Canadian Food Agence canadienne Inspection Agency d'inspection des aliments

CFIA Risk modelling Examples of food safety Risk assessment

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Outline of presentation

Food risk assessment at the Canadian Food Inspection Agency (CFIA)

- Food Import Risk Explorer (FIRE) model for prioritizing imported food risks
 - Using FIRE model results to make decisions to manage food safety risks
- Risk Model to support the development of a <u>Performance Standards</u>
 - Salmonella in Poultry (an example)

What CFIA Does

The CFIA develops regulations and delivers inspection and other services to:



Vision

To excel as a science-based regulator, trusted and respected by Canadians and the international community.



Food Risk Assessments in the Government of Canada

- Health Canada
 - Primarily Qualitative risk assessments
- CFIA
 - Responsible for risk assessments using modelling to inform food risk management priorities, program design & implementation
 - For specific questions such as risk of a food-hazard combination of concern
 - Applies broadly at the program level to inform prioritization and resource allocation
 - Primarily use quantitative risk assessment methodology

Risk Assessments/Modelling in CFIA

- Risk assessment activities conducted by three groups in CFIA's Science Branch:
 - Animal Health Risk Assessment and Intelligence (AHRAI),
 - Plant Health Risk Assessment (PHRA) and
 - Food Advanced Data Analytics and Risk Modelling (FADARM)

Risk Assessment Fundamentals





World Organisation for Animal Health Founded as OIE

Identify the hazard Determine the likelihood of exposure Determine the consequence of exposure Integrate likelihood and consequence to provide a final risk estimate

- Identify the hazard (pest, bacteria, virus, etc.) that may cause harm to food safety, animal health or plant health
- What is the likelihood that the hazard will be introduced into Canada?
- What is the prevalence of the hazard in Canada?
- What is the likelihood of exposure to the hazard in Canada?

- What is the likelihood that the hazard causes harm in Canada?
- How severe are the consequences associated with the hazard in Canada?

- Includes an estimation of uncertainty
- Used to inform risk management options and decision-making

Uncertainty in Risk Assessment

- Results from incomplete or conflicting information
- Can be reduced or eliminated with more or higher quality information
- Must be documented in a risk assessment
 - Ensures risk management decisions account for this uncertainty
 - Ensures transparency in the process

Risk Assessors

- Risk assessment is carried out by highly trained subject matter experts in each business line:
 - Plant Botanists, Plant Pathologists, Entomologists
 - Animal Veterinarians, Epidemiologists,
 - Food Food Microbiologists, Epidemiologists, Veterinarians, Statisticians & Toxicologists

Advanced Data Analytics and Risk Modelling Team at the CFIA (Food)

Science-based evaluations and data-driven analytical solutions to support and inform program design and risk management decisions

Expertise in: Advanced data analytics (artificial intelligence) Epidemiology Risk modelling Statistical services

Examples of analytical and risk modelling solutions:

- Meat Slaughter Program Design
- Trend analysis methodology
- Food Import Risk Explorer (FIRE) model

Managing Food Risks to Canadians



Risk Communication

Food Risk Modelling Outputs









Estimate risk (high risk food-hazards combinations)

• e.g., *E. coli* O157:H7 in Raw ground beef

Estimate risk reduction (control or an inspection activity)

• e.g., Food safety defects removal in poultry (Modernized Poultry Inspection Program) Design Risk-informed performance standards

• e.g., *Salmonella* and *Campylobacter* Performance Standards in poultry (Pathogen Reduction)

Design Risk-based sampling

 e.g., Listeria monocytogenes Risk-based Sampling in Ready-To-Eat meat (Weatherill Recommendations)

Contribution to Managing Food Safety risks

Our products and activities provide scientific evidence to:

- Inform program design
- Develop policies
- Prioritize and manage risks



Respond to existing and emerging food issues

Tools

Software

- Literature Review (FIESCA)
- Statistical analysis and data visualization (Stata, SAS, R, Power BI, ArcGIS)



Power BI, Arc Risk modelling (FDA-iRisk, Analytica)



Collaboration

 Sharing intelligence and signals Sharing surveillance data, lab information and trend analysis reports Collaborate on data analysis
 Bilateral (e.g. US-FDA & USDA-FSIS) Sharing expertise and information (e.g. FDA-iRisk)
 Masters Student projects Consult with academics

Developing Food Risk Assessment Models Food Import Risk Explorer (FIRE) Model

Work is underway to develop:

A new innovative model that estimates imported food safety risks in Disability Adjusted Life Years (DALYs)

