Canadian Food Inspection Agency | Agence canadienne d'inspection des aliments

Canadian Food Inspection Agency

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

Our mission:
Dedicated to safeguarding food, animals and plants, which enhances the health and well-being of Canada's people, environment and economy.

CFIA's Risk-based sampling model

NAPPO RBS Symposium, June 2017

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Introduction

- Risk-Based Sampling Approach for *Listeria monocytogenes* in Ready-to-Eat Meat and Poultry Products (RBSA)
- Pilot study
- Potential Adaptation to Plant Imports

Purpose

- To share a proposed new CFIA risk-based sampling approach (RBSA) for *Listeria* in Ready-to-Eat meat products
- Potential adaptation of the model to plant commodity imports

Background

- Following the 2008 Listeriosis outbreak in Canada
  - Recommendation16 in Weatherill's Report impresses on CFIA to revise its sampling approach as it states, *"The CFIA should revise its monitoring programs (M200 and M205), by tailoring the sampling frequencies to each plan based on risk factors including compliance history, product risks and target market etc. (i.e. higher sampling frequency in some establishments, lower in others)".*
- Two sampling plans were implemented in 2011
  - M200RB: risk-based sampling plan
  - M205RB: risk-based environmental sampling plan
- A new sampling approach (RBSA) was developed to refine M200RB and tested via a pilot study in 2015-16 in consultation with CFIA and Health Canada.

OBJECTIVE of RBSA

- Refine the current CFIA **M200RB** sampling plan by:
  - Allocating CFIA samples to establishments more likely to produce *Lm* contaminated products
  - Targeting CFIA resources more efficiently via establishment risk rating
  - Using quantitative risk-based approach
    - Risk-based algorithm
    - Accounts for risk factors
    - Sample each establishment at least once
    - Easy to implement
    - Flexible to allow future evolution

Current M200RB Sampling Plan

Sample size ≈ 687 samples (2013-14)

- Sampling frequency is determined according to:
  - The risk category of RTE products produced
  - Control procedures for *Listeria*

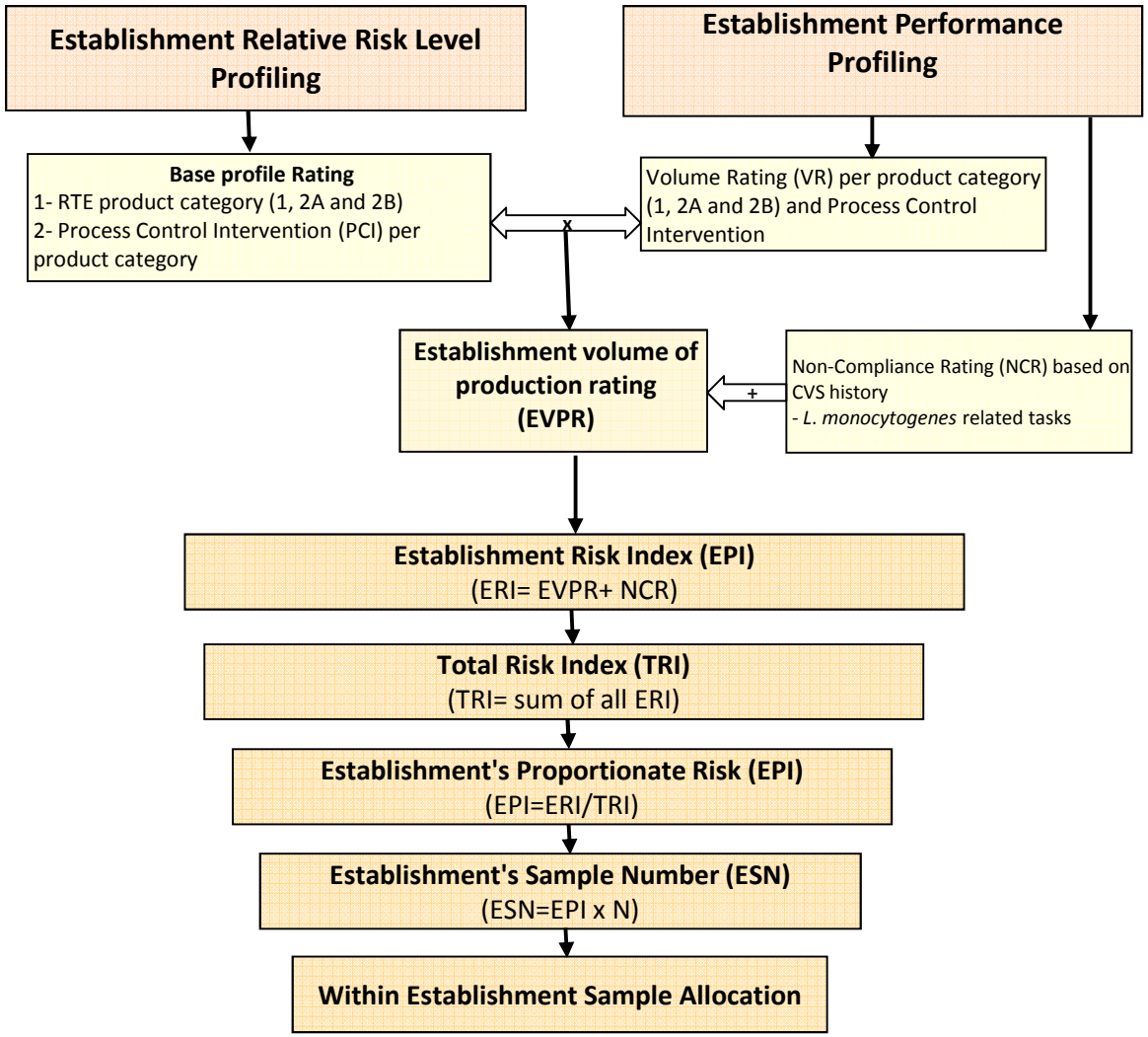
Sampling frequencies based on Relative Risk Level

