regarding the source attribution for poultry products associated with *Campylobacter* spp., experts' estimates are in agreement with the findings from Moore et al. (2002), as commercially available RTE
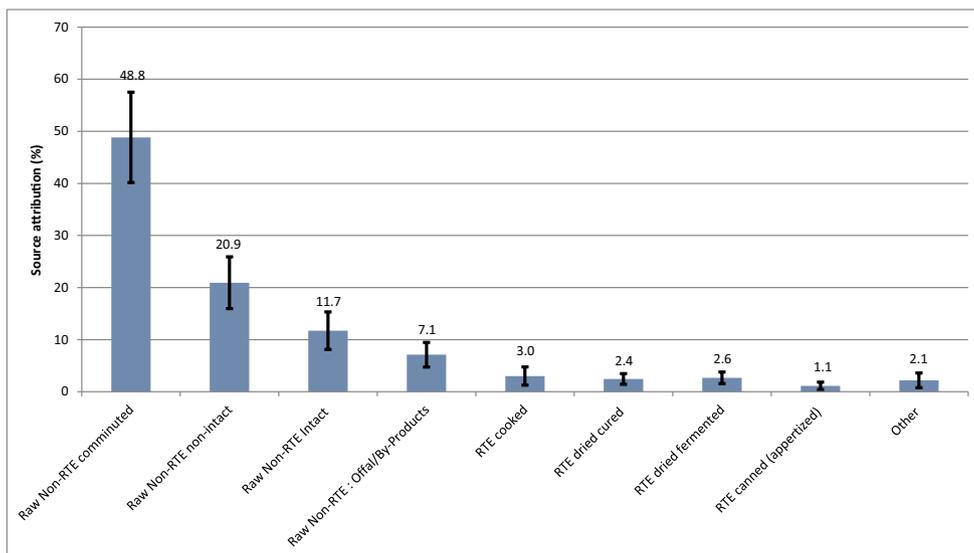
a: Campylobacter spp.
(n = 30, C = 4.6)
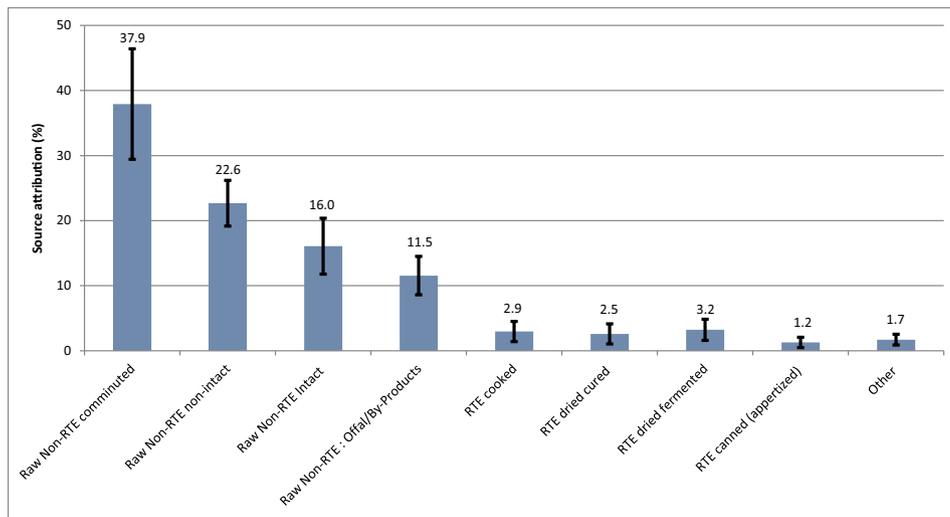
b: Salmonella non typhoidal
 (n = 28, C = 5.1)
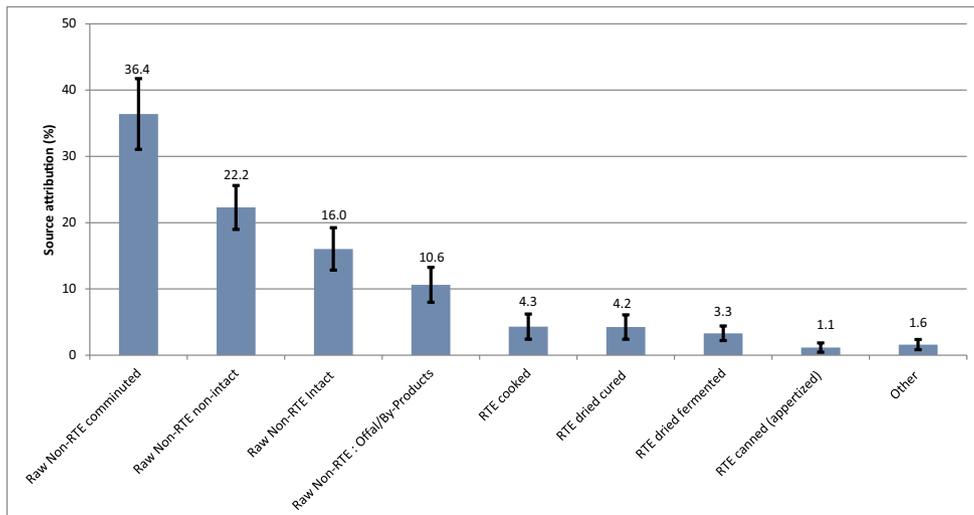
c: STEC
(n = 26, C = 5.3)

(caption on next page)

Fig. 3. a–f. Relative Contribution of individual Pork sub-products to the Total Number of Canadian Illnesses caused by different pathogens (n = number of participants, c = mean level of certainty).

foodstuffs, including cooked poultry, are not commonly contaminated with *Campylobacter*, and thus do not appear to represent a significant source of human infection. In contrast, raw poultry products, including fresh and frozen chicken, frequently tested positive (77%–94%) for *Campylobacter* spp. (Moore et al., 2002). The attribution given by experts to the health burden associated with *Salmonella* in raw intact poultry products (Fig. 4b) also agree with the frequent contamination of chicken leg samples (30%) with this pathogen, as reported by Bohaychuk et al. (2006).

Estimates for source attribution related to egg products for *Salmonella* (non-typhoidal) did not correlate with the previously reported proportion of outbreaks related to the particular sub-products. However, different studies may consider egg products differently, i.e., complex foods having eggs as an ingredient could be also considered in the analysis. For example, in a review of egg-associated *S. enterica* serotype Enteritidis outbreaks (St-Louis et al., 1988), eggs were implicated as simple food vehicles in 20% of the outbreaks, but complex foods containing eggs were implicated in an additional 57% of the outbreaks. Even though the source attribution estimates in our study may suggest that there is a significant hazard associated with *Campylobacter* spp. in shell eggs, it is important to note that our results are based only on the attribution of health burden at the sub-product level. Indeed, the number of DALYs associated with *Campylobacter* spp. in eggs (as a whole commodity) only represents one fifth of the DALYs attributed by experts to poultry for this pathogen (see Fig. 1). Thus, before its inclusion in the CFIA ERA model, the results from this expert elicitation will need to be linked to the DALYs at the commodity level, resulting in a much lower impact towards the final risk associated with this sub-product. A similar tendency was observed in the source attribution for STEC and pork products, yet, the number of DALYs associated with this commodity is 14 times smaller than the number of DALYs attributed to STEC in beef products; hence its final impact towards the risk will be reflected accordingly in the model.

The majority of the produce health burden was associated with intact and minimally-processed fresh fruits and vegetables that include leafy vegetables, which have been previously reported as being strongly associated with foodborne illness. Previous investigations attributed 22% of these illnesses (considering all pathogens) to leafy vegetables, being the second most frequent cause of hospitalizations (14%) and the fifth most frequent cause of death (6%) in the U.S. (Painter et al., 2013). Similarly, Hall et al. (2012) reported that 33% of produce-related foodborne disease outbreaks could be attributed to a single sub-product (leafy vegetables). Furthermore, when assessing trends and causes for reported campylobacteriosis outbreaks due to fresh produce and specific pathogens, Callejon et al. (2015) attributed 44% and 66% of the cases to salads and 22% and 33% of the cases to leafy vegetables for the U.S and the European Union (E.U.) respectively. When consulted on the relative role of specific food categories to enteric diseases caused by *Campylobacter* spp. in Canada, raw produce was assessed as having approximately twice the risk compared to cooked produce, the latter having a similar attribution as nuts and seeds (Butler et al., 2016). Thus, even though the food categorization scheme used in the latter study does not fully resemble the one used for the current expert elicitation,

