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.

Establishment-based Risk Assessment Model

International Symposium on Food Safety

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Canada

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Agenda

- Background
- Overview of the Establishment-based Risk Assessment (ERA) model
  - ERA Model Development
  - Refinement and selection process
  - Pilot Project and Performance Evaluation
- ERA Results and Benefits

Background

- As part of the inspection system modernization initiative, the Canadian Food Inspection Agency (CFIA) has developed an Establishment-based Risk Assessment (ERA) model.

- The objective was to have a more systematic approach to food safety risk across all commodities to inform program design, program management and allocation of resources.

- The ERA model is a mathematical algorithm that was developed based on scientific literature, international benchmarking exercises, and experts' advice.

- The ERA model's algorithm is built on three clusters of factors; inherent risk factors, mitigation factors and compliance factors.

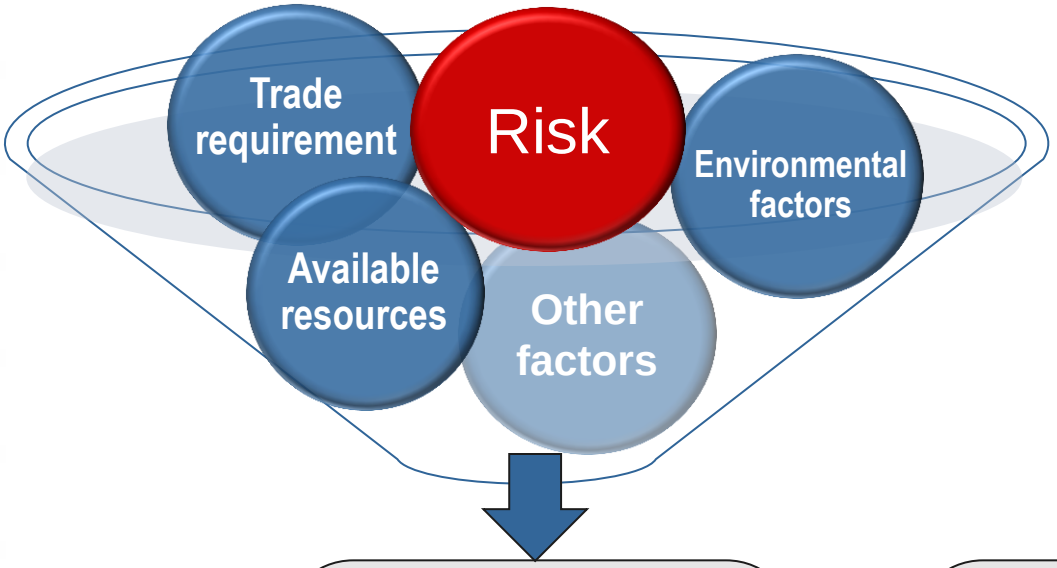
Objective of the ERA Model

ERA model will provide a documented, evidence-based standard and consistent approach to:

- Inform the CFIA's level of oversight at an establishment based on risk
- Focus priorities and resources to sectors and regulated parties representing the greatest risk

ERA in Decision Making

Risk based approach



Program design

- Oversight approach
  - Surveillance
  - Blitzes
  - Audit
- Inspection priorities

Field Operations

- Oversight approach according to risk.
- Resources will be dispatched to sectors/regulated parties of greatest risk.

ERA Model Development

Development Team

- Academics (U.Manitoba, U.Guelph, U.Montreal, Dalhousie U.)
- Canadian Food Inspection Agency, Public Health Agency of Canada and Health Canada
- Risk Sciences International (Consultants)

Benchmarking

- France
- Belgium
- Australia
- New Zealand

ERA Model Development - Methodology

Step 1

Identification of factors associated with food safety risk

- ✓ Expert elicitation through a web-based questionnaire with 75 Canadian experts.
- ✓ Over 150 risk factors gathered from scientific literature and expert's advice were assessed.

