

## Foundations of an Outcome-based Approach

### Introduction

Global supply chains are changing the way agricultural and agri-food products are produced, processed, packaged, distributed and sold. Consumer demands are also changing. Demand for new and more information on the safety, production methods, and sources of these products has increased. Similar trends have been observed in the agricultural input industry, with enhanced demand for information on the fertilizer, pesticide and seed sectors. Change has become the norm. To keep pace, regulators must develop a modern suite of legislative, regulatory, and inspection tools. There is an opportunity through modernization to improve safety, while also enabling regulated parties to adapt to the pace of innovation and demand for more and better information.

The Agency has embarked upon an integrated change agenda with a goal of allowing Canada to modernize and maintain one of the best food safety, and plant and animal health systems in the world, while allowing for adaptation to consumer, global and scientific trends. Among the Agency's goals is standardizing the inspection approach, and providing for consistent and appropriate oversight across all regulated commodities. The Agency is pursuing an outcome-based approach to help achieve these goals.

An outcome-based approach specifies what to achieve and how compliance will be measured, but does not prescribe how to achieve an outcome. It affords regulated parties the opportunity for innovation, and provides flexibility to introduce new technologies, processes, and procedures that enhance safety and/or reduce costs. It is rooted in the need to be adaptable to changing scientific, technological and economic conditions. The flexibility of an outcome-based approach will help the Agency be more nimble and better able to incorporate scientific and technological advancement without compromising safety. For the Agency, the outcome-based approach may also hold promise in establishing comparability with safety regimes in other jurisdictions that are based on similar outcomes. Ultimately, it is a more progressive way to achieve safety and health outcomes for consumers, regulated parties, and the Agency alike.

An outcome-based approach reinforces the responsibility of regulated parties to ensure the safety of their products. While many regulated parties already proactively identify potential hazards, an outcome-based approach requires greater due diligence to demonstrate that their processes and controls are effective. Consumers, regulated parties, and the Agency benefit from this added due diligence as more accurate and real-time data become available to identify hazards before they

become problems. In this regard, the Agency will maintain its role in frontline inspection and will continue to verify that safety outcomes are achieved. This means the Agency will assess performance data to identify trends and ways to enhance system integrity, as well as verify that outcomes are met.

## Purpose

The objectives of this paper are to:

- set out the Agency's overall approach to regulation and provide a framework for implementing an outcome-based approach at the Agency;
- review experience with the outcome-based approach at the Agency and in other jurisdictions;
- highlight key considerations for the approach; and,
- invite feedback from Canadians on the approach.

## The Agency's Approach to Regulation

Traditionally, the Agency has relied on a combination of three basic approaches to regulation: prescriptive, systems-based, and outcome-based. Fundamental changes to the production, processing, packaging, distribution and sale of agricultural products, coupled with changing consumer demands, industry consolidation and rapidly evolving science and technology, however, have prompted the Agency to re-examine the mix of approaches used to verify the integrity and safety of the agriculture and agri-food sector. The Agency has committed to modernize its regulations. As it does, the Agency intends to systematically evaluate how best to increase use of outcome-based regulatory approaches. Without modernization the Agency will not be well-positioned to address safety in response to changing scientific, technological, and economic circumstances.

Many of the Agency's current regulations are based on the prescriptive approach, where technical requirements for compliance are defined in regulatory text that prescribes a process to follow or action to take by a regulated party. This common regulatory approach has the advantage of clarity and precision in terms of what is necessary for compliance, but the process to modify regulations takes time. When process and procedures are prescribed in regulation, adjusting to changes in technology or process improvements can be difficult. The prescriptive approach lacks flexibility to adjust to such changes, which can be constraining given the Agency's constantly evolving and increasingly complex operating environment.

The Agency also employs systems-based regulation, which includes mandatory requirements for preventive control plans in meat and an adapted version called the Quality Management Program in fish. With systems-based regulation, regulated parties are obliged to develop internal risk management plans that include procedures, training, documentation and internal risk analyses to identify and mitigate risks in the context of a corporate compliance system. An advantage of systems-based regulation is that regulated parties must commit time and resources to understand and mitigate risk rather than simply follow a set of specification and process requirements. Systems-based regulation also lays the groundwork for enhanced accountability on the part of regulated parties as they exercise due diligence to identify, understand, mitigate, and eliminate risks.