the results clearly highlight the significance of these sub-product types (e.g., raw, minimally processed) on health burden. In the case of outbreaks caused by *Salmonella*, Callejon et al. (2015) reported that 11% were associated with both leaves and salads in the U.S., while 30% and 20% were associated with the same two sub-products for the E.U. Similar findings were reported by the latter authors for *E. coli*, supporting the estimates given by the experts during the current study. Furthermore, Butler et al. (2016) attributed 20% and 44% of the *Salmonella* spp. (non-typhoidal) cases to cooked produce and raw produce, respectively (data normalized for the produce category). The same authors found the attribution of *E. coli* STEC non-O157 to be 17% and 54% for cooked and raw produce, respectively, while 5% and 80% of the same categories were attributed to *E. coli* STEC O157. During the current study, both *E. coli* STEC non-O157 and O157 were assessed together by experts, and the results confirmed the trend related to the highest source attribution being associated with raw or minimally processed fruits and vegetables. With respect to norovirus, outbreaks have been strongly correlated with the consumption of salads (44%) and berries (51%) in the U.S. and E.U., respectively (Callejon et al., 2015). Painter et al. (2013) reported that most foodborne viral illnesses in the U.S. were attributed to leafy vegetables (35%), fruits and nuts (15%) and grains (4%). The relatively high levels of attribution of *Salmonella* to spices/herbs and nuts/seeds/grains (15%) may be related to previous indications of the internalization capacity of this pathogen, which can lead to protection from disinfection by internalized bacteria (Golberg et al., 2011). In this regard, previous studies have reported that for this specific pathogen, raw produce is twice as risky as cooked produce, with nuts and seeds sharing similar risk with the former (Butler et al., 2016).

Finally regarding dairy products, past studies have shown that L. *monocytogenes* is usually ranked high because of a large number of recorded outbreaks due to soft un-aged cheeses such as Mexican-style *queso fresco* (Batz et al., 2012), which support the findings of this study. Similarly, Rangel et al. (2005) reported that of the 7 outbreaks associated with dairy products between 1982 and 2002 in the U.S., 4 were caused by raw milk products including cheese curds. Based on our findings of source attribution for soft and semi-soft cheeses made with unpasteurized milk, aged less or > 60 days, the CFIA ERA technical committee proposed to merge certain dairy sub-product categories that shared similar levels of risk attribution, as follows: (i) blue or surface ripened cheese made from pasteurized milk (aged less than and > 60 days); (ii) firm and hard cheese, blue cheese or surface ripened cheese aged for 60 days or more and made with unpasteurized milk; (iii) Firm and hard cheese, blue cheese or surface ripened cheese aged < 60 days and made with unpasteurized milk; and (iv) Soft and semi-soft cheeses made with unpasteurized milk (aged less than or > 60 days). This proposal was later shared with the SAC members and approved for inclusion in the model.

Even though some of the estimates provided by experts closely resemble previous findings and trends reported in the literature (i.e., attribution based on outbreaks), a quantitative comparison cannot be drawn, as different methodologies/approaches were used. Several methodologies for attribution of foodborne diseases to specific sources

d: Toxoplasma gondii
(n = 21, C = 4.4)
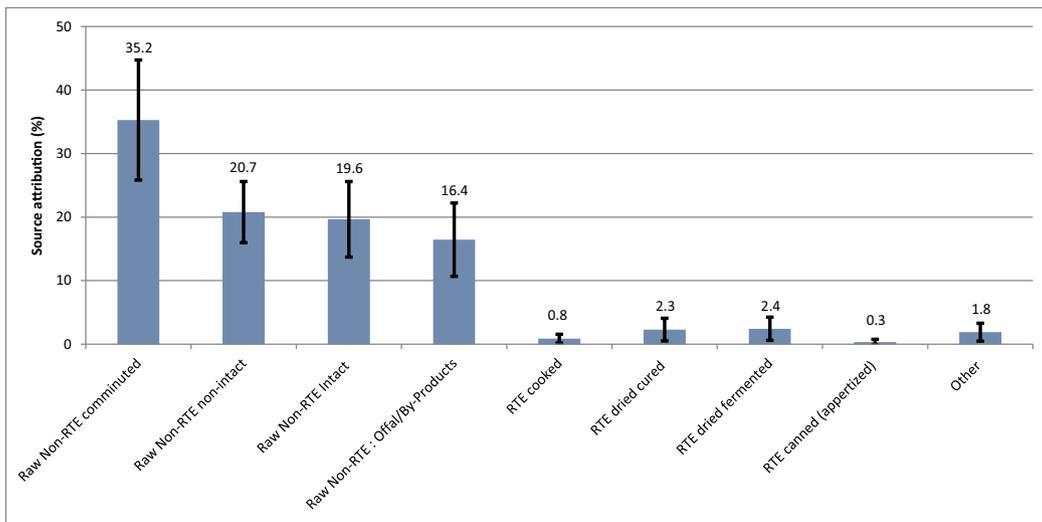
e: L. monocytogenes
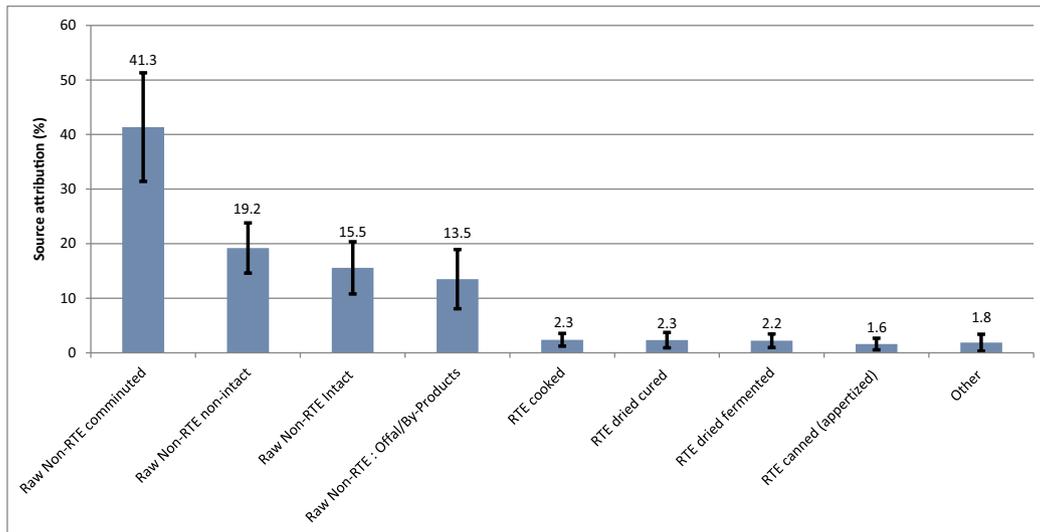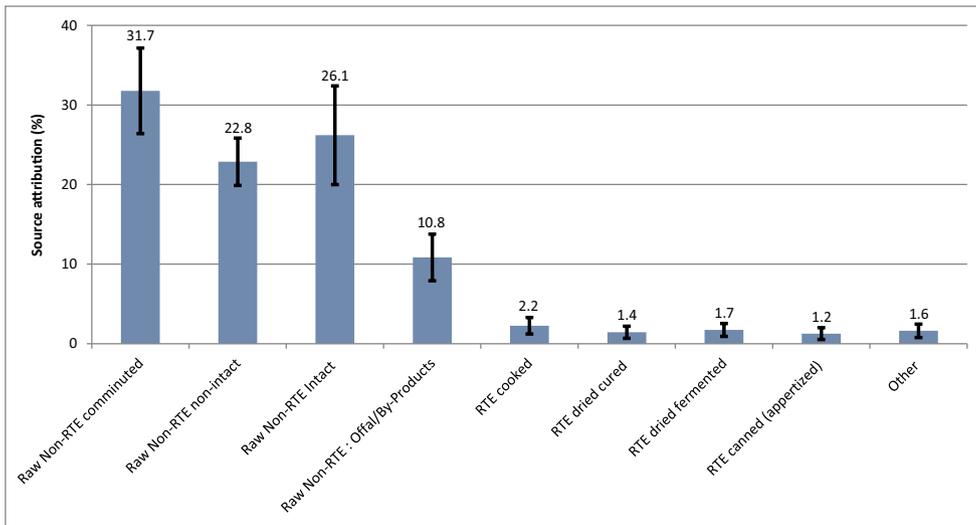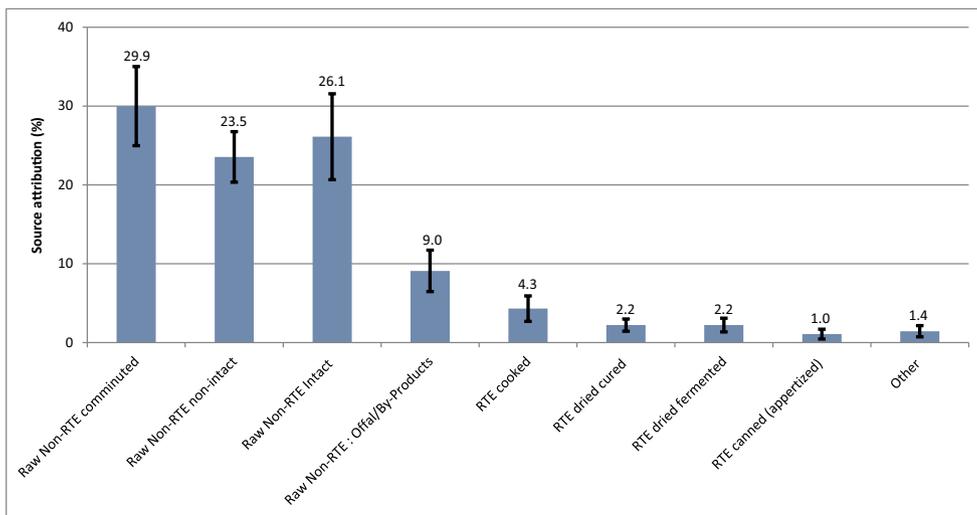(n = 27, C = 5.3)
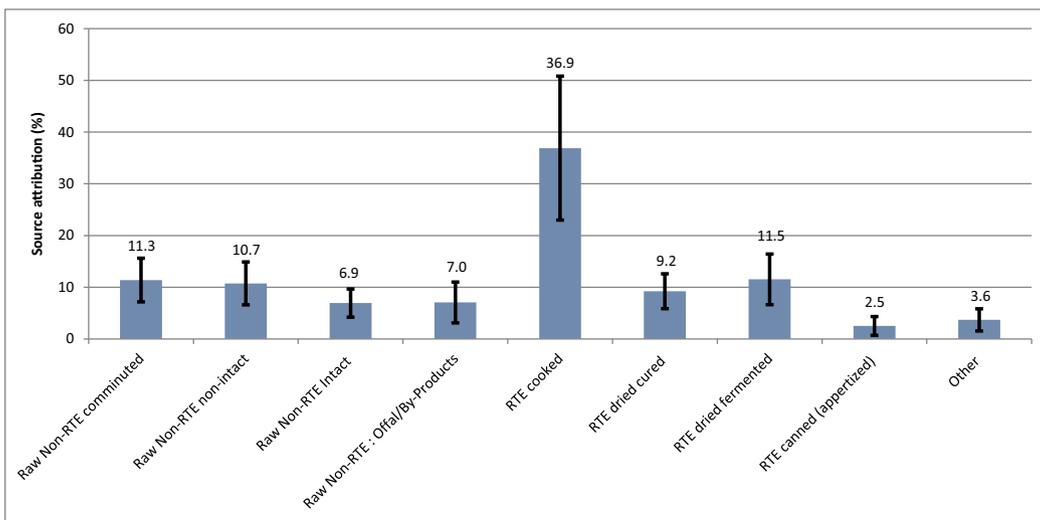
f: Yersinia enterocolitica
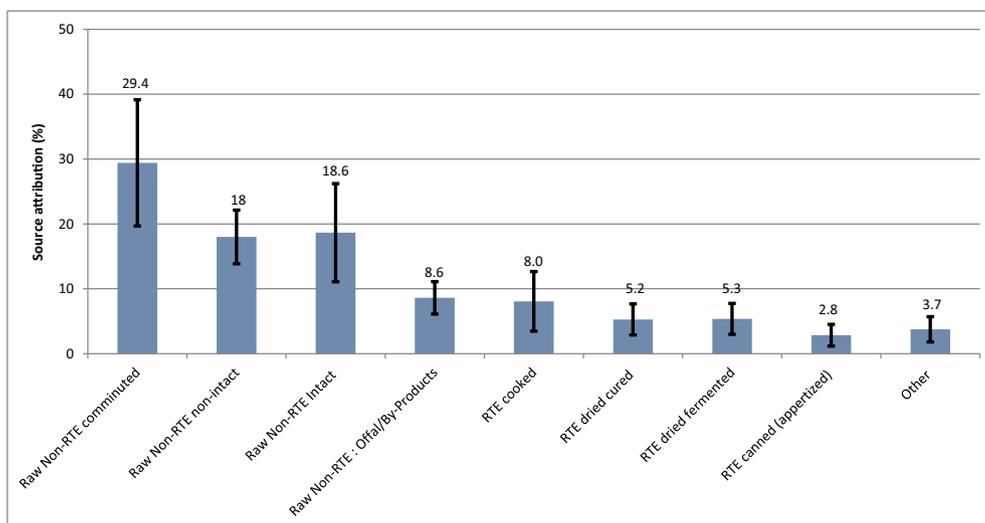(n = 22, C = 4.0)