Step 2

Refinement and Selection of risk factors

- ✓ Refinement and further re-assessment of criteria to be used for measuring risk factors, considering data availability and potential sources of information.
- ✓ Cyclic-continuous process.

ERA Model Development - Methodology

Step 2: Refinement and selection process

Criteria	Examples
Elimination of lower-rated risk factors (below 8) – Expert elicitation 1	Cost of the test/method to identify the hazard in product
Availability of data sources	Number of vulnerable individuals consuming this type of product
Risk factor already covered by another one	'Mortality rate in humans attributable to the hazard' already covered by 'Health impact of pathogens'
Grouping of risk factors with similar focus	'Results of pre-operational inspections' combined with 'Efficacy of sanitation practices is validated through testing'
How measurable the selected factors were (e.g. possibility to be objectively assessed during an audit process)	Equipment appropriate for the intended use

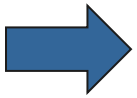
ERA Model Development - Methodology

Step 2: Refinement and selection process

- Categorization by ERA Technical Committee and approved by a Scientific Advisory Committee
- Re-definition' of risk factors:

From a '*less*' defined to a '*more concrete and measurable*' risk factor definition

Recall system in place with past achievement showing efficacy



Recall program in place that incorporates procedures for complaint management, incoming ingredients/returned product/finished product traceability, and mock recall, to verify its efficiency.

ERA Model Development - Methodology

Step 3

Risk factors' criteria weighting and design of the model

- ✓ Algorithm development
- ✓ 2nd Expert Elicitation: Assessment of relative risks (weighting) for each risk factor

Step 4

Testing of the Model (Pilot project)

- ✓ Issue risk assessment results, validation of the establishment questionnaire & Inspector spreadsheets and refinement of criteria for the model (sensitivity analysis)

ERA Model Development - Methodology

Step 5

Performance assessment of the ERA model outputs

- ✓ Output values obtained with the ERA model were correlated with the risk scores assigned by experts to the same establishments.
- ✓ Refinement of the model based on performance exercise.