In the context of food inspection modernization, the Agency has signalled in its consultation document *The Improved Food Inspection Model: The Case for Change* that the development and implementation of a preventative control plan would be a condition for licensing, thereby extending system-based regulation to a wider industry base. The increase of systems-based regulation will require good record keeping and documentation to verify that a preventive control plan has been implemented properly. Regulated parties will be responsible for identifying the risks posed in their operations, determining appropriate control measures to mitigate those risks, and then monitoring and documenting application of the control measures to demonstrate compliance. The Agency will assess the effectiveness of the preventive control plan, taking into account performance records, operating environment, and product risk (e.g. presence of a pathogen). Demonstrating performance against the preventive control plan will be essential for the Agency to know that regulated parties are meeting the outcomes. This will require an adjustment for regulated parties as well as for the Agency.

The Agency uses a third type of regulation, albeit to a lesser extent, called outcome-based regulation or performance-based regulation. The rapidly evolving and increasingly complex operating environment is driving the Agency, as well as regulators in other jurisdictions, toward increased use of an outcome-based regulatory approach. Outcome-based regulation places greater emphasis on specific and measurable outcomes and less emphasis on prescriptive provisions to achieve compliance aims. With this approach, the regulation specifies the required outcome and allows the regulated party to choose reasonable concrete measures to achieve that outcome. It is based on the premise that by exercising due diligence, regulated parties and their management can apply cost effective, scientific, and/or technological measures to best achieve a given regulatory outcome. As a result, instead of focusing on the processes or actions that regulated parties must take, the regulator defines the outcomes that regulated parties must achieve and how compliance with those outcomes will be measured. The approach can facilitate incorporation of scientific and technological advancement, new production and processing methods, and changing consumer demands without compromising safety and health.

In the past, the Agency developed regulations where the outcome or intent of a regulation was decided in policy and the practices or procedure to achieve that outcome were written as prescriptive regulatory requirements. Through its modernization initiatives, the Agency aims to make the outcome explicit in the regulatory text, and to describe practices or procedures to achieve that outcome in policy and guidance material. This is a key difference between outcome-based regulation and prescriptive regulation: detail in regulatory text is used to define the outcome, not the practices or procedures to achieve the outcome. This means that much of the information embedded in a prescriptive regulation would appear in guidance material that provides reasonable options to meet the outcome. An outcome-based approach specifies what outcomes to achieve and how compliance will be measured, but does not prescribe how to achieve the outcome.

In developing new regulations, the Agency will systematically evaluate whether and where best to integrate outcome-based approaches with prescriptive and system-based approaches. Where the outcome-based approach cannot uphold safety outcomes with surety, an outcome-based approach will not be used. The Agency will use the approach only where it is confident that better results can be achieved. Furthermore, the Agency intends to employ specific and measurable performance measures to verify if the outcome is accomplished.

## Experience

As noted in the previous section, the rapidly changing and increasingly complex global environment has created a trend away from prescriptive regulation and towards outcome-based regulation in a number of countries and in a variety of sectors. The United States, Australia, New Zealand and the United Kingdom have moved in this direction, and the Agency can draw important lessons from the implementation of an outcome-based approach in these jurisdictions.

In food safety, this trend aims to prevent food from being unsafe at the point of consumption by a “through-chain” food safety system.<sup>1</sup> Australia and New Zealand, in particular, have established principles for food safety that require regulations to be outcome-based and for the effective enforcement of clearly stated objectives. Together, the two countries have reformed their food product standards with an aim to reduce prescription and utilize standards that apply across all foods or a range of foods.<sup>2</sup>

Australia has facilitated the transition to an outcome-based approach by providing model systems for compliance with food regulations. A model system for compliance is a non-binding model that provides guidance to a regulated party to meet a specified outcome. It provides added comfort that the outcome is achieved, where a lack of prescription may make achieving compliance more difficult. The model system sets out practices and procedures for premises and equipment that, when implemented, facilitate compliance. Very simply, a model system is a tool to help regulated parties achieve a regulatory outcome (see Annex A for a description of model systems for compliance).

The Agency has some recent experience with outcome-based regulatory text through amendments to the *Meat Inspection Regulations, 1990*, made in October 2011. The amendments included revising room temperature requirements, and construction and facility requirements for registration of an establishment. The Agency used outcome-based language to make Section 36 of the regulations more flexible. Section 36 of the *Meat Inspection Regulations, 1990*, previously stated:

“Where a low temperature is required for the preservation of a meat product, the temperature in a room or area of a registered establishment in which that meat product is processed, packaged, labelled or handled shall not exceed 10°C.”

This prescriptive provision, which specified a maximum temperature threshold, was replaced with a more flexible provision as follows:

“The temperature in a room or area of a registered establishment where a meat product is processed, packaged, labelled, or handled shall be appropriate to ensure the preservation of a meat product.”

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<sup>1</sup> Szabo, E.A., W.R. Porter, and C.L. Sahlin, “Outcome based regulations and innovative food processes: An Australian perspective,” *Innovative Food Science and Emerging Technologies* 9 (2008): 249-254.