Product category*	Sanitation alone	Antimicrobial(s)	Post-lethality Treatment	Antimicrobial(s) and Post-lethality Treatment
Category 1	4	3	3	2
Category 2A	2	1	1	1
Category 2B	1	1	0	0

- Time to incorporate additional risk factors:
  - Volume of production
  - Non-Compliance history

* Category 1 – RTE products support the growth of *Lm* (Zero tolerance)
Category 2A – RTE products with limited growth of *Lm*
Category 2B – RTE products which growth of *Lm* can not occur in stated shelf-life

Quantitative Risk-Based Sampling Approach (RBSA)



Relative rates for RTE product categories and Process Control Interventions

- RTE Product Categories (1, 2A, 2B)

Product category	Proposed Relative Rating
1	0.9
2A	0.35
2B	0.3

- Process Control Intervention (PCI)

Process Control Interventions	Proposed Relative Rating
Sanitation only	0.9
Anti-Microbial (AM)*	0.5
Post-Lethality treatment (PL)	0.5
AM+PL	0.3

* As per Health Canada's "Policy on Listeria monocytogenes in Ready-to-Eat Foods-2011"; Antimicrobial agent allowing no more than 2 log CFU/g increase in *L. monocytogenes* throughout the stated shelf-life of the product.

Establishment Performance Profiling (EPP)

1. Production volume rating (VR) assigned in house based on:
   - ISO-2859-1 sampling protocol

Establishment volume of production (kilograms/year)	**Relative Rating**
under 850	0.05
850 - 1,550	0.1
1,551 - 2,550	0.15
2,551 - 5,050	0.2
5,051 - 9,050	0.25
9,051 - 15,050	0.3
15,051 - 28,050	0.35
28,051 - 50,050	0.4
50,051 - 120,050	0.45
120,051 - 320,050	0.5
320,051 - 1,000,050	0.6
1,000,051 - 3,500,050	0.7
3,500,051 - 15,000,050	0.8
15,000,051 - 50,000,050	0.9
over 50,000,050	0.99

Establishment Performance Profiling (EPP)

2. Non-Compliance Rating (NCR) based on inspection tasks

- Proportion of the total number of non-compliant inspection tasks found to the total number of selected inspection tasks conducted
  - Operator Sampling
  - CFIA Domestic Sampling

Establishment risk index

- Once the ratings are developed and ready, then:

Base profile rating (BPR)

Product category / Interventions	Category 1 (0.9)	Category 2A (0.35)	Category 2B (0.3)
Sanitation only (0.9)	0.9 × 0.9=0.81	0.315	0.27
Anti-Microbial (AM) (0.5)	0.45	0.175	0.15
Post-Lethality (PL) (0.5)	0.45	0.175	0.15
AM + PL (0.3)	0.27	0.105	0.09

Establishment volume of production rating (EVPR)