Step 6

Further improvements to the ERA model

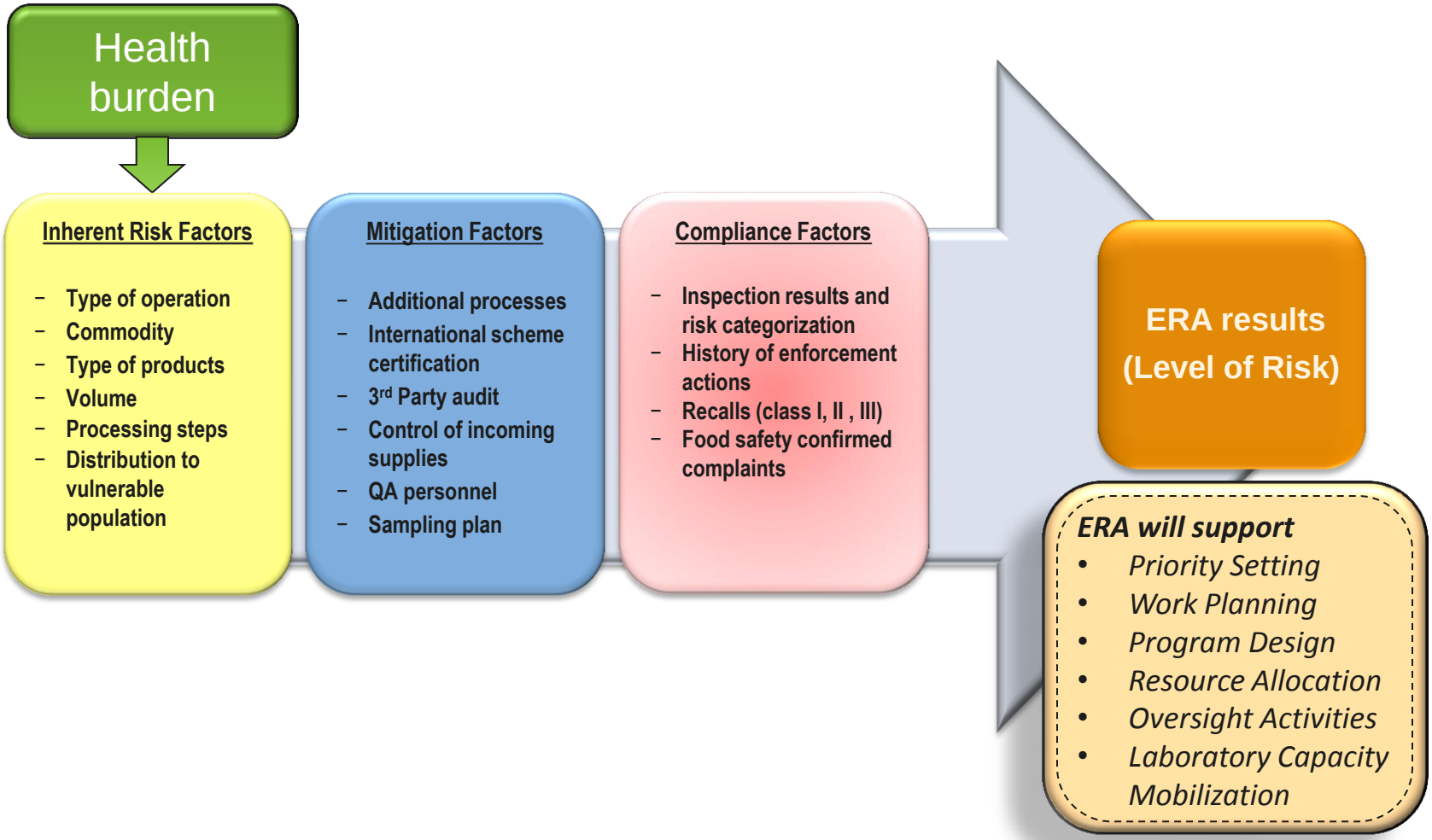
- ✓ Attribution of sources to the sub-product level (3rd Expert Elicitation – ongoing)
- ✓ Expansion of the model application to other food products (pilot project in other regulated food commodities) – Fall 2016.