- Uses food-hazard-country of origin level data
- Able to compare relative risks across different hazard types (microbiological, chemical, allergens)
- Able to rank and prioritizes risk to inform program design and work plans

Model Building Blocks & Architecture



*Model Proof of Concept developed using microbial hazards in Fresh Fruit and Vegetables (FFV)

FIRE Methodology

$$DALYs_{CFH} = \frac{Trade_{CF}}{SS_F} \times P(Exp)_{CFH} \times P(Ill|Exp)_{CFH} \times DALYs_H$$

Where the <u>output</u> ($DALYs_{CFH}$) is **Canadian DALYs** for a food-hazard-country of origin combination, and:

- C, F, H Country, food, and hazard respectively.
- $\frac{Trade_{C,F}}{SS_F}$ Number of servings of the specified food from the specified country.
- $P(Exp)_{C,F,H}$ Probability the food from the given country is contaminated with the hazard (i.e., prevalence).
- $P(III|Exp)_{C,F,H}$ Probability of a becoming ill after exposure to a contaminated serving (by country, food and hazard). This value is affected by dose (i.e. dose-response relationship), and incudes consideration of cooking and/or growth.

 $DALYs_H$ - DALYs per case for the specified hazard.

Salmonella in Fresh Herbs from Country X

Step 1: Calculate the proportion of imported food consumed.

$$DALYs_{CFH} = \frac{Trade_{CF}}{SS_F} \times P(Exp)_{CFH} \times P(Ill|Exp)_{CFH} \times DALYs_H$$

Amount of Fresh Herbs imported from Country X¹: $Trade_{CF} = 146,057$ kg

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Serving size of Fresh Herbs<sup>2</sup>: SS_F = 41 \text{ g}
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¹ Data retrieved from Statistics Canada - <u>Canadian International Merchandise Trade Database</u>. ² Lyons, J (2013). *The Irish Food Portion Sizes Database*. Available at: <u>https://www.iuna.net/</u>

Salmonella in Fresh Herbs from Country X

Step 2: Calculate the probability that food from a given country is contaminated by the hazard.



¹ Data from CFIA food surveillance programs.

Salmonella in Fresh Herbs from Country X

Step 3: Calculate the probability that a person will become ill after exposure to the hazard.

$$DALYs_{CFH} = \frac{Trade_{CF}}{SS_F} \times P(Exp)_{CFH} \times P(III|Exp)_{CFH} \times DALYs_H$$

$$P(III|Exp)_{CFH} = f_H(dose_{CFH})$$

$$= 1 - (1 + (dose_{CFH}/51.45))^{-0.1324}$$

$$= 1 - \left(1 + \left(\frac{2.46 \ CFU/serving}{51.45}\right)\right)^{-0.1324}$$

$$P(III|Exp)_{CFH} = 0.0062$$

Beta-Poisson model for Salmonella¹: $f_H(dose_{CFH}) = 1 - (1 + (dose_{CFH}/51.45))^{-0.1324}$

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Where,

dose_{CFH} = SS_F \times 10^{C_{CFH}+G_{FH}-LR_{FH}}

= 41 \ g \times 10^{\log(0.06\frac{CFU}{g})+0-0}

dose_{CFH} = 2.46 \ CFU/serving
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 $f_H(d)$ - Hazard specific dose-response model dependent upon the ingested dose d

 C_{CFH} - Concentration of hazard (log₁₀) by country, food, hazard

 G_{FH} - Growth of hazard (log₁₀) by food and hazard; 0 for *Salmonella* on Fresh Herbs

 LR_{FH} - Reductions in hazard concentration (log₁₀) post sampling, and prior to consumption (e.g., cooking); 0 for Fresh Herbs

¹ World Health Organization. *Risk assessments of Salmonella in eggs and broiler chickens*. Vol. 2. Food & Agriculture Org., 2002.

Salmonella in Fresh Herbs from Country X

Step 4: Multiply by the number of DALYs per case for the specified hazard



¹ Havelaar, Arie H., et al. <u>"Disease burden of foodborne pathogens in the Netherlands, 2009."</u> International journal of food microbiology 156.3 (2012): 231-238.

Salmonella in Fresh Herbs from Country X

Putting it all together...

 $DALYs_{CFH} = \frac{Trade_{CF}}{SS_F} \times P(Exp)_{CFH} \times P(III|Exp)_{CFH} \times DALYs_H$ $= \frac{146,057 \ kg}{41 \ g} \times 0.0143 \ \times 0.0062 \ \times 0.049 \frac{DALYs}{case}$ $DALYs_{CFH} = 15 \ DALYs$

Result is 15 DALYs for *Salmonella* in Fresh Herbs from Country X.

