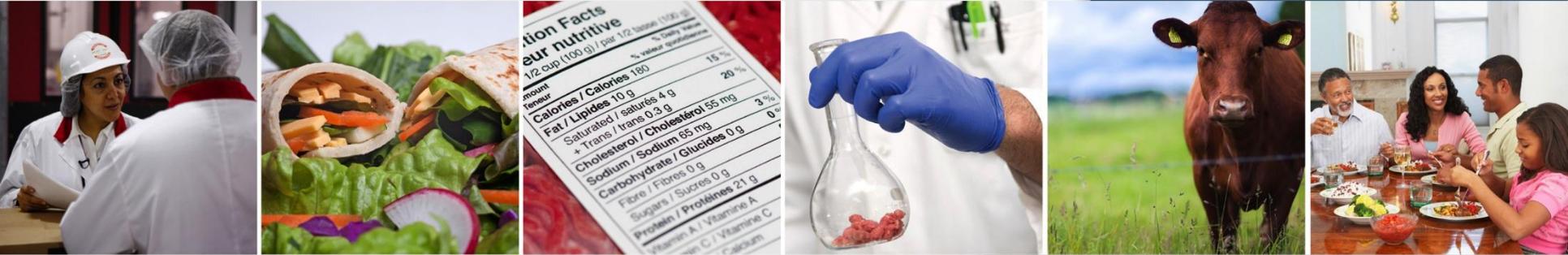


THE CANADIAN FOOD INSPECTION AGENCY'S FOOD SAFETY REGULATORY FORUM



Foundations of an Outcome-based Approach



Canadian Food Inspection Agency

Agence canadienne d'inspection des aliments



Canada

Purpose

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- Explain the foundations of an outcome-based approach including performance measurement
- Outline the Agency's thinking around implementing the approach
- Explore stakeholder views

Context

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- In response to a changing operating environment, the CFIA has embarked on an ambitious transformation agenda with four strategic areas of focus:
 - Stronger food safety rules
 - More effective inspection
 - Commitment to service
 - More information for consumers
- The outcome-based approach to regulation and inspection contributes to the strategic areas stronger food safety rules and more effective inspection

Outcome-based approach is one of many

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- The Agency uses three approaches to regulation as appropriate: prescriptive, systems-based, and outcome-based
 - Prescriptive regulation (technology- or standards-based)
 - Process or procedure requirements are defined in regulation
 - Regulated parties have little or no choice regarding how to comply
 - Systems-based regulation (management-based)
 - e.g. Quality Management Plan in fish, HACCP for meat
 - Regulated parties required to develop valid internal risk management plans and the Agency verifies that the plans are properly and effectively implemented
 - Outcome-based regulation (performance-based)
 - Required outcome or level of performance is written into regulation

Foundations of outcome-based regulation

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- Emphasis on specific and measurable outcomes versus prescriptive provisions:
 - Clear definition of the outcomes in regulation (*the what*), and how compliance will be measured
 - Regulated parties choose method to achieve the outcome (*the how*)
- Performance measures (indicators, criteria, tests) used to assess whether an outcome is achieved:
 - Act as the basis to understand compliance obligation
 - May accompany the outcome in regulation
- Regulated parties validate their compliance approach using performance measures
- Inspectors use the performance measures to verify that compliance approaches are effective

Key benefit – increased due diligence

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- Proactive/preventive – regulated parties focus on achieving outcomes rather than fulfilling prescribed behaviours
 - No simple checklist for what to do
 - Compliance assurance – need to evaluate whether the outcomes are consistently achieved
- Reporting on outcomes – Agency could seek performance data from regulated parties to inform:
 - Risk-based prioritization of inspection activities
 - Auditing the integrity of the inspection system
 - Examination of trends

Key benefit – flexibility

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- Provides flexibility for regulated parties to introduce new technologies, processes, procedures that enhance safety and/or reduce costs
- Allows the regulator to adjust to changing science, technology, and economic conditions more easily
- Holds promise in establishing comparability with safety regimes in other jurisdictions based on similar outcomes

Practical implementation

- In many cases, accepted or existing industry practice will achieve the outcomes – easing transition
- To ensure practical use of the outcome-based approach the Agency will:
 - Maintain safety as paramount consideration
 - Seek input from stakeholders early and often
 - Develop performance measures and guidance material at the same time as the outcomes
 - Work with regulated parties that wish to implement innovative compliance approaches
 - Consider consistency with international standards and major trading partners

Adapting to the approach

- The Agency will be transparent about use of performance measures
 - Developed in concert with regulation – stakeholder buy-in
 - Written into regulation where appropriate – to provide legal certainty
 - Provide training and guidance for inspectors – consistent interpretation and application
- Development of model systems for SMEs
 - Non-binding model practices or procedures that facilitate compliance
 - The Agency will explore creating a focal point to develop model systems
- Comprehensive and targeted guidance documents – compliance promotion

Questions for discussion

1. What do you like about the outcome-based approach?
2. What are your concerns, and how might they be addressed?
3. Given that the Agency aims to increase use of the outcome-based approach where appropriate, what is industry's readiness to move in this direction?

Feedback

- The Agency welcomes your input and feedback on the outcome-based approach. Please send comments or questions:
 - By email: CFIA-Modernisation-ACIA@inspection.gc.ca
 - By mail:
 - Strategic Partnerships Division
 - 1400 Merivale Road, Tower 1
 - Floor 6, suite 218
 - Ottawa, ON K1A 0Y9
 - Canada
 - Attn: Outcome-based approach
 - By fax: 613-773-5606

Annex – Transport Canada Example

- Outcome and performance measures are specified in law
- Sections 104(3) and (4) of Schedule IV of the *Motor Vehicle Safety Regulations*, which states:
 - (3) Every vehicle shall have a powerdriven windshield wiping system that has at least two frequencies or speeds and that has, irrespective of engine speed and engine load,
 - (a) one frequency or speed of at least 45 cycles per minute
 - (b) a difference of at least 15 cycles per minute between the highest frequency or speed and one of the lower frequencies or speeds, and
 - (c) the lower frequency or speed referred to in paragraph (b) equal to at least 20 cycles per minute
- Section 104(3) specifies the outcome – every vehicle shall have a powerdriven windshield wiping system, no matter its design, that has at least two speeds
- Sections 104(3)(a), (b), and (c) are the performance measures to determine if the system meets the outcome regardless of speed or engine load

Annex – Australian Example

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- Australian Meat Standard (AS 4696) and the Export Control Orders – specify the outcome in law, and performance measures are in guidance
- Outcome: the plant and equipment are not a source of contamination to carcasses, meat or meat products
- Performance indicators:
 - Procedures are in place to ensure that, prior to commencement of operations, plant and equipment that could contact product, either directly or indirectly, are cleaned and sanitised.
 - Other areas of the establishment, including storage areas, amenities and establishment environs are kept in a suitable sanitary state.
- Guidance has detailed checklists to help use the performance indicators

Annex – Safe Food For Canadian's Regulations Example

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- Outcome and performance measures are specified in law
- Requirement for Preventive Control Plan Element 1: Processes and Products – 2(c) Product Coding And Labelling Control
- Outcome: each food commodity shall be marked with a code mark on the label or container
- Performance indicators:
 - The code mark shall be applied in a legible and permanent manner.
 - The exact meaning of the code shall be available to the inspector.