ERA Pilot and Performance Assessment

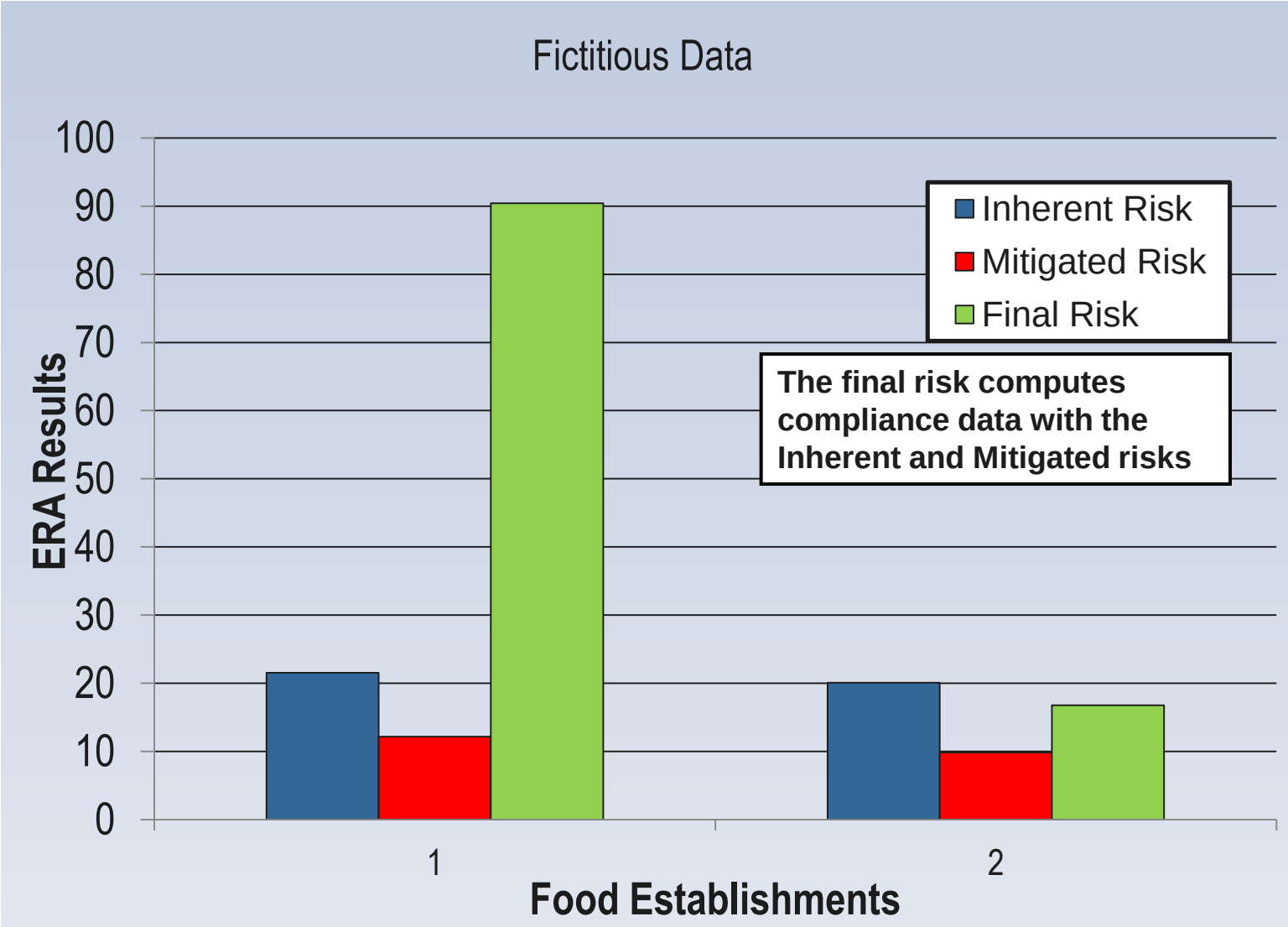
- 49 meat/poultry and 29 dairy establishments participated in the pilot
- Pilot conducted to test and provide an initial validation of the ERA mathematical model and make improvements based on the results and on stakeholders and CFIA inspectors input
- Performance assessment of the model conducted to estimate the agreement between the risk assessment results calculated by the ERA model and those assigned by expert CFIA senior inspectors
- Overall there was a good correlation between the scores assigned by the experts and those obtained with the ERA model

Pilot project demonstrated the ERA model's ability to appropriately assess the risk associated with the participating meat/poultry and dairy establishments

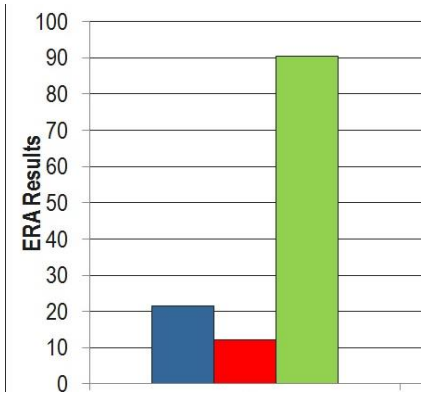
The ERA Model at a Glance



Example Risk Result



Example Establishment Risk Profile



LIST OF CHARACTERISTICS IN THE ESTABLISHMENT INFLUENCING THE RATING

INHERENT FACTORS

Production Volume: 80000000
Exports: 5000000
Dried, concentrated or frozen dairy products Less than 10%
Blue or surface ripened cheese aged <60 days made with unpasteurized milk More than 90%