Fig. 3. (*continued*)

a: Campylobacter spp.
(n = 30, C = 5.6)

b: Salmonella non typhoidal
(n = 30, C = 5.9)

c: Norovirus
(n = 19, C = 4.8)

(caption on next page)

Fig. 4. a–f. Relative Contribution of individual Poultry sub-products to the Total Number of Canadian Illnesses caused by different pathogens (n = number of participants, c = mean level of certainty).

are available (Havelaar et al., 2008; Pires, 2013), each having its own strengths and drawbacks and none seems to be exactly and universally appropriate for all enteric diseases (Greig and Ravel, 2009). Both outbreak analysis and expert elicitation have been shown to be useful and applicable for attributing disease to several pathogens (Pires, 2013). Notwithstanding this, the working group chose to use the latter approach as the researchers agreed that the source of outbreak-related incidents might not be representative of all cases (e.g. sporadic) (Batz et al., 2005; Greig and Ravel, 2009; Hall et al., 2012). For example, *Campylobacter* spp., are estimated to be among the two most common bacterial cause of foodborne illness, but the proportion of outbreak related cases among all is extremely low (Pires et al., 2010; Scallan et al., 2011). In addition, sources can be very different between outbreak-related vs endemic cases, so extrapolation can be hazardous. Likewise, illnesses due to pathogens that are difficult to identify or rarely cause outbreaks are underrepresented (Batz et al., 2005 and 2012). Because the outbreak approach for source attribution did not address the public health question being assessed through the CFIA risk assessment model, an expert elicitation was chosen. Other approaches could have also been considered (e.g., meta-analysis of previously conducted source attribution), but time restrictions and literature availability further supported this selection (e.g., estimates were not available for all pathogens considered within the model). In this regard, Batz et al. (2012) reported that outbreak-based attribution estimates for *Campylobacter, Toxoplasma* and *Yersinia* are not representative; therefore expert-based attribution seems better for these pathogens. Hoffmann et al. (2008) also advocated the use of expert opinion because outbreak data generally are incomplete, whereas using a structured approach for eliciting expert opinion, allowing for assessment of the reliability of the expert-based data, would cover all commodity-pathogen combinations.

Previous foodborne source attribution studies (Batz et al., 2012; Hoffman et al., 2007; Vally et al., 2016) have reported varied levels of uncertainty around the estimates at the commodity level, which could be expected to be greater when linking a disease rarely reported with sub-product categories. Given the number of participants and the range of relevant disciplines represented, it was not surprising that the level of expertise varied somewhat. The bimodal distribution of certainty for *Toxoplasma* and norovirus points to a greater uncertainty about attributing cases to these two pathogens at the sub-product level. Batz et al. (2012) also found that expert opinions for *Toxoplasma* and *Yersinia* at the commodity level differ significantly among experts, while Hall et al. (2012) stated that there were challenges in food attribution of norovirus outbreaks, given the potential for multiple transmission pathways, contamination of multiple vehicles by an ill food handler, and the time lags in reporting consumer complaints. This agrees with Vally et al. (2016) who found that much of the uncertainty in burden of disease studies arises from uncertainty in transmission routes. Nonetheless, wide distributions not only reflect disagreement between experts, but may also indicate a need for additional data collection and research (Hoffman et al., 2007; Vally et al., 2016). However, it was expected that experts would draw on a wide range of scientific

evidence, not just outbreak information, to provide their estimates for source attribution at the sub-product level. Along with these specific areas of variability, these results show how difficult it is to estimate the role of specific foods in foodborne illness exposure, even in settings with the best available disease surveillance and sampling (Hoffmann et al., 2017).