Product category / Interventions	Category 1	Category 2A	Category 2B	Total
Sanitation only	BPR × VR			
Anti-Microbial (AM)				
Post-Lethality (PL)				
AM + PL				
Total				EVPR

- Establishment risk index (ERI) = EVPR + NCR

Pilot study for 2013-14 data

- Data gathered from 26 establishments surveyed in 2015
  - Volume of production of RTE
    - 13% produced up to 100,000 kg (very small size)
    - 50% produced between100,000 to 2,000,000 kg (small size)
    - 23% produced 2,000,000 to 6,000,000 kg (Medium size)
    - 14% produced more than 6,000,000 kg (Large size)

M200RB delivery for 2013-14

- Samples collected under sampling plan pilot
  - 83 samples
  - Those 83 samples were re-allocated based on new RBSA
  - Results are presented and compared to traditional sampling plan M200RB

Comparison of RBSA's results to M200RB

Est #	Establishment volume of production rating (EVPR)	Non-Compliance rate (NCR)	Establishment Risk index (EVPR+NCR)	RBSA	M200RB samples+ (83)	Change
1	0.7470	0	0.7470	5	4	Yes (+)
4	0.5670	0	0.5670	4	4	No
5	0.5670	0.0263	0.5933	4	4	No
8	0.3645	0	0.3645	3	4	Yes (-)
14	1.0530	0.0256	1.0786	7	4	Yes (+)
17	0.5670	0.0625	0.6295	4	4	No
18	0.3600	0	0.3600	3	4	Yes (-)
19	0.6480	0.0513	0.6993	5	4	Yes (+)
21	0.1890	0	0.1890	1	4	Yes (-)
26	0.1350	0	0.1350	1	1	No

Findings and comparison to M200RB

- 73% of establishments have zero non-compliance rate
- The number of samples collected ranged from 1 to 7
- Changes in sample allocation occur in 62% of the establishment. For example:
  - Increase number of allocated samples from 4 to 7 in establishment #14
    - Highest risk index, highest risk category products, Very large establishment, use of sanitation and antimicrobial agent
  - Reduction number of allocated samples from 4 to 1 in establishment #21
    - Category 2B products, very small size establishment and use of sanitation alone.
- No changes in sample allocation occur in 38% of the establishments

Conclusion and considerations

- Preliminary results indicate
  - RBSA is effective in allocating sampling frequency
- Limitations
  - Requires one full year of data collection prior to implementation
- Considerations
  - Annual data collection

Next steps

- Proposed validation of RBSA
  - Large-scale study include all RTE federally registered establishments (on going right now)
  - Incorporate more inspection tasks, such as sanitation related tasks
- Collaboration with industry
  - To carry out a large-scale study to validate the RBSA approach
  - To collect volume of production per product category and process control interventions