Comparative Risks using FIRE Model Results in Fresh Fruits and Vegetables

Countr	Food	Hazard	Risk
<u>у</u> 		E coli $O157$	(DALTS) 820
 		Salmonella	658
<u> </u>	Fresh	Salmonella	262
C	Herbs	Camonona	202
А	Blackberrie	Norovirus	136
	S Die else envie		
A	S Blackberrie	E. COILUT57	59
М	Blackberrie	Salmonella	51
	S		
A	Fresh Herbs	Salmonella	39
G	Fresh	E coli Q157	27
U U	Herbs		
A	Lettuce	Salmonella	21
А	Fresh	Salmonella	16
	Herbs	<u>ΔΙ Υs· 2118</u>	
G	Blackberrie '	Norovirus	11
M	Lettuce	E. coli O157	8
М	Fresh	Salmonella	6
	Herbs		
М	Blackberrie	Norovirus	4

Risk Profiles (FFV demonstration)

Data Visualization



Applications: Putting the model to work

FIRE will help the CFIA....

- 1 Identify and prioritize food safety risk management reviews, which can trigger changes to program design (risk control measures in place).
- 2 Identify offshore workplan priorities i.e. which countries/commodities/products/systems could be subject to offshore activities.
- 3 Identify if importers of certain foods from a specific country/region require a targeted Preventive Control Inspection (PCI) above and beyond the frequency prescribed by Importer Risk Assessment model, and/or a targeted communication.
- 4 Identify sampling gaps.
- 5 Identify signals e.g. changes to risk levels, emerging issues etc.

FIRE will become a hub that connects diverse datasets (trade, sampling, incident/recall, illness etc.) and generates reports that many other groups can use to support their work and decision-making

The Road Ahead



- Continue to onboard more food commodities (e.g. fish and seafood & dairy) and include chemical hazards
- Add new data elements to enhance the food safety story (incident/recall, outbreak, other government department data)
- Explore Artificial Intelligence tools for automation

Continue to collaborate with internal, external and international partners....

Break/Questions?

Agence canadienne d'inspection des aliments



Risk Model to Support the Development of a Performance Standards (e.g. Salmonella in Poultry)

Canada



Overview

- Pathogen Reduction Program
- Risk model
 - Objectives and expected outcome
 - FDA-iRISK software
 - Process model elements
 - Performance standards scenarios (microbial sampling plans)
 - Scenario outputs
- Next steps

Pathogen Reduction Program Past, Present and Future





Exports based Model (Export requirement using FSIS standards) (1998-2016)

Hybrid Model (Domestic requirement using FSIS Standards) 2017 - Present Canadian Model (Domestic requirement using Domestic Standards) Moving Forward

CFIA is working on modernizing the poultry pathogen reduction program by expanding its scope and developing Canadian standards.

Objective of Risk Model

- 1. Provide a "proof of concept" for the use of risk modeling to estimate the population level health burden, and
- 2. Demonstrate the use of these risk models to compare the predicted reduction in health burden associated with a series of hypothetical performance standards for *Salmonella* in broiler chickens.

Expected Outcome:

Guide the design of Canadian performance standards for Salmonella in raw poultry products.

Process model elements



FDA-iRISK

- Web-based tool¹:
 - Developed by US Food & Drug Administration (FDA).
 - Provides structure for creating multi-process food safety risk models.
 - Population level health burden as the output

1. Food and Drug Administration Center for Food Safety and Applied Nutrition (FDA/CFSAN), Joint Institute for Food Safety and Applied Nutrition (JIFSAN), & (RSI), R. S. I. (2020). FDA-iRISK® version 4.2i. from FDA CFSAN https://irisk.foodrisk.org/

FDA-iRISK[®] 4.2i Home Risk Models Reports Home -> Risk Models (ashwani.tiwari@inspection.gc.ca: Broiler Models Imported Nov 10 2021). CONDITIONS Baseline data Whole Chicken - Salmonella Log CFU) -> Name and Initial Condition View Process Model Instructions Name and Initial Conditions Process Stages (0) Downstream Models (4) Model Name: INITIAL CONDITIONS Baseline data Whole Chicken -Salmonella Log CFU **Initial Conditions:** Parameter Value Uncertainty Hazard: Salmonella N/A **Broiler** Chicken N/A Food: Initial Units Yes N/A are Contaminated: Initial Prevalence: 0.169 Mass Units: N/A α Initial Unit Mass: Distribution Value Uncertainty Parameter Fixed Value Variability Distribution: N/A Value: 1400 Chart is not displayed when the distribution is set to Fixed Value Initial Concentration: Parameter Value log₁₀ cfu / a Units:

	1.210	
Distribution:	Empirical (linear)	
The cumulative empirical distribution (cubic or linear) is used to enter a distribution using cumulative probability/value pairs.	0,-3.1 0.21,-2.06694679 0.74,-1.08167004 6	
It may be entered as a table (default) or in a textbox.	0.949,-0.0683968 56 0.986,0.49692964	
When entered as a table, insert, delete or add rows as required. When entered in a textbox, each pair must be on a separate line and the format must be "cumulative probability,value" (e.g. 0.1, -3).	8 1,0.756961951	



Prevalence & concentration

2013 CFIA Baseline Survey¹

- Whole chicken carcass (~1.7 Kg)
- Prevalence of *Salmonella* = 16.9%
- Concentration = -0.67 log CFU/g (-3.1 log CFU/g – 0.76 log CFU/g)



Figure. Empirical cumulative probability distribution of the initial concentration of *Salmonella* in fresh broiler carcasses.

1. Canadian Food Inspection Agency. (2016). National Microbiological Baseline Study in Broiler Chicken 2012-2013.

Growth Models for Transport & Storage Stages



Growth model for *Salmonella* Typhimurium in cooked chicken breast^{1,2}.



Time and temperature during storage and transport estimated from previous JEMRA² and Audits International³ reports.



Figure. Empirical cumulative probability distributions of the temperature profiles use for storage at retail (A) and transport from retail to consumer (B) created from Audits International survey data³.

1. Oscar, T. P. (1999). Response surface models for effects of temperature and previous growth sodium chloride on growth kinetics of Salmonella typhimurium on cooked chicken breast. J Food Prot, 62(12), 1470-1474. doi:10.4315/0362-028x-62.12.1470

2. Food and Agriculture Organization of the United Nations. (2002). Risk assessments for salmonella in eggs and broiler chickens: interpretative summary. In. Rome: World Health Organization

3. Audits International, & FDA. (1999). U.S. Food Temperature Evaluation. Retrieved from http://foodrisk.org/resources/display/20

Inactivation of Salmonella (Consumer Cooking)

- Temperature-dependent *D*-value calculated from thermal inactivation data of *Salmonella* in chicken matrices^{1,2,3}.
- Maximum internal temperature distribution modelled from Ecosure 2007 survey data⁴.

- 1. Murphy, R. Y., Duncan, L. K., Johnson, E. R., Davis, M. D., & Smith, J. N. (2002). Thermal inactivation D- and z-values of Salmonella serotypes and listeria innocua in chicken patties, chicken tenders, franks, beef patties, and blended beef and turkey patties. J Food Prot, 65(1), 53-60. doi:10.4315/0362-028x-65.1.53.
- Murphy, R. Y., Marks, B. P., Johnson, E. R., & Johnson, M. G. (1999). Inactivation of Salmonella and Listeria in ground chicken breast meat during thermal processing. J Food Prot, 62(9), 980-985. doi:10.4315/0362-028x-62.9.980.
- Murphy, R. Y., Osaili, T., Duncan, L. K., & Marcy, J. A. (2004). Thermal inactivation of Salmonella and Listeria monocytogenes in ground chicken thigh/leg meat and skin. Poult Sci, 83(7), 1218-1225. doi:10.1093/ps/83.7.1218.
- EcoSure, & FDA. (2008). 2007 U.S. Cold Temperature Evaluation. Retrieved from https://www.foodrisk.org/resources/display/21.

Carcass Chilling Instal Instal Instal Concentration Child Baseline Onda (2013) Child Baseline Onda (2013) Carcass Chilling Consumer Consumer Transport Storage Consumer Transport Consumer Transport Consumer Transport Consumer Transport Consumer Transport Consumer Consumer



Figure. Empirical cumulative probability distributions of the temperature profiles use for consumer cooking, created from Ecosure survey data⁴.

Serving Consumption



- Model is based on 1,000,000 servings of each type of poultry product.
- Distribution of consumer serving size (grams)
 - from US-CDC Nutritional Health and Nutrition Examination Survey (NHANES)¹.



Figure. Empirical cumulative probability distribution of the average serving size of chicken per eating occasion.