Furthermore, variations in the way aetiological agents and foods are defined and categorized impedes direct comparison of food attribution between studies. No consensus exists on how to categorize foods for attribution (Batz et al., 2012), and the need for a single food categorization scheme has been defined as a critical issue for food safety (Batz et al., 2005). Throughout the duration of this study, no participant raised concerns or opposed the food categorization scheme proposed. This classification considers the processing status of the food product, for example, by distinguishing between cheeses made with pasteurized or unpasteurized milk, and the ripening period (less or > 60 days). This is increasingly important since unpasteurized milk has been implicated in a number of dairy outbreaks and this number has increased in recent years (Currie et al., 2018; Richardson et al., 2017). Having this level of sub-categorization and the source attribution related to it could inform future decisions about the prioritization scheme for oversight and surveillance, helping inform prevention efforts. Furthermore, in the long term application, such information could help to quantify the effect of policies and regulations on the number of cases, and capturing more detailed processing information could also help determine if certain food types or processing methods require different prevention efforts than others (Richardson et al., 2017). However, some limitations of the proposed categorization should also be noted, as it could be expected that as the number of categories increase, the same will apply to the level of specificity, leading to inconsistent "granularity" in attribution analyses. A larger panel participated in the process which was reported to be beneficial as filling the gap requires the synthesis of information from a broad range of disciplines and professional backgrounds (Hoffman et al., 2007). Furthermore, a larger panel can allow the use of statistical analyses, help assess the value of further research and data collection, and help guide the choice of aggregation method, because the inherent variability in expert judgement is captured. Based on that, this research group considered the self-assessment certainty values of experts in the final calculations of the source attribution for the pathogen-commodity combinations. The mean certainty values listed at the top of each figure shows the level of variability on the expert's judgements, and also highlight some areas where more research is needed (e.g., *Toxoplasma gondii*). When individual experts' certainty was high on average (e.g., *Salmonella,* non-typhoidal, in egg products), variability in individual uncertainty was low, and experts agreed strongly with one another in their estimates.

It is important to highlight that at the time this study was conducted chemical hazards were not considered in the CFIA ERA model when assessing the inherent risk associated with a food commodity/product. However, this model does consider both biological and chemical hazards when evaluating the mitigation and compliance history associated with a food establishment (e.g., by assessing the control of

d: STEC
(n = 21, C = 5.0)
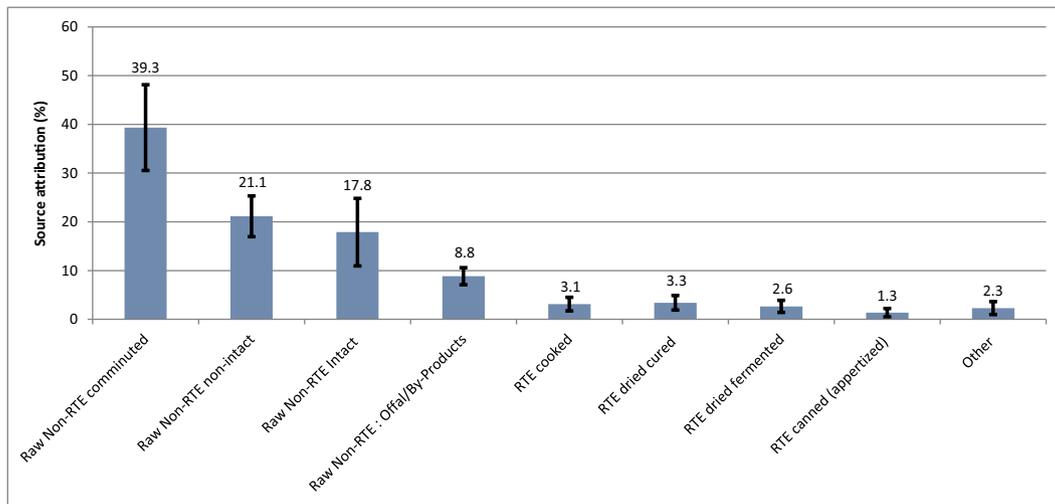
e: Toxoplasma gondii
(n = 18, C = 4.1)
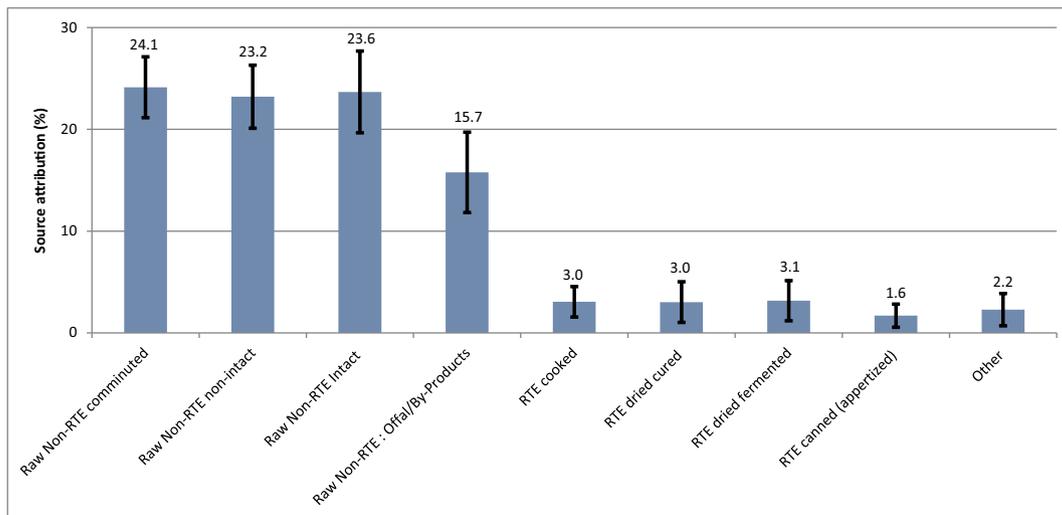
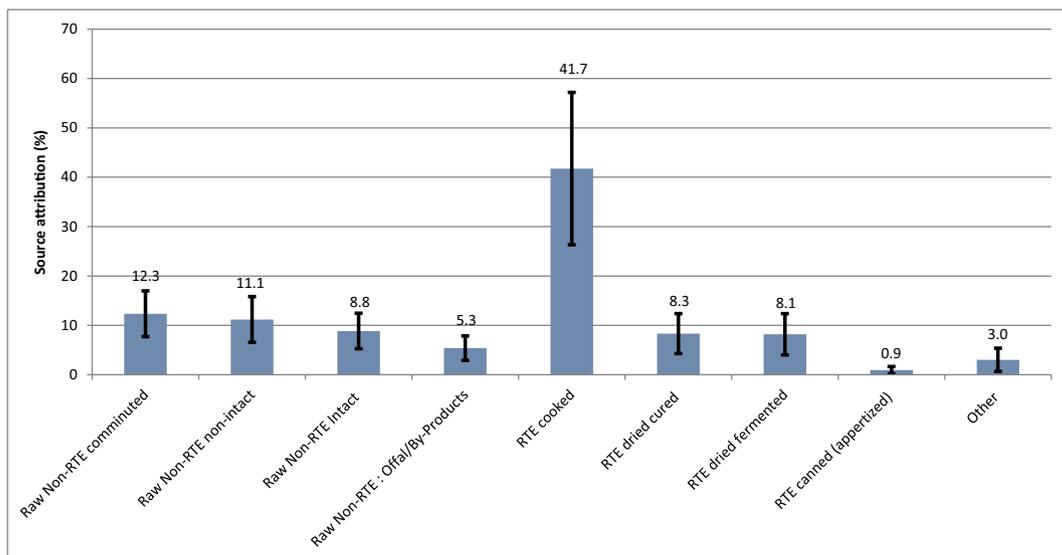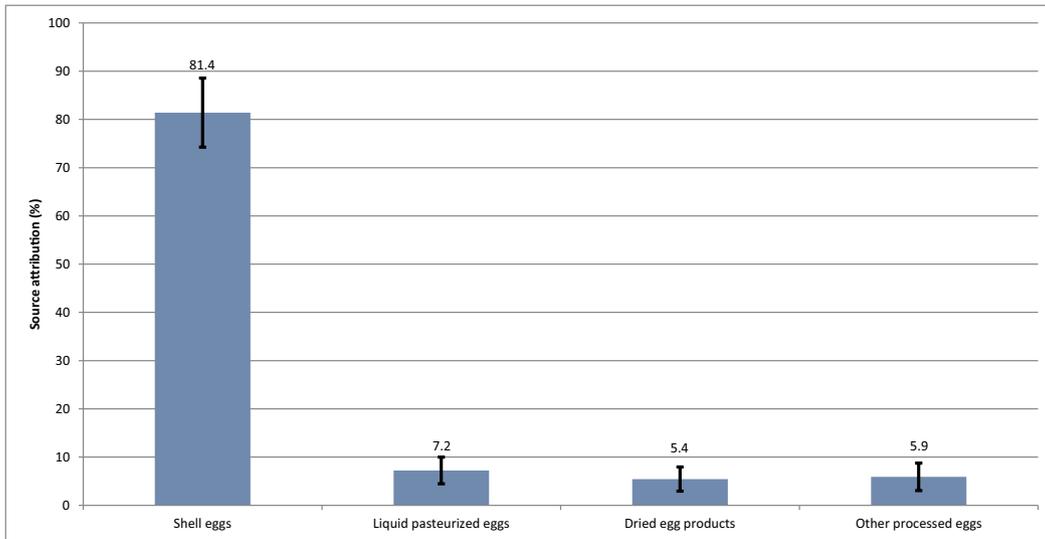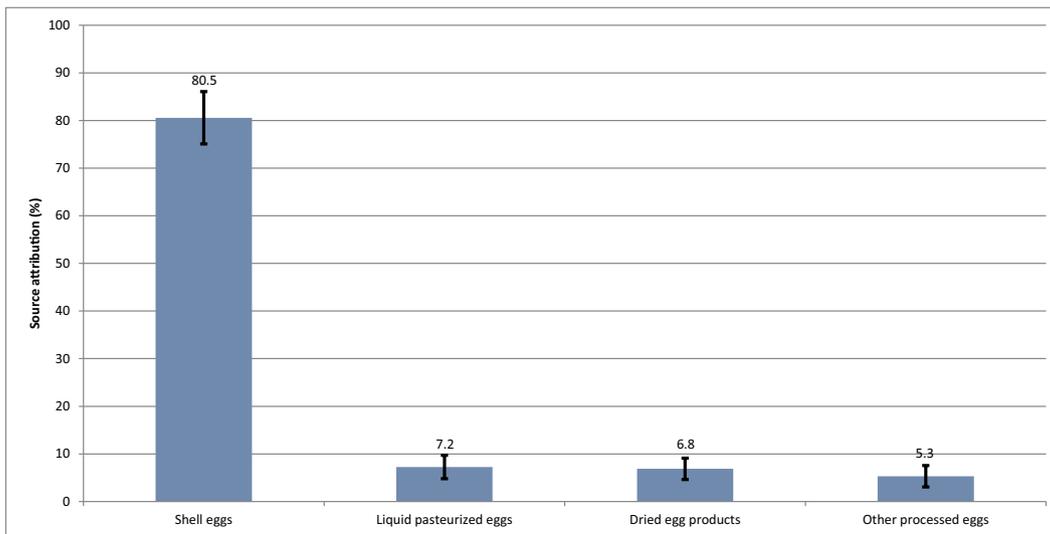f: L. monocytogenes
(n = 24, C = 5.4)
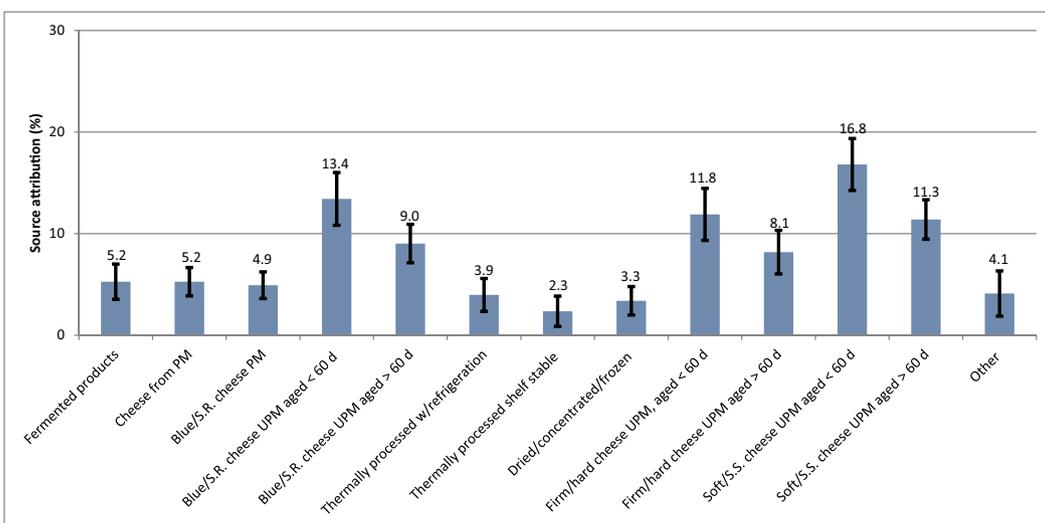