MITIGATION FACTORS

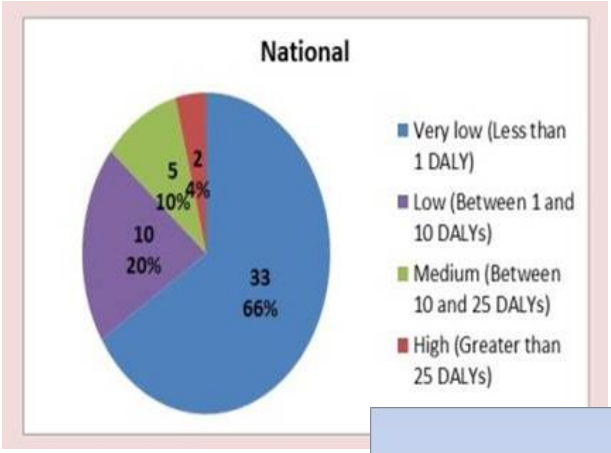
Incoming Material Control - Letter of Guarantee
Returned products refused for rework or sale
Full time food safety employee on site
Sampling plan, trend analysis and corrective action in place
PCP Certification - CFIA Food Safety Program
PCP - Third-party audit

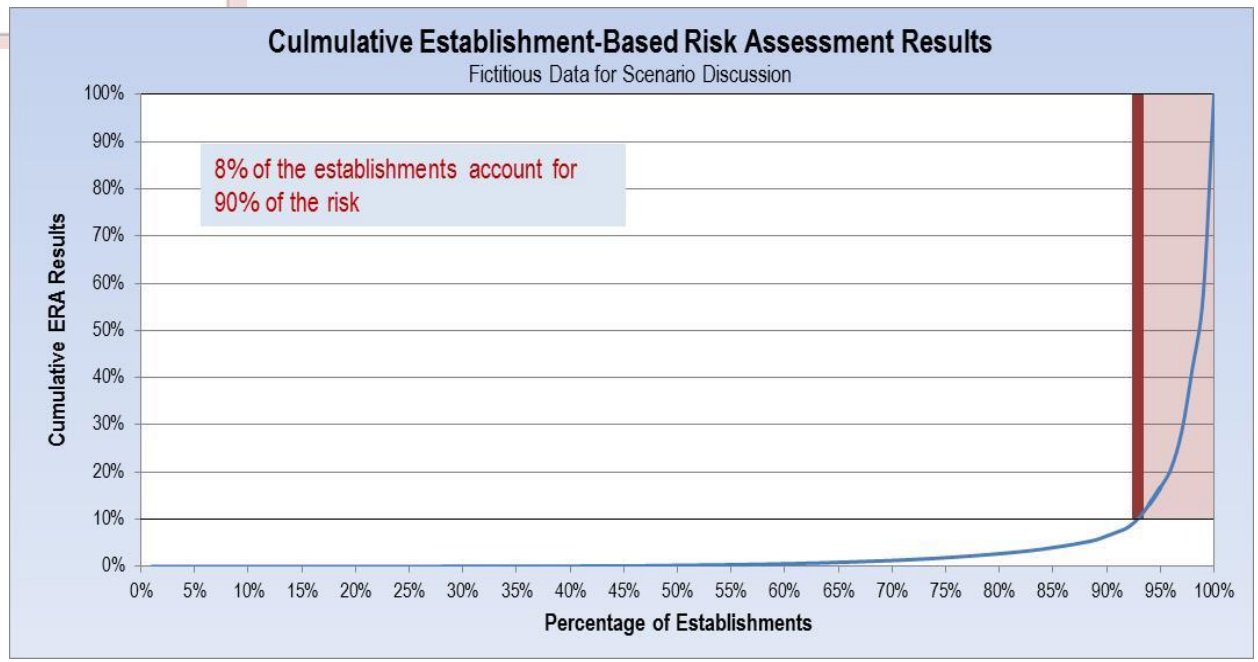
COMPLIANCE FACTORS

1 Moderate Non-compliance in previous 3 audits - Employee Training Program
1 Moderate Non-compliance in previous 3 audits - Sanitation Program
2 Moderate Non-compliance in previous 3 audits - General Food Hygiene Program