<sup>2</sup> Healy, Marion, Simon Brooke-Taylor, and Peter Liehne, “Reform of food regulation in Australia and New Zealand,” *Food Control* 14 (2003): 357-365.

The intent of the provision is to control the growth of microorganisms on the product while in the room or area used for the processing, packaging, labelling or handling of meat products. Room or area temperatures must ensure control of product temperature such that there is no bacterial growth in the product that would affect the success of further lethality steps (e.g. cooking, pasteurization) or product shelf life. The requirements and methods for meeting the outcome in Section 36 are laid out in the *Meat Hygiene Manual of Procedures*, which is incorporated by reference into the regulations. Refrigeration, freezing, and crust freezing are three possible options. Regulated parties can use alternative meat preservation procedures provided they can justify that such procedures achieve the same or better outcome. Since the Manual is incorporated by reference, its application means the onus is on the regulated party to demonstrate that the requirements are achieved.

Ideally, an outcome-based regulatory provision should specify both an outcome and the performance measures to meet that outcome in order to create legal certainty.<sup>3</sup> Failure to state the performance measures can result in a vague regulation, the enforcement of which can then be subject to challenge. It is essential to identify and define performance measures for each outcome-based regulatory provision, although it can be difficult. Should it prove problematic to include performance measures in a regulatory provision, it will be necessary to clearly describe them in guidance to industry in order to create a clear understanding of compliance obligations. Pairing the outcome with performance measures provides both regulated parties and the Agency with a basis to measure achievement of the outcome. Indeed, performance measures become the foundation for demonstrating and verifying compliance with an outcome-based approach. The Agency is responsible for setting the performance measures used to verify compliance.

A common misperception is that an outcome-based approach is less detailed and offers less precision than other regulatory approaches. Indeed, the experience of other federal government departments in Canada suggests otherwise. Examples of outcome-based regulatory provisions can be found in Transport Canada regulations, which have helped the Agency understand what will be required to implement this approach. One such example that is very specific and includes performance measures is Subsections 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.
- (4) Compliance with subsection (3) shall be demonstrated by testing under the conditions specified in sections 4.1.1 and 4.1.2 of SAE Recommended Practice J903a, (May 1966).”

The intent of the provision is to provide for appropriate windshield visibility. Subsection 104(3) specifies the outcome: every vehicle shall have a powerdriven windshield wiping system that has at least two frequencies or speeds. Paragraphs 104(3)(a), (b), and (c) are the performance measures used

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<sup>3</sup> Note: a performance measure could include a numerical measure, an indicator, a set of criteria, and/or a testing methodology.

to verify whether the outcome in 104(3) is achieved—the provisions define the difference in frequency and speed that will be measured. Subsection 104(4) further identifies the conditions under which performance is measured. These regulatory provisions do not specify the mechanics required in a windshield wiping system (i.e. how to achieve the regulatory outcome), rather they specify what outcome to achieve and how compliance will be measured.

An ideal outcome-based regulatory provision would state very clearly the outcome and the performance measures used to measure if that outcome is achieved. For the regulator, this means providing clarity about the intent of a regulation and precision about how it will measure compliance. The example from the *Motor Vehicle Safety Regulations* demonstrates that outcome-based does not mean less detailed. To implement an outcome-based approach, the Agency should develop performance measures at the same time as it develops new regulations.

## Considerations for Strengthening the Practice of an Outcome-based Approach

The Agency has signalled its intent to more systematically integrate an outcome-based approach into regulation. The Agency recognizes a number of key benefits that it will derive from an outcome-based approach. There are also a series of considerations the Agency will need to factor in to determine when and where to take an outcome-based approach, as it will not be suitable in all cases.

### Benefits to Consumers

Since regulated parties are not bound to a specific procedure, they can “raise the bar” by applying new technologies and/or improved procedures. This can foster a culture of continuous improvement, as competing regulated parties implement new technology and strive to meet the standard more consistently and efficiently. Ultimately, consumers may benefit from increasing levels of safety as regulated parties continue to innovate and improve.

Implementing an outcome-based approach will also introduce an additional level of due diligence and accountability into the system. While many regulated parties already proactively manage risk, an outcome-based approach requires that regulated parties ensure, through proactive monitoring, that their practices and procedures are effective and consistently achieve the outcome.

### Benefits to Regulated Parties

A principal benefit from an outcome-based approach is the opportunity for innovation. It provides regulated parties flexibility to determine how to achieve an outcome, without binding them to a particular procedure or process. This provides an opportunity to meet safety requirements, while also choosing the most efficient and effective manner in which to comply with a regulation. The flexibility of outcome-based regulation also serves as an incentive to comply, which has direct benefits for consumers.