Fig. 4. (*continued*)

a: *Eggs - Campylobacter spp.*
(n = 35, C = 6.1)

b: *Salmonella non typhoidal*
(n = 34, C = 5.9)

c: Dairy - Salmonella non typhoidal
(n = 23, C = 5.0)

(caption on next page)

Fig. 5. a–e. Relative Contribution of individual Egg and Dairy sub-products to the Total Number of Canadian Illnesses caused by different pathogens (n = number of participants, c = mean level of certainty, S.R. = surface ripened, PM = Pasteurized milk, UPM = Unpasteurized milk, S.S. = Semi soft).

incoming materials and considering any recall due to chemical hazards). These in turn, have an impact on the final risk result of an establishment as described in Racicot et al. (2018). Investigation is on-going by this research team to identify and prioritize those chemical hazards that have a significant impact on the Canadian health burden, and to include them in a future and improved version of the model.

In summary, this study used a structured expert elicitation approach to develop estimates of specific foods that contribute to the Canadian health burden; information that could help public health, regulatory agencies and food industry better target food safety and risk management efforts. It should be noted, however, that these estimates represent the current level of knowledge for the different pathogen-commodity combinations, and these numbers should therefore not be taken as static, but rather it is recommended to continuously review and update the source attribution estimates, as possible changes over time may occur (e.g., new pathogens, new food vehicles, etc.).

5. Conclusions

Several studies on source attribution at the commodity level for foodborne pathogens are available, yet none is detailed enough to provide information at the sub-product level. The current elicitation process allowed estimating this attribution for 31 pathogen-commodity combinations, which in turn support risk-based prioritization by identifying those that are responsible for the greatest burden of public health. This study also highlights the need for further research on the relationship between attribution of foodborne illness and food sources, particularly for pathogens where the level of uncertainty is high (i.e., *Toxoplasma gondii* in meat products, norovirus in beef). Estimates for

source attribution have been included in the CFIA ERA model and will be used to enhance its applicability by helping inform risk managers on effective inspection resource allocation. While substantial uncertainty around the central tendency estimates was found, these estimates provide a good basis for regulatory oversight.

Note

Health Canada and the Public Health Agency of Canada Research Ethics Board executive committees reviewed this project and determined that it did not need to undergo ethics review by the Research Ethics Board.