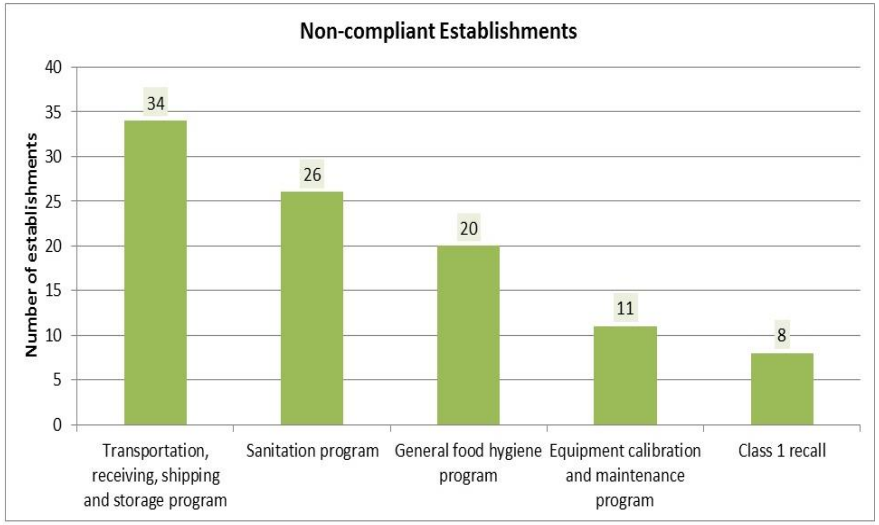
Example Risk Profiles

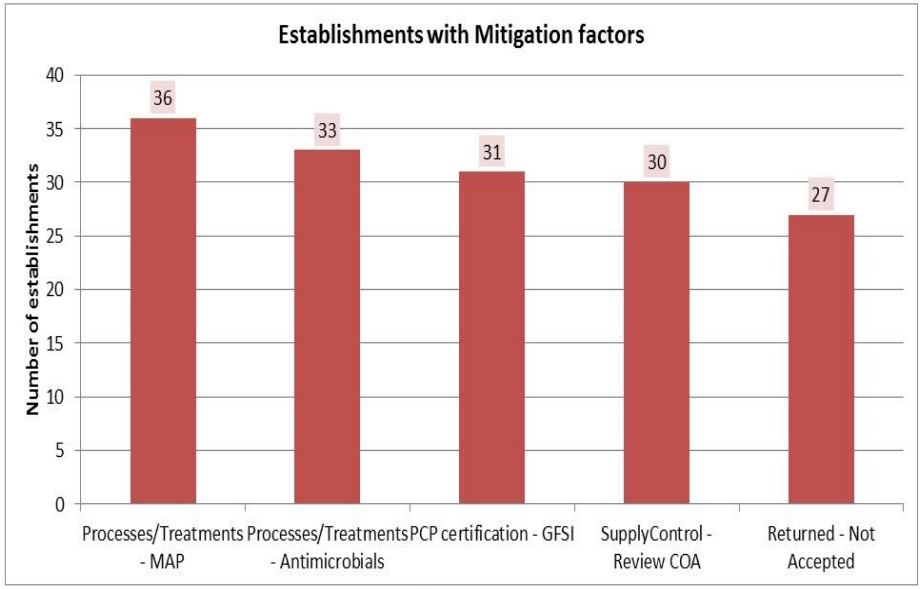
- Distribution of Establishments





Example Risk Profiles





Benefits of the ERA Model

- ✓ An evidence-based, standard, consistent and transparent approach to deliver timely results supporting risk-based decision making. Uniform inspections across all food commodities will allow similar risks to be treated with similar rigor.
- ✓ Efforts made by industry to mitigate risk will be recognized as well as the compliance through time is considered.
- ✓ Flexibility to adapt to emerging and scientific trends in food safety and to changes within establishments.
- ✓ Ability to use the information individually and collectively to identify areas for improvement in compliance and mitigation approaches.

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