The approach has the added advantage of accommodating technological change and mitigating against the emergence of new hazards in ways that prescriptive, technology-based standards

generally do not. In this regard, the approach is particularly useful because it affords a regulated party an opportunity to be innovative, capitalize on new science and technology, and be cost effective, while still meeting regulatory requirements. This is an added advantage in the agriculture and agri-food sector where profit margins may be narrow.

### **Benefits to Government**

The outcome-based approach can help enhance the Agency's effectiveness. A key benefit is that an outcome-based regulation will not necessarily require updating to keep pace with changing scientific, technological and economic conditions. The flexibility of the approach will allow the Agency to better incorporate scientific and technological advancement into regulation without compromising safety. For the Agency, the outcome-based approach may also hold promise in establishing comparability with safety regimes in other jurisdictions that are based on similar outcomes.

### **Competitiveness Considerations**

An outcome-based approach may impose additional costs on business; particularly, small- and micro-sized enterprises that must develop internal systems to demonstrate compliance. Those that have not invested in internal quality control systems may be disadvantaged, as they are not well-positioned to provide performance data to the regulator. Indeed, some regulated parties may prefer prescriptive regulation because it is more predictable for them and provides cost certainty.

To facilitate the transition to an outcome-based approach, the Agency will provide guidance material to regulated parties with options or model designs, and the performance measures that will help them achieve the desired outcomes (see Annex B for a description of how the Agency envisions the transition). Such designs constitute model systems, as previously mentioned, and are particularly important to those regulated parties that do not have the capacity to take advantage of the flexibility of an outcome-based approach, and may therefore consider the lack of prescription a vulnerability to their compliance.

Development of model systems that provide guidance to small- and micro-sized enterprises that lack resources to determine how to meet regulatory requirements has been helpful in other jurisdictions. The Agency has examined experiences of Australia, New Zealand, and the United States in this regard, and will draw on the expertise of these like-minded parties to advance understanding of the approach. Improving the availability of guidance and model systems enhances the Agency's approach to compliance promotion, with an aim to ensuring that regulated parties fully appreciate their obligations and have the tools to meet them. It also presents an opportunity for the Agency to work with industry leaders to promote best practices for compliance.

### **Institutional Considerations**

The Agency has embarked on multiple initiatives to increase transparency, accountability and service delivery. Investments made in Budget 2011 provide for improved training for inspectors, and new tools to keep inspectors informed and connected. There is a Statement of Rights and Service to provide regulated parties and other stakeholders with information about their rights and obligations related to Agency activities. The Agency has also launched a new complaints and appeals process

that provides stakeholders with a centralized method to register complaints and appeals related to service delivery, administrative errors and regulatory decisions. These initiatives represent an important shift for the Agency, and we will continue to build upon them.

An outcome-based approach will require that the Agency develop and strengthen its problem solving capabilities, break down broad risk categories into well-defined problems and develop specific solutions.<sup>4</sup> It is different from a traditional view of a regulator as enforcing legal compliance with existing and specific statutory requirements, and will require a significant culture change within the Agency and by regulated parties. The Agency's ongoing efforts to improve transparency, accountability and service delivery position it well to make the necessary change.

### Operational Considerations

With an outcome-based approach, the onus is on the regulated party to ensure that its products are safe, and on the regulator to verify that the regulated party has mechanisms in place to meet the outcomes.<sup>5</sup> The regulator wants to know that the mechanisms are working and that the regulated party is achieving the outcome. By using risk analysis, the regulator can establish management priorities and options that steer regulated parties and/or their practices in the right direction. The process to identify risk and define outcomes requires the regulator to consider a number of elements. It includes a determination of its objectives—what risks it wants to control—and a determination of its risk appetite—what type of risk is it prepared to tolerate and at what level. To be successful in this endeavour, the Agency will apply comprehensive risk analysis frameworks that include technical process assessment, hazard identification, and effective risk assessment.

Measuring industry performance against outcomes will require that the Agency adjust its approach to inspection. Since an outcome-based approach affords regulated parties greater flexibility, reliable and appropriate information regarding their performance is imperative. As such, the Agency will need considerable information from regulated parties to sustain its regulatory oversight. Regulated parties and the Agency must exercise rigorous due diligence for oversight to be effective. Such due diligence benefits consumers, regulated parties, and the Agency, as it provides more accurate and real-time data to identify and address hazards before they become problems. This performance information may also facilitate both the regulator and regulated party to evaluate system integrity more closely and to investigate potential problem areas more deeply, which has benefits for overall system performance.<sup>6</sup>

Capacity must also be built in inspection and enforcement communities. Training and guidance material will help address potential capacity gaps, and will help prepare inspectors to use the improved inspection model. The Agency has already incorporated information on and examples of an outcome-based approach in training material for new inspectors to prepare them for changes to inspection and regulation. This material will also be important for bringing about culture change at

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<sup>4</sup> Peterson, Deborah, and Sally Fensling, "Risk-based regulation: good practice and lessons for the Victorian context," Conference paper presented at the Victorian Competition and Efficiency Commission Regulatory Conference, Melbourne April 1, 2011.