d: Dairy - STEC
(n = 25, C = 5.0)
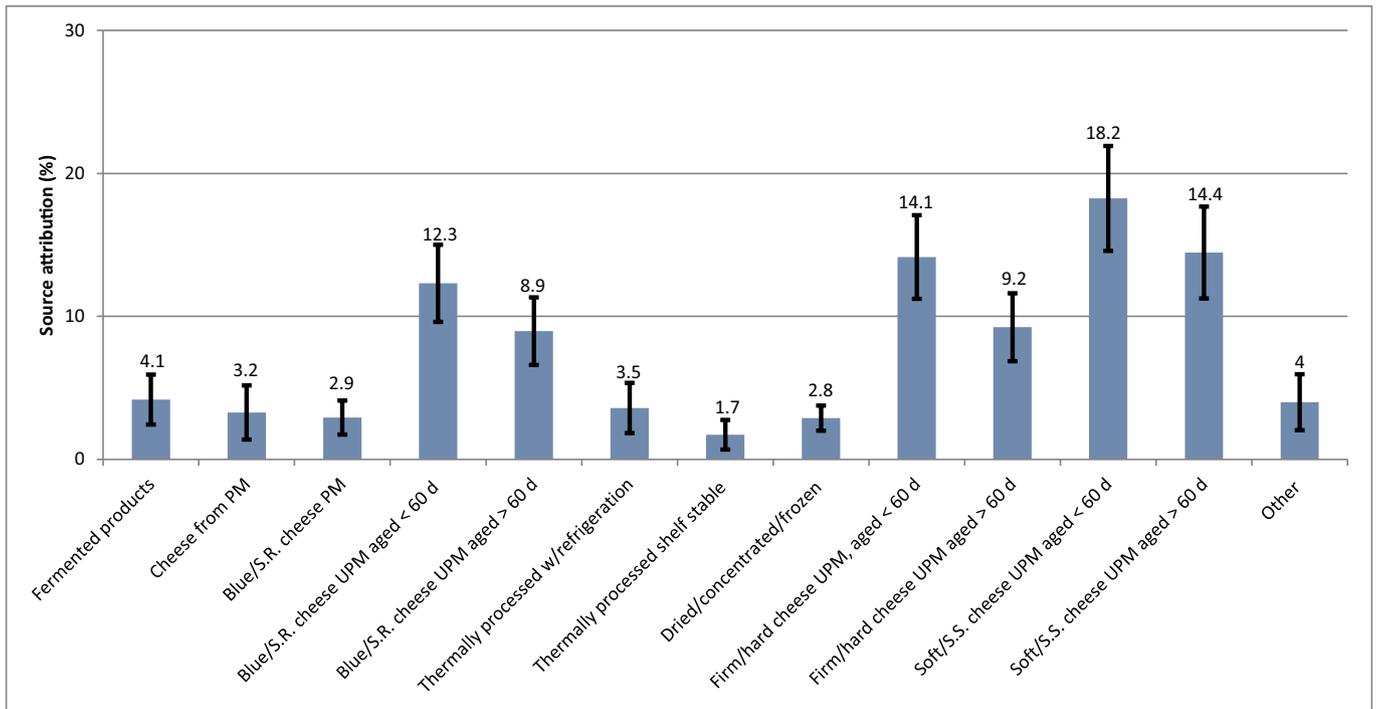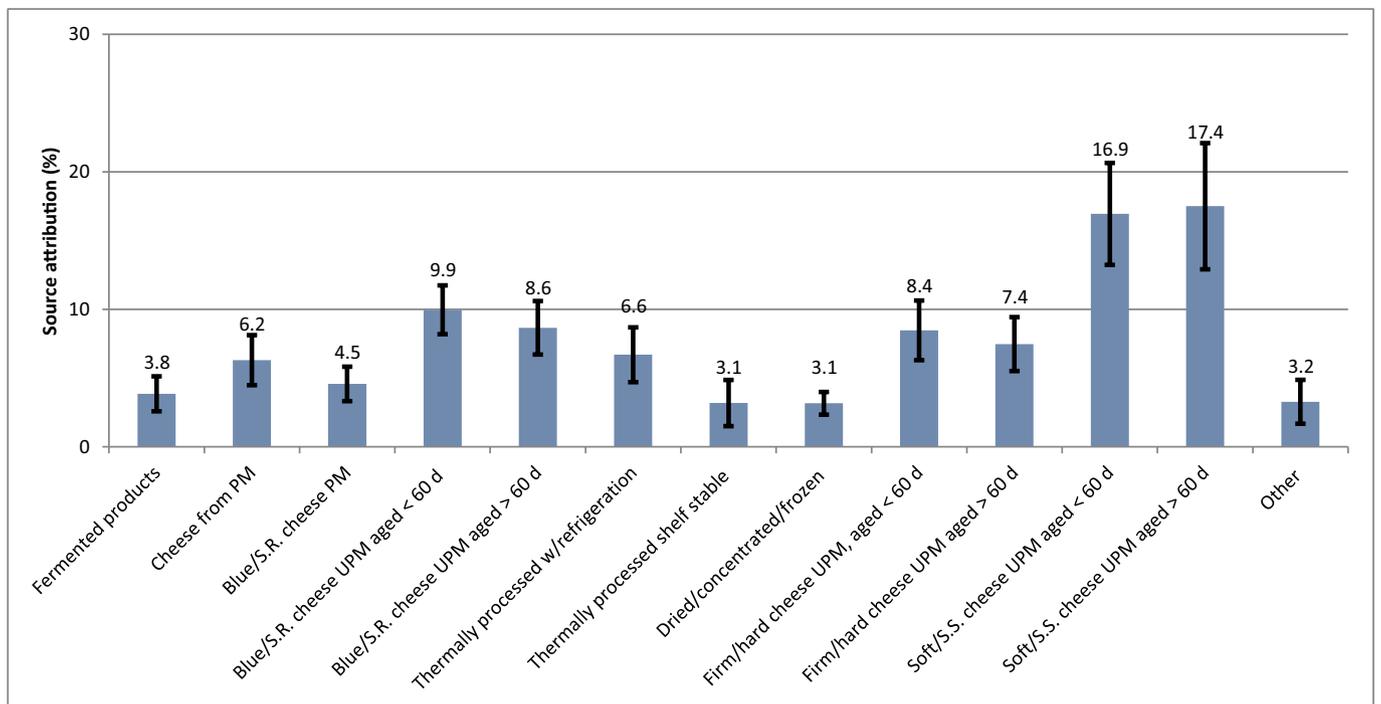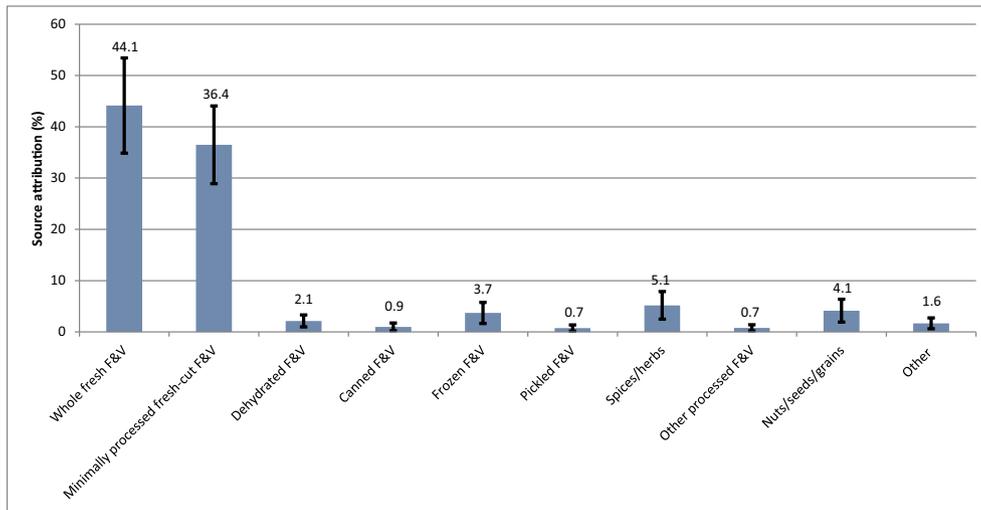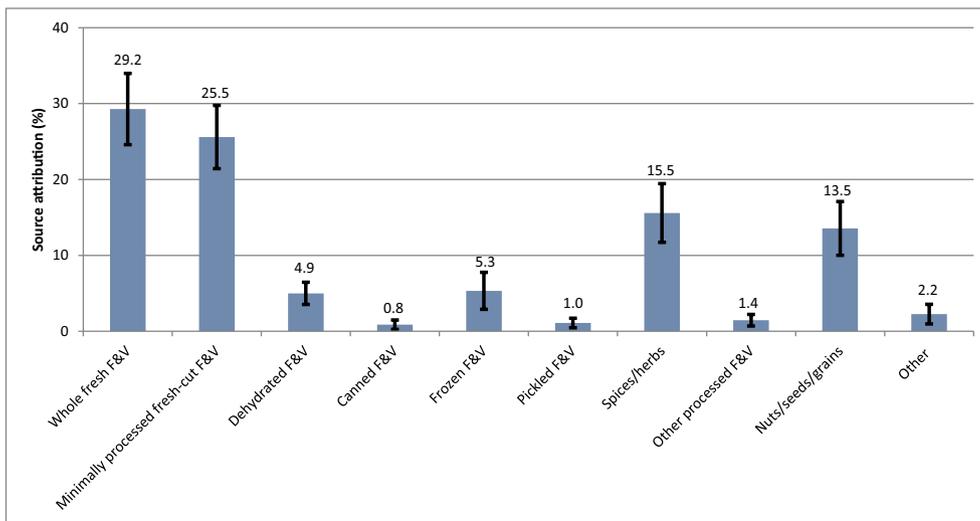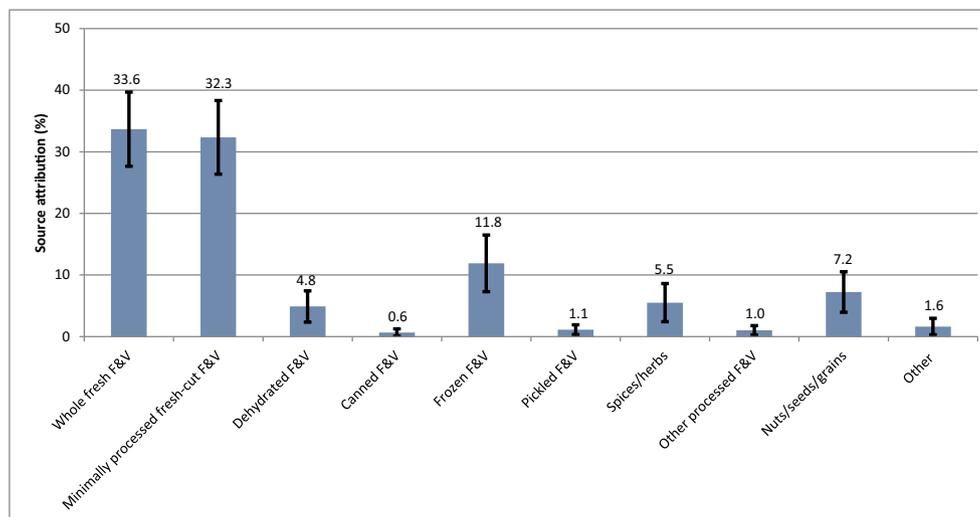

e: Dairy - L. monocytogenes
(n = 22, C = 4.9)

