

Australia and New Zealand Food Regulation Compliance, Monitoring and Enforcement Strategy 2017

1. INTRODUCTION

Stakeholders in the joint food regulation system expect a reliable and credible food regulation system. The stakeholders are extensive and include individual consumers, industry bodies, primary producers, food manufacturers, importers and retailers, public health organisations, consumer advocacy organisations, community groups, and all levels of government in Australia and New Zealand.

Australian, State and Territory, and New Zealand government food regulators implement, monitor and enforce food laws. The regulatory activities of these food regulators occur in a continuum of generating compliance, monitoring and assessing compliance, and responding to non-compliance.

This bi-national Food Regulation Compliance, Monitoring and Enforcement Strategy (the Strategy) covers all of this continuum and includes the application of the Strategy to food labelling (Appendix 1), a suite of compliance generating activities (Appendix 2), a suite of activities for monitoring compliance (Appendix 3), and a suite of actions for responding to non-compliance (Appendix 4).

2. OBJECTIVES AND PURPOSE OF THE FOOD REGULATION COMPLIANCE, MONITORING AND ENFORCEMENT STRATEGY

Food regulators use a wide range of tools, including education and advocacy, to achieve good public understanding of the law and compliance by regulated parties (see section 3 for a description) and consumers. Regulated parties need to understand and comply with laws.

If non-compliance is identified the enforcement responses available to food regulators and what factors are taken into account when deciding which response to use need to be clearly identified and consistently applied. The community can expect that non-compliance will be treated seriously by Australian and New Zealand food regulators.

Therefore the objectives of the Strategy are to achieve compliance with laws and to facilitate consistent and effective administration of food regulation in Australia and New Zealand.

This Strategy transparently sets out the principles and approaches used by Australian and New Zealand food regulators to achieve legislative compliance and regulatory outcomes.

3. WHO ARE THE AUSTRALIAN AND NEW ZEALAND FOOD REGULATORS AND THE REGULATED PARTIES?

Australian, State and Territory, and New Zealand government food regulators implement, monitor and enforce food laws through their own Food Acts and other food related legislation. The Department of Agriculture and Water Resources enforces these laws at Australia's borders in relation to imported food.

The food regulators vary in each jurisdiction but generally include areas within Departments of Health, Departments of Industry, Agriculture and/or Primary Industries and/or Food Authorities. Across both countries, the bodies include:

- New Zealand government departments;
- Australian State and Territory government departments and authorities; and
- Local government – there are more than 530 local councils in Australia, and 67 territorial authorities in New Zealand.

Food regulators work closely with a range of government regulators to coordinate an effective response to achieve a compliance outcome.

Regulated parties are diverse and extensive because they are any person that produces, supplies or sells food for human consumption, including primary food producers, food manufacturers, importers, retailers, food service businesses (e.g. restaurants, cafes, caterers and hotels), community groups and on-line businesses.

4. WHAT IS THE SCOPE OF LEGISLATION COVERED BY THE STRATEGY?

In Australia and New Zealand, the regulation of food for domestic sale is covered by a range of laws and policies.

Each Australian State and Territory has a Food Act based on the Model Food Provisions and, except for ACT, has one or more Acts which regulate aspects of Primary Food Production.

The Australian Government regulates imported food through the Imported Food Control Act.

New Zealand also has a Food Act, Animal Products Act, Wine Act and Agricultural Compounds and Veterinary Medicines Act, all of which regulate aspects of food production.

The administration of all the above legislation is the scope of this Strategy.

5. WHAT IS THE SCOPE OF REGULATORY FUNCTIONS COVERED BY THE STRATEGY?

The scope is the following continuum of regulatory