<sup>5</sup> Sazbo, Porter, and Sahlin, 2008.

<sup>6</sup> Note: the Agency is sensitive to compliance and administrative burden that may be created by enhanced data collection and reporting requirements.



the Agency. Indeed, all Agency staff will benefit from learning the principles of an outcome-based approach and how the Agency's role may change under modernized inspection and regulation.

The Agency's efforts to enhance transparency are a critical factor in building trust with stakeholders, and provide a basis for the Agency to work with regulated parties to design regulations to reduce the compliance burden, while also improving information sharing and cooperation. To support transparency, the Agency will make a variety of documents available to the public, including food safety investigation reports, licence suspensions/cancellations, Complaints and Appeals Office data, and the number of import shipments received, type and country of origin.

### Communication Considerations

An outcome-based approach depends on the ability of the regulator to clearly specify the outcome desired, as well as measure and monitor performance against it.<sup>7</sup> The regulator must clearly lay out responsibilities of the regulated parties, as well as each outcome and the intent of the regulations. This presents an important communication challenge for the Agency. Well-defined performance measures are crucial; they serve as a guide to assess achievement of outcomes as well as overall effectiveness of the system. The greater the clarity, the easier it will be for the regulator to achieve consistency and for regulated parties to achieve compliance.

The Agency's efforts in the area of transparency are a sound basis to communicate the benefits of an outcome-based approach. Building trust between regulated parties and the Agency, and between consumers and the Agency, is imperative. By revealing inspection approach, performance information and compliance records, the Agency will empower consumers to make informed choices about safety, and regulated parties will have greater incentive to comply. Effective communication about risk, uncertainty, and performance puts information into the hands of consumers, and promotes their confidence in an outcome-based approach.

### Conclusion

The Agency is committed to capitalizing on the advantages of an outcome-based approach, and understands it will need to manage the considerations identified above when increasing its use. In so doing, the Agency will continue to use a mix of prescriptive, systems-based and outcome-based regulation, and will decide to use the outcome-based approach only under the appropriate conditions where it is practical. Outcome-based regulation is not a panacea for modern regulation, but is one instrument in a suite of instruments used to build a credible and modern regulatory system. This means using it where the outcome can be stated clearly and where performance can be measured against the outcome.

Safety remains paramount to the Agency. It will not use an outcome-based approach where the approach cannot uphold safety and health outcomes with surety. In such cases, a prescriptive approach may be more appropriate. As such, the Agency will follow the outcome-based approach only where it is confident that it can achieve better results.

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<sup>7</sup> Coglianesi, Nash, and Olmstead, 2003.

The Agency is mindful that adjustment to an outcome-based approach may be challenging in certain sectors. Where regulated parties' capacity to adopt an outcome-based approach may be lacking, guidance material and model systems for compliance will help ease the compliance burden and achieve regulatory outcomes. The Agency also recognizes that adjusting to an outcome-based approach may take time, and may require a period of transition.

For most regulated parties, the transition will not entail major changes to the practices and processes currently used to meet safety and health outcomes. Where a particular practice or procedure to meet a safety or health outcome is well-established, the practice or procedure will remain valid under an outcome-based approach. The Agency will work with regulated parties that wish to implement a novel technology, practice or process to determine, based on sound science, that such a measure achieves the outcome. The Agency will also collaborate with external centres of excellence to assist regulated parties adopt valid practices and processes.

Validation and verification of compliance remain key features of the Agency's regulatory oversight. Regulated parties are responsible for validating their compliance approaches, and the Agency's inspectors are responsible for verifying that the approaches are implemented effectively and that outcomes are achieved. With outcome-based regulation, the Agency will specify what outcomes to achieve and how compliance will be measured, but will not prescribe how to achieve the outcome. The Agency will verify achievement of an outcome using its associated performance measures.

Canadians will be best served if performance measures and guidance material are developed at the same time as the Agency consults stakeholders on an outcome-based regulation. Early input from regulated parties on the regulations, performance measures, and guidance material will be critical to implementation of an outcome-based approach. Ultimately, collaborative work with stakeholders will help to clarify and define the performance measures, which will make the regulations effective and enforceable.