Potential Adaptation to Plant Imports

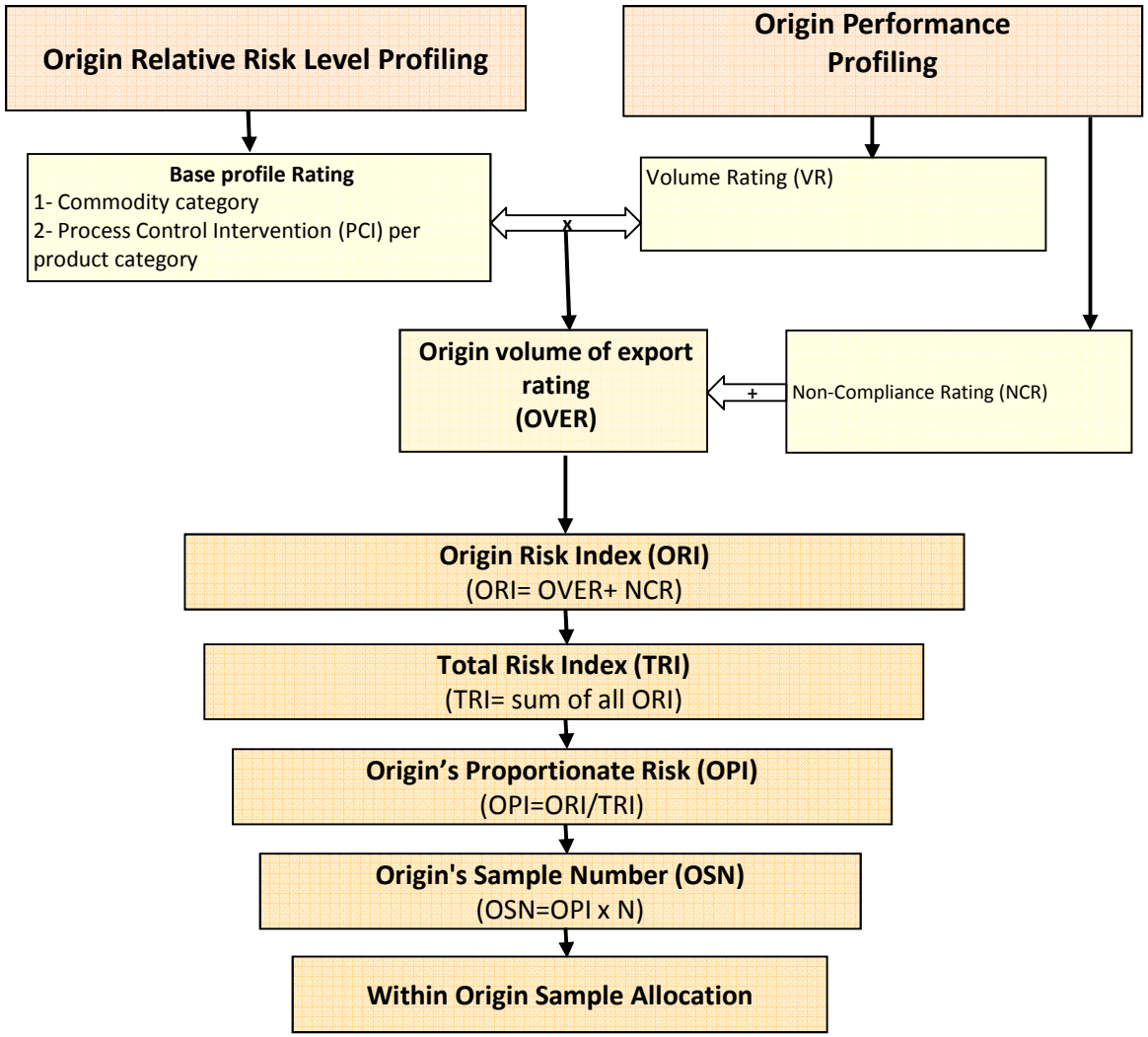
Model inputs:

Listeria Model	Potential Plant Health Variables
Food Establishment	Country of Origin
Product Category	Plant Commodity groups
Process Controls/Intervention	Same concept with plant production controls*
Non-compliance	Same concept applied to country of origin**

* Data in plant health is binary as opposed to continuous in Listeria Model (function of import requirements) but does not affect algorithm

** Possibility of incorporation of exporter if data available

Potential Adaptation to Plant Imports



Potential Adaptation to Plant Imports

SRM = possibly in association with soil and related matter

NSRM = not in association with soil and related matter

Product category	Proposed Relative Rating
1 - Temperate propagative, SRM	0.9
2 - Temperate non-propagative, SRM	0.4
3 - Tropical, SRM	0.35
4 - Temperate propagative, NSRM	0.7
5 - Temperate non-propagative, NSRM	0.5
6 – Tropical, NSRM	0.3
Process Control Interventions	**Proposed Relative Rating**
Pre-shipment NPPO inspection	0.7
Pre-shipment NPPO approved treatment	0.5
Produced under NPPO program	0.4
Intended for processing	0.3

Potential Adaptation to Plant Imports

Base profile rating (BPR)

Product category / Interventions	1 (0.9)	2 (0.4)	3 (0.35)	4 (0.7)	5 (0.5)	6 (0.3)
Pre-shipment NPPO inspection only (0.7)	0.9 × 0.7 **0.63**	0.28	0.24	0.49	0.35	0.21
Pre-shipment NPPO approved treatment (0.5)	0.45	0.20	0.175	0.35	0.25	0.15
Produced under NPPO program (0.4)	0.36	0.16	0.15	0.28	0.20	0.12
Intended for processing (0.3)	0.27	0.12	0.105	0.21	0.15	0.09

Origin volume of export rating (OVER)

Product category / Interventions	1	2	3	4	5	6	Total
Pre-shipment NPPO insp. only	BPR × VR						
Pre-shipment NPPO treatment							
Produced under NPPO program							
Intended for processing							
Total							EVPR

Origin risk index (ORI) = OVER + NCR

Thank you for your attention!

Questions?