1. National Center for Health Statistics. (2022). National Health and Nutrition Examination Survey. Retrieved from https://www.cdc.gov/nchs/nhanes/index.htm

Salmonella Dose-Response Model



- Describes the relationship between the ingested dose and the probability of illness
- Beta-Poisson model used by FAO/WHO in 2002 Salmonella in broilers risk assessment¹.
 - No minimum infectious dose (note the log₁₀ scale)
- DALYs/illness estimated as 0.051^{2,3}.
- 1. Food and Agriculture Organization of the United Nations. (2002). Risk assessments for salmonella in eggs and broiler chickens: interpretative summary. In. Rome: World Health Organization.
- Gibney, K. B., O'Toole, J., Sinclair, M., & Leder, K. (2014). Disease burden of selected gastrointestinal pathogens in Australia, 2010. Int J Infect Dis, 28, 176-185. doi:10.1016/j.ijid.2014.08.006.
- Havelaar, A. H., Haagsma, J. A., Mangen, M.-J. J., Kemmeren, J. M., Verhoef, L. P. B., Vijgen, S. M. C., . . . van Duynhoven, Y. T. H. P. (2012). Disease burden of foodborne pathogens in the Netherlands, 2009. International journal of food microbiology, 156(3), 231-238 %@ 0168-1605.

Probability of Response and Adverse Effect

Dose Response Chart

Figure. Empirical cumulative probability distribution of the average serving size of chicken per eating occasion.

Microbiological Sampling Plan Analysis Tool



FAO Microbial Sampling Plan Analysis Tool¹.

 Assess the performance of a range of sampling plans, independent of the pathogen or commodity.



1. Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment. (2022). Microbiological Sampling Plan Analysis Tool. http://tools.fstools.org/Samplingmodel/

Operating Characteristic Curve (OC curve)



- Describes the relationship between mean concentration and probability of lot rejection
- Each sampling plan has a specific OC curve
- 4 curves with decreasing stringency (from left to right) as number of acceptable positive samples increases



Figure. Operating characteristic curves describing the relationship between mean concentration of Salmonella in a lot and the probability of rejecting that lot. Each curve represents a unique scenario where n = 51 samples are collected from the lot, and a performance standard representing the maximum allowable number of unacceptable samples (i.e., positive for Salmonella; c = 3, 5, 10, 15) before rejecting the lot.

FDA-iRISK Output Reports



FDA-IRISK[®] 4.0

Report Title: Salmonella Whole Chicken PS analysis

Report Date: 2

Disclaimer

Report Title: FDA-iRISK Risk Estimates and Scenario Ranking Report

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Ranking Summary

All reported summary values are per year. For chronic scenarios, results for the total lifecourse have been divided by the lifecourse duration (e.g. 70 years) specified for the life stages included in the scenario.

Scenario or Scenario Group	Total DALYs per Year	Uncertainty Results
_Salmonella Whole Chicken No PS	62.1	N/A
_Salmonella Whole + PS 1ml n=51 c=15	30.9	N/A
_Salmonella Whole + PS 1ml n=51 c=10	21.5	N/A
_Salmonella Whole + PS 1ml n=51 c=5	13.3	N/A
_Salmonelia Whole + PS 1ml n=51 c=3	10.3	N/A
_Salmonella Whole + PS 1ml n=51 c=15 _Salmonella Whole + PS 1ml n=51 c=10 _Salmonella Whole + PS 1ml n=51 c=5 _Salmonella Whole + PS 1ml n=51 c=3	30.9 21.5 13.3 10.3	N/A N/A N/A N/A

Scenario	Lifecourse Duration	Eating Occasions or Consumers	Total Ilinesses	Mean Risk of Illness	Total DALYs per Year	DALYs Per EO or Consumer	Total DALYs per Year (Weighted)
_Salmonella Whole Chicken No PS	N/A	1.00E+6	1220	0.00122	62.1	0.0000621	62.1
_Salmonella Whole + PS 1ml n=51 c=15	N/A	1.00E+6	605	0.000605	30.9	0.0000309	30.9

Risk scenarios (without & with performance standards testing)



Table. Predicted public health burden of Salmonella under a various performance standards scenarios. Each scenario represents a collection of 51 samples from each establishment over 52 weeks, and a performance standard of the maximum number of unacceptable samples allowed (c) before failure of the establishment.

		Scenario	Total Illnesses/million	Total DALYs/million
Increasing Stringency		No Standards	servings 1250	servings 64.0
		c = 15	37.6	1.92
		c = 10	17.6	0.90
₹	Y	c = 5	5.91	0.30
		c = 3	3.36	0.17

Next Steps

- Improve the current Salmonella risk model,
 - Include uncertainties
 - Improve time/temperature
 - Include cross-contamination
- Collaborate with stakeholders to guide the development of Canadian performance standards for Salmonella in fresh poultry,
- Adapt the current risk model to Campylobacter in raw poultry, and
- Adapt the current risk model to other raw poultry products
 - Frozen breaded and/or stuffed raw chicken products

Thanks & Questions ?

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