Fig. 5. (continued)

a: Campylobacter spp.
(n =28 , C = 5.7)

b: Salmonella non typhoidal
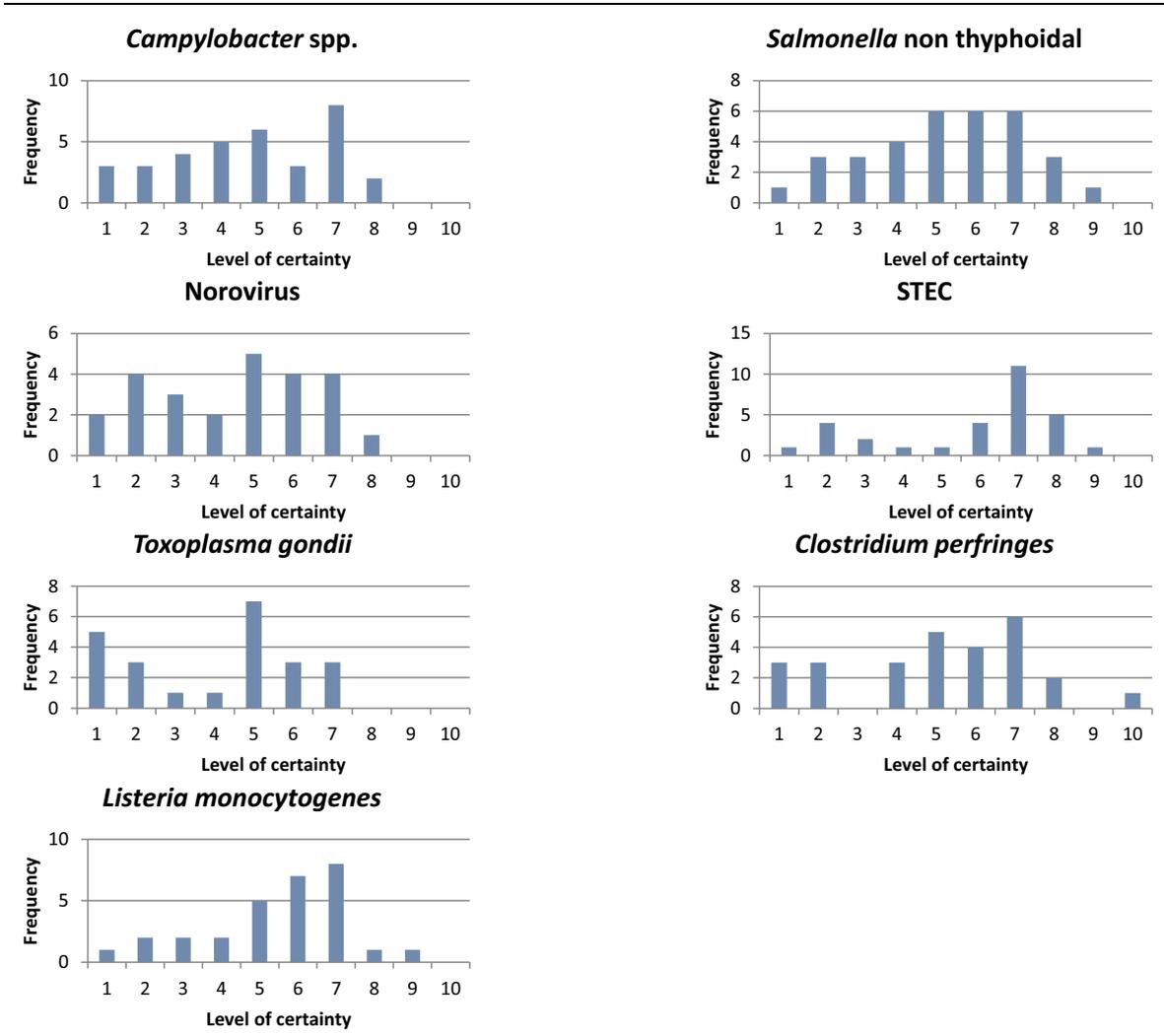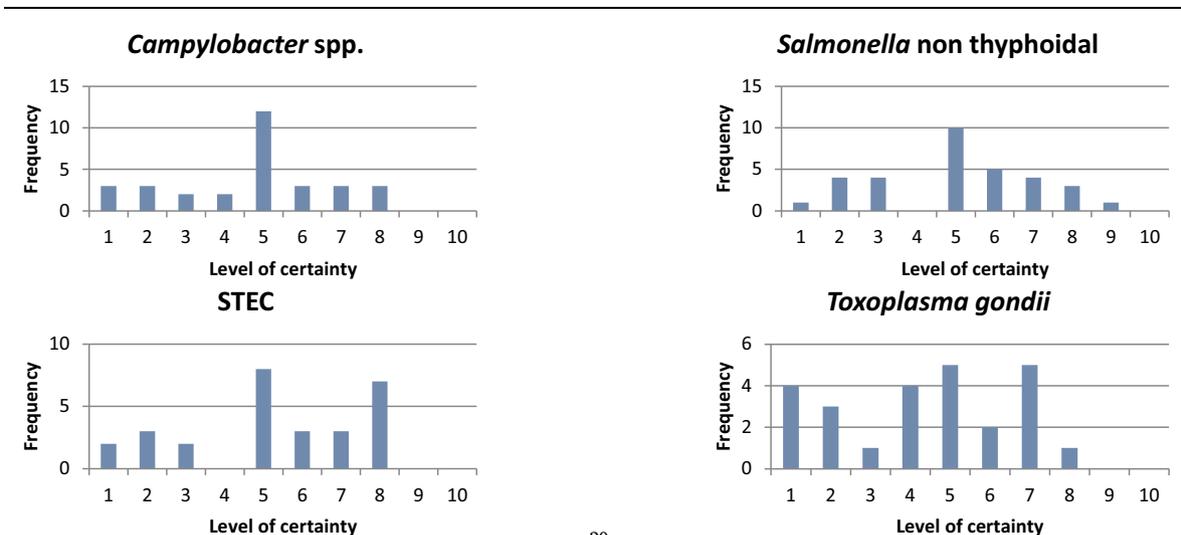(n = 32 , C = 5.7)

c: *Norovirus*
(n =24 , C = 5.3)

Fig. 6. a-e. Relative Contribution of individual Produce sub-products to the Total Number of Canadian Illnesses caused by different pathogens (n = number of participants, c = mean level of certainty, F&V = fruits and vegetables).
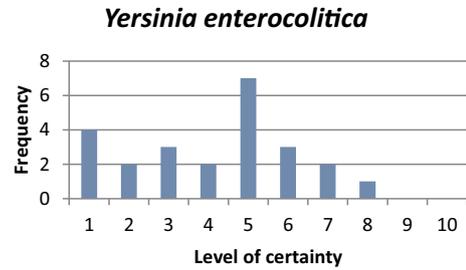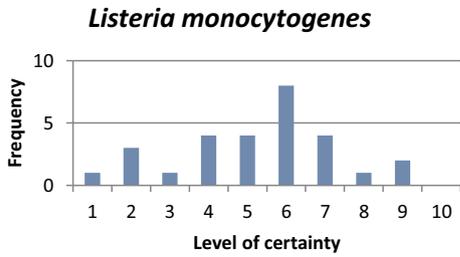
Appendix A

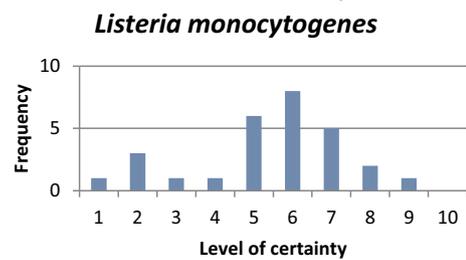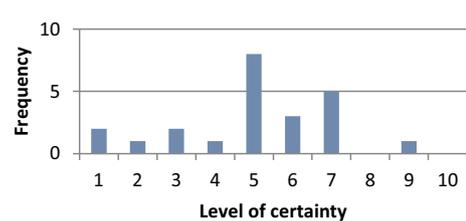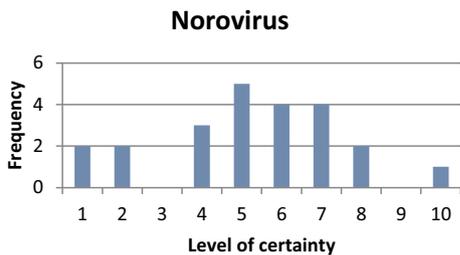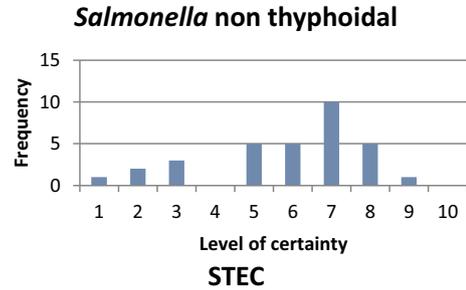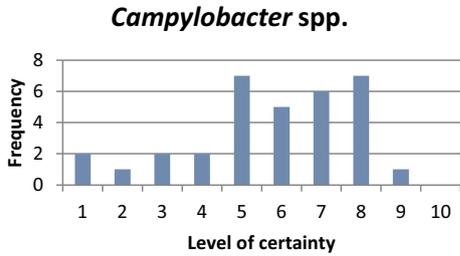*Number of experts by level of certainty for Beef sub-products*

Number of experts by level of certainty for Pork sub-products

Listeria monocytogenes

Yersinia enterocolitica

Number of experts by level of certainty for Poultry sub-products

Campylobacter spp.

