Fact sheet: Outcome-based regulations under the Safe Food for Canadians Regulations

The Safe Food for Canadians Regulations (SFCR) include outcome-based regulations, which specify the desired result that a regulation is intended to achieve, rather than describing a specific process or action that must be followed to achieve compliance, as in prescriptive regulations.

Why do the SFCR include outcome-based regulations?

This approach enables industry to innovate and respond to emerging threats and make the food system even safer.

For example, to prevent risks due to standing water, rather than stipulating the number of floor drains required, an outcome-based requirement would simply state that there must be no standing water and let businesses decide how best to prevent it. In this case the outcome-based requirements could possibly prevent industry from making costly renovations that may not be necessary. In both approaches, the result is the same: risks to food safety are reduced.

Does that mean that the Canadian Food Inspection Agency (CFIA) is handing over responsibility for food safety to industry and that businesses don't have to follow rules anymore?

No. Outcome based-regulations do not lower food safety standards or allow companies to cut corners. While CFIA is open to innovation, it will be vigilant in verifying high standards of food safety.

In the case of outcome-based requirements, businesses need to provide evidence that their chosen methods of meeting the requirements are effective.

How are businesses expected to prove that their chosen method is effective?

The level of evidence needed depends on the associated level of risk.

For well-documented and known control measures like a cooking process that meets pre-established time and temperature parameters, industry needs to show that they are meeting the established standards.

However, for a newer control measure, like using high-pressure processing to control pathogen growth, businesses must have evidence that this method meets all desired outcomes so that the food will be safe for consumption. In this case, the evidence could take the form of existing peer-reviewed literature.



Does this mean that prescriptive requirements no longer exist?

No. Not all regulatory requirements are suitable for the outcome-based approach. To best mitigate risks to food safety, CFIA is continuing to use a mix of outcome-based and prescriptive requirements. In addition, many regulated parties need to continue to meet other regulatory requirements that may include prescriptive requirements that were not developed by CFIA, such as the Food and Drugs Act and Regulations and certain foreign country requirements.

How will businesses understand what needs to be done to comply with the outcome-based requirements of the SFCR?

CFIA recognizes that some businesses, in particular micro and small businesses, may require additional support to meet requirements. The CFIA is committed to helping these businesses adapt to outcome-based requirements by providing up-to-date guidance.

The CFIA has developed guidance documents for each requirement that explain why the requirement is necessary, what an inspector would expect to see, and sets out proven controls to meet the desired results.

Under the SFCR, businesses are required to have preventive controls in place. If they choose an innovative new approach, will CFIA validate it?

No, CFIA will not pre-approve preventive controls. The agency verifies that regulated parties comply with the requirement to have documented evidence that their control measures are effective. It is the responsibility of business owners to ensure they are meeting the requirements of the SFCR.

How will inspectors verify if the requirements for making safe food are met?

The CFIA has developed <u>guidance for inspectors</u> for each requirement that explain why the requirement is necessary, what an inspector would expect to see, and sets out proven controls to meet the desired results.

Unlike with prescriptive regulatory requirements, CFIA inspectors focus on verifying that:

- Regulated parties have controls in place to meet the requirements;
- These controls are appropriate for the specific situation and based on solid evidence that shows the controls are effective in addressing the hazards; and
- The regulated party is achieving the desired result.



CFIA inspectors follow the <u>Standard Inspection Procedure</u> (SIP). This procedure applies a consistent method of inspection. Verification activities can include making visual observations, evaluating documentation, interviewing personnel, sampling, measuring, testing, and commodity inspection. The SIP provides inspectors with the flexibility to adapt to different situations that may arise during an inspection.

Learn more at www.inspection.gc.ca/SafeFood.