Increased use of outcome-based regulation will require a made-in-Canada approach; however, the Agency will make every effort to align with international standards and major trade partners. Our efforts will not compromise our international commitments and obligations.

### Opportunity to Provide Input

The Agency welcomes your input and feedback on the outcome-based approach. Please e-mail any questions or comments to the Regulatory Transformation Office ([CFIA-modernisation-ACIA@inspection.gc.ca](mailto:CFIA-modernisation-ACIA@inspection.gc.ca)) or in writing to:

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## ANNEX A – MODEL SYSTEMS FOR COMPLIANCE

### Description

A model system for compliance is a non-binding means of providing assistance to a regulated party to meet a systems-based or outcome-based regulatory provision. The model system is intended to set out practices and procedures for premises and equipment that, when implemented, facilitate regulatory compliance. For regulated parties lacking capacity to implement an outcome-based approach, a model system can ease the compliance and administrative burden. Rather than being required to develop new processes and controls, small- and micro-sized enterprises can follow the tools embedded in the model system (e.g. procedure for preservation of meat, sample preventive control plan, etc.). Model systems may have several options or plans for achieving an outcome, and some may be well-established practices or procedures. As a result, if the model is followed, both the regulator and regulated party can be relatively confident that the regulatory outcome will be met.

When applying a model system for compliance it is important that each regulated party tailor the model to fit its particular business, products, and/or market requirements. Following a model system does not provide limitless protection from the legislative and regulatory requirements—the regulated party remains responsible for ensuring that all potential safety hazards are identified and controlled.

### Considerations

Incorporating model systems provides flexibility to regulated parties, encourages behaviour that fulfills regulatory outcomes, and enhances compliance. Some fixed points are necessary, however, as use of model systems can very easily reintroduce regulatory prescription, and in a much less transparent and accessible way. Great care must be taken in the formulation of model systems. A model system will best facilitate regulatory compliance if it is understandable and accessible. In this regard, the regulator should strive to provide materials to regulated parties that are not—and do not become over time—overly complex, prescriptive and inaccessible. Provision of case studies and examples that illustrate “good” and “bad” practice will also be useful.

Experience in the United Kingdom suggests that regulated parties frequently treat this material as though it is binding, thus undermining the goal of giving greater flexibility to achieve outcomes. To avoid this, relevant parties must recognize that there may be various means by which the regulatory requirements may be implemented and attained.

There is also a risk that development and implementation of model systems for compliance will be interpreted as bypassing key statutory requirements to consult publicly on the content of regulation, since the model system is not in law. A key solution will be to develop a shared understanding between the regulator and regulated parties as to the role and purpose of the regulatory regime through regular and open communication. Use of model systems will only work if there is ongoing dialogue as to the interpretation and application of the regulatory requirements.

## Examples

As set out in the *Fish Inspection Regulations*, all establishments in Canada that process fish and seafood for export or inter-provincial trade must be federally registered. To become federally registered, a fish processor is required to develop and implement a Quality Management Program (QMP) Plan. A QMP Plan is an inspection and control system, similar to a preventive control plan, for verifying and documenting the processing, safety and quality of a commodity.

To help processors prepare a QMP Plan, the Agency provides a Step-by-Step Guide that outlines its views regarding the major steps of a plan development process. Although not mandatory, a processor can tailor the model QMP Plan to its products, processes, plant, and specific hazard-avoidance needs using the Step-by-Step Guide. The Agency also provides a QMP Reference Standard, which is the blueprint for development of a QMP Plan.

Together, the Step-by-Step Guide and QMP Reference Standard comprise a model system for compliance. Its intent is to guide development, implementation, and maintenance of a QMP to assist in the safe production of fish and seafood products in accordance with the requirements of the Fish Inspection Regulations, and to provide guidance in ensuring that such processing is conducted in establishments which also meet regulatory requirements. It acknowledges that the controls and methods described are not necessarily the only valid means to achieve the desired results, and alternative strategies for achieving compliance can be considered. This model system provides regulatory guidance while also affording flexibility for regulated parties to develop and implement processing procedures customized to the nature of their production.

Another example of a model system for compliance is the Agency's Food Safety Enhancement Program (FSEP). FSEP is a non-mandatory mechanism for operators in the federally registered sector (other than in fish and meat) to demonstrate their ability to control food safety hazards in order to ensure that food is safe. The objective is to specify minimum requirements for an effective food safety management system.

FSEP is based on the principles of the Hazard Analysis and Critical Control Point (HACCP) system. It specifies the requirements for an effective HACCP system, outlines the process for HACCP recognition by the Agency, and details the changes to a recognized HACCP system that should be communicated to the Agency. When implemented, FSEP can enhance a regulated party's ability to achieve and maintain compliance with the relevant regulatory requirements.

