Establishment-based Risk Assessment Model

International Symposium on Food Safety

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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

- Trade requirement
- Environmental factors
- Other factors
- Available resources

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

**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.

**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

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

Health burden

Inherent Risk Factors
- Type of operation
- Commodity
- Type of products
- Volume
- Processing steps
- Distribution to vulnerable population

Mitigation Factors
- Additional processes
- International scheme certification
- 3rd Party audit
- Control of incoming supplies
- QA personnel
- Sampling plan

Compliance Factors
- Inspection results and risk categorization
- History of enforcement actions
- Recalls (class I, II, III)
- Food safety confirmed complaints

ERA results (Level of Risk)

ERA will support
- Priority Setting
- Work Planning
- Program Design
- Resource Allocation
- Oversight Activities
- Laboratory Capacity Mobilization
The final risk computes compliance data with the Inherent and Mitigated risks.
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

- Cumulative Establishment-Based Risk Assessment Results
  Fictitious Data for Scenario Discussion

- 8% of the establishments account for 90% of the risk

- National Distribution of Establishments:
  - Very low (Less than 1 DALY):
  - Low (Between 1 and 10 DALYs):
  - Medium (Between 10 and 25 DALYs):
  - High (Greater than 25 DALYs):

- Chart showing cumulative distribution of establishments with respect to risk levels.
Example Risk Profiles

Non-compliant Establishments

- Transportation, receiving, shipping and storage program: 34
- Sanitation program: 26
- General food hygiene program: 20
- Equipment calibration and maintenance program: 11
- Class 1 recall: 8

Establishments with Mitigation factors

- Processes/Treatments - MAP: 36
- Processes/Treatments - Antimicrobials: 33
- PCP certification - GFSI: 31
- Supply/Control - Review COA: 30
- Returned - Not Accepted: 27
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.