Salmonella non thyphoidal

Norovirus

STEC

Toxoplasma gondii

Listeria monocytogenes
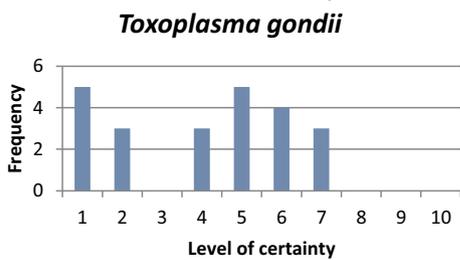
Number of experts by level of certainty for Game sub-products

Campylobacter spp.

Toxoplasma gondii

Number of experts by level of certainty for Eggs sub-products

Campylobacter spp.

Salmonella non thyphoidal
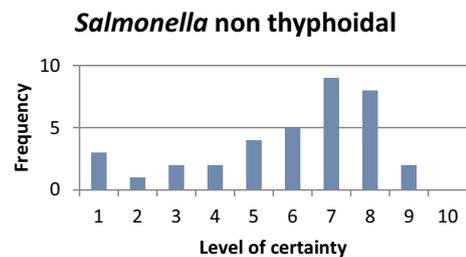
Number of experts by level of certainty for Produce sub-products

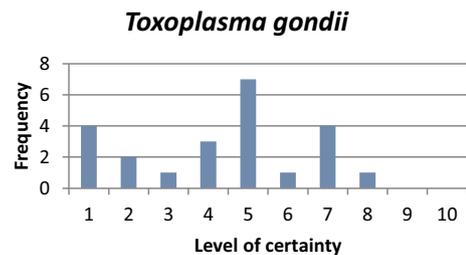**_Campylobacter_ spp.**

Salmonella non thyphoidal

Norovirus
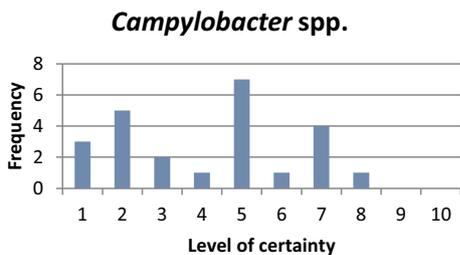
STEC

Toxoplasma gondii
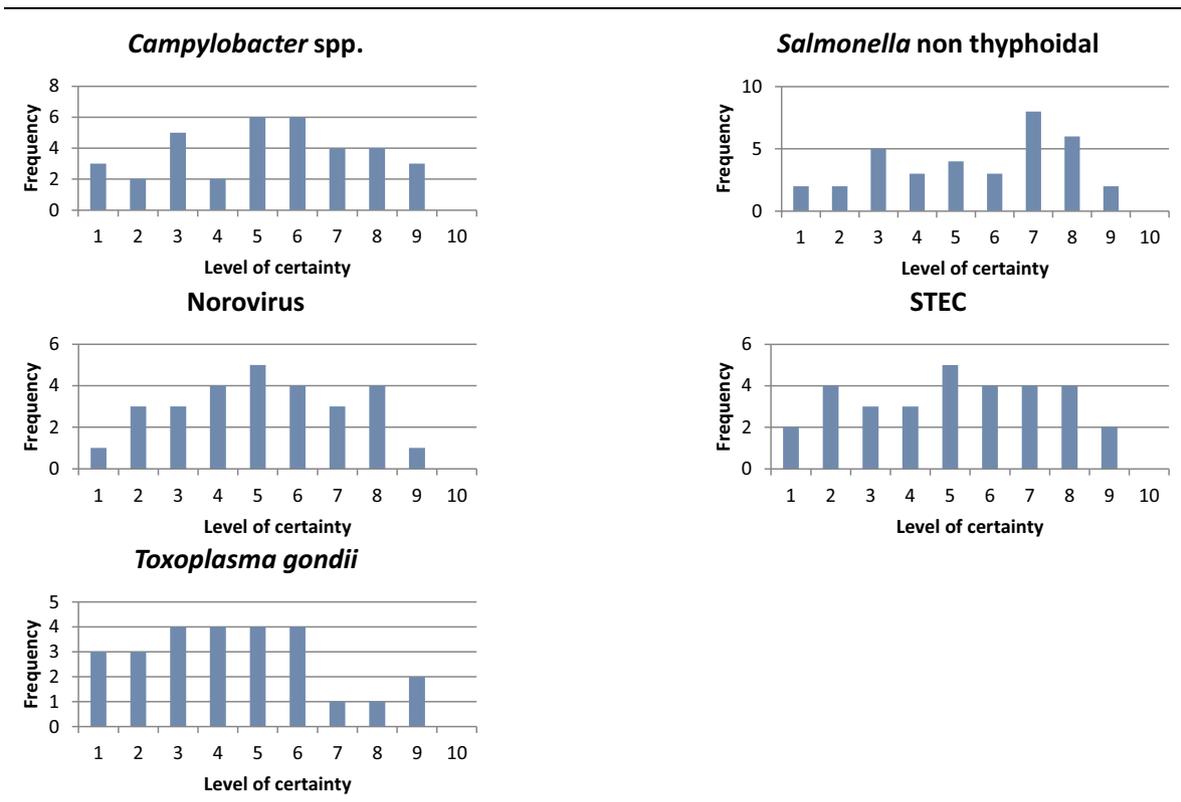
Number of experts by level of certainty for Dairy sub-products

Salmonella non thyphoidal

STEC

Listeria monocytogenes
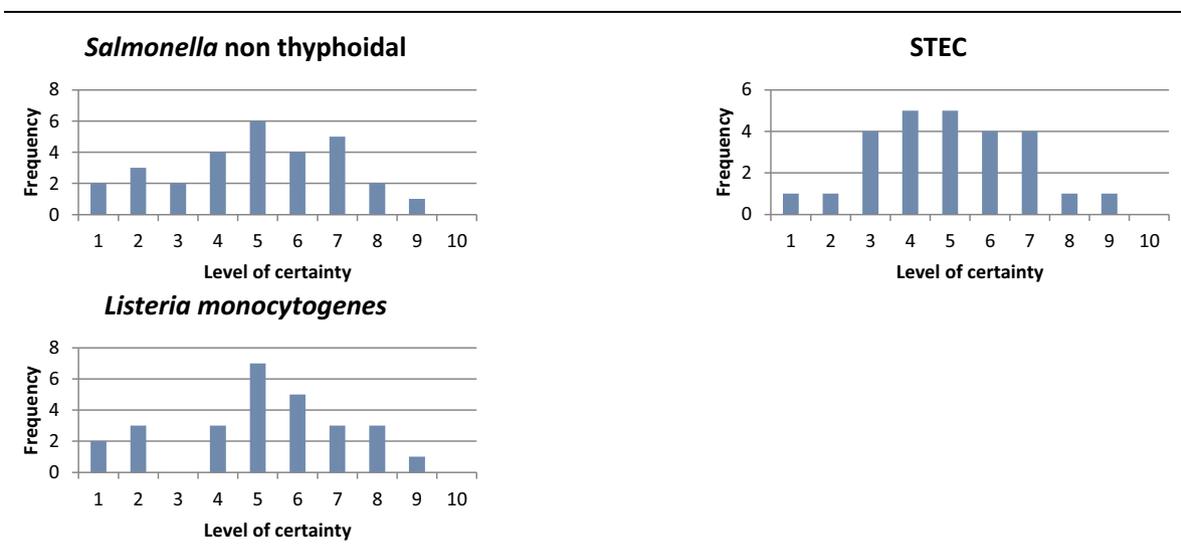
Appendix B. Supplementary data

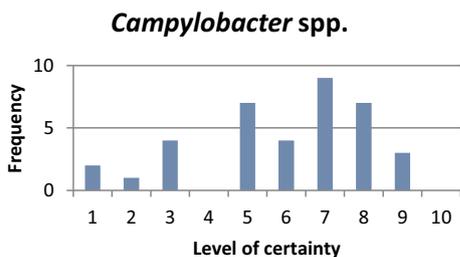Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijfoodmicro.2019.108241.

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