Under the Agency's improved food inspection model, regulated parties who import or export food, or operate as manufacturers or processors of food products for trade between provinces, may be licenced. This may require the development and implementation of a preventive control plan, suitable to each regulated party's products and operations. In this case, subject to any specific direction in the regulations as to content of the plan and outcomes to be met, regulated parties will be responsible for the design and implementation of their preventive control plan, and the Agency will be responsible for verifying that such plans appropriately prevent, eliminate or reduce hazards to acceptable levels.

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To support regulated parties in this process, the Agency can provide generic model preventive control plans. When adapted and implemented to fit a regulated party's particular circumstances, such models help meet the requirements for an effective preventive control plan.

## ANNEX B – COMPLYING WITH OUTCOME-BASED REGULATION: ALTERNATIVE APPROACHES

Greater emphasis on outcome-based regulation will require a period of transition for both regulated parties and the Agency alike. This starts with how the Agency develops regulations. Through modernization, the Agency aims to make the intent of regulations it administers explicit by providing outcome-based requirements, together with performance measures, in regulatory text, and to describe the practices or procedures to achieve that outcome in policy and guidance material (e.g. as model systems for compliance). This contrasts with past practice, where the Agency defined the outcome or intent of a regulation in policy, and wrote the practices or procedure to achieve that outcome into prescriptive regulatory requirements.

Where an outcome is based on an existing safety or health standard, this transition should not entail major changes to the practices and processes currently accepted to meet the standard. Well-established practices or procedures with which the Agency is familiar—that have already been validated and/or a have history of safe use—will remain valid in an outcome-based regulation. In some cases though, the Agency will introduce new requirements or extend requirements to new sectors or areas. This will likely be more challenging for regulated parties as they are not familiar with the new requirements in the context of an outcome-based regulation. The Agency's development of model systems for compliance will assist regulated parties to adjust to new requirements. Another adjustment for regulated parties will be less reliance upon the Agency's approval of safety processes and procedures, and more integration into their own decision making of what is learned from performance data collection, monitoring, and reporting of performance.

### Validation and Verification of Compliance Approaches

In order for a smooth transition to outcome-based regulation, the regulated party would need to establish or validate that a new compliance approach achieves the outcome, and maintain records and documents that demonstrate such validation and assist the Agency to verify compliance.

Validation means answering the questions "is there a scientific basis for this approach? Or is there a history of safe use?" Validation assesses whether an approach will work as it was designed.<sup>8</sup> It involves obtaining evidence that the approach effectively achieves the outcome, if properly implemented. The aim is to confirm that the approach is capable of controlling a given hazard or meeting a specified outcome within established limits and that it can be achieved consistently. Validation may be necessary, for example, when an alternative compliance approach—a new practice or procedure not covered by a model system—is designed and implemented, or when an existing preventive control system is amended.

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<sup>8</sup> CFIA, *Guide to Food Safety*, <http://www.inspection.gc.ca/food/non-federally-registered/safe-food-production/guide/eng/1352824546303/1352824822033#s2-6>

Verification means a determination by the Agency that a regulated party has properly implemented the approach to its particular circumstances. Verification assesses if the approach has been implemented as it was designed and is operating to achieve the outcome. It involves examining the accuracy, correctness or effectiveness of validated approaches through testing, investigation or comparison against a standard.<sup>9</sup> Examples of verification activities include reviewing records, testing products, observing employee practices, etc. In most cases, a complete verification requires both record review and on-site inspection.

Where appropriate, the Agency may require through regulation that regulated parties validate their compliance approaches, and that the Agency approve alternative compliance approaches before implementation. As part of modernization, the Agency will explore creating a focal point to support the review of the validation data and information provided by regulated parties regarding alternative compliance approaches.

### Compliance under Outcome-based Regulation

The Agency envisions a number of scenarios for compliance with outcome-based regulations, three of which are described here. The scenarios are illustrative, and outline in general terms how the Agency will treat compliance with both new and existing regulatory requirements. They have been developed recognizing that the practices and procedures used by regulated parties to achieve safety and health outcomes are not static, and will continue to evolve with changing science and technology. In the first scenario, an outcome and its associated performance measures apply to an existing, well-known regulatory requirement. As such, well-established practices or procedures that achieve the outcome (e.g. heat treatment for pasteurization) continue to be valid. The Agency will assess achievement of the outcome using the associated performance measures (e.g. demonstration that appropriate time and temperature parameters are consistently achieved in a pasteurizer).

*Scenario 1 – A regulated party uses a well-established practice or procedure to comply with an outcome*

The Agency envisions the following regarding outcome-based regulation:

1. Clear outcome-based requirements, accompanied by quantitative or qualitative performance measures, in regulatory text.
2. The Agency provides examples of acceptable approaches for compliance through model systems for compliance, guidance material, and other compliance promotion tools.
3. Where the regulated party uses an alternative compliance approach, the party would need to establish or validate that their approach meets the outcome, and maintain records and documents of such validation.
4. The regulated party must be in a position to demonstrate compliance with the outcome, and upon inspection, provide the Agency with all relevant records and documents.
5. The Agency's inspectors verify compliance with the requirements.

<sup>9</sup> CFIA, *Guide to Food Safety*, <http://www.inspection.gc.ca/food/non-federally-registered/safe-food-production/guide/eng/1352824546303/1352824822033#s2-9>

Pasteurization is one such scenario. Food safety science regarding pasteurization (temperature and duration of treatment) is well-known. As such, the Agency would not seek evidence from the regulated party of validation of pasteurization; rather, the Agency would verify that the regulated party's approach to pasteurization was implemented properly and is operating effectively. The regulated party can comply with the outcome-based regulation with little or no adjustment to its approach.

In the second scenario, an outcome and its associated performance measures are completely new or fall within the context of a preventive control system. In this case, the Agency's guidance material or model system for compliance will provide regulated parties with information regarding how to achieve the outcome. As noted elsewhere, a model system for compliance is a non-binding model that provides guidance to a regulated party to meet a specified outcome (i.e. practices and procedures for premises and equipment that facilitate compliance). Again, the Agency will assess achievement against the associated performance measures, and focus on the outcome rather than the specific practice or procedure. By providing a model system for compliance the Agency does not alter a regulated party's obligation to comply with an outcome-based regulatory requirement.

*Scenario 2 – The Agency specifies a new regulatory outcome or preventive control requirement, accompanied by a new model system for compliance*

Imagine a scenario where the Agency changes the performance indicator for pasteurization (e.g. from elimination of the phosphatase enzyme to a logarithmic reduction of specific pathogens), and develops a model system for compliance to assist regulated parties implement the new approach to performance measurement. A regulated party that follows the model system to meet that outcome will still not have to validate the approach in the context of its operations, provided it follows that system, if applicable, or has appropriately adapted and implemented the model system to fit its particular circumstances. The Agency would verify through inspection that the model system was properly implemented, and is effectively controlling the pathogen.

In the third scenario, a regulated party wants to use an alternative compliance approach. In this case, the Agency has little or no experience with the new approach, and thus has not yet developed guidance material or a model system regarding how to achieve the outcome using the new approach. In such a case, the regulated party would need to establish or validate that their approach achieves the outcome, and maintain records and documents to demonstrate compliance with the outcome. Validation can be either through internal analysis or by a recognized third party. Upon inspection, the Agency will verify compliance by assessing achievement of the outcomes against the associated performance measures.

*Scenario 3 - A regulated party proposes an alternative compliance approach*

Imagine a scenario where a milk producer proposes to use high pressure treatment to achieve pasteurization of milk rather than high temperature and duration. Given that the Agency has little or no experience with this new approach, as a responsible regulator it will seek evidence that the new approach achieves the same or better milk pasteurization outcome. In this regard, the Agency would review the approach and relevant records of the regulated party upon inspection for compliance to determine if it had validated the approach met the outcome. In



assessing compliance, the Agency could apply relevant food safety science and undertake testing. The validation and verification of these new approaches would be guided by the performance measures associated with the outcome-based regulation.

Indeed, the opportunity to use new compliance approaches is a key reason why the Agency seeks to capitalize on the flexibility of outcome-based regulation. The Agency will work closely with regulated parties to facilitate introduction of these new approaches; however, regulated parties remain responsible for ensuring that all potential safety hazards are identified and controlled. Once an alternative compliance approach has been implemented, the Agency will verify on an ongoing basis that it achieves the same or better outcome.

### **Due Diligence and Outcome-based Regulation**

Key to adjusting to outcome-based regulation will be the collection and maintenance of performance data records by regulated parties. If this information is provided to the Agency, it could be used on a number of fronts that contribute to greater due diligence. At its foundation, performance data will be used by inspectors to verify that outcomes are achieved. It could also contribute to risk-based prioritization of inspection activities. As well, the information could be used to audit the integrity of the inspection system, allowing the Agency to analyze how inspection activities contribute to consistent achievement of regulatory outcomes. Furthermore, the information could be used to evaluate overall performance of the regulatory system, which would involve examining trends, compliance rates, innovation, etc. to ensure that Canada maintains one of the best food safety, and plant and animal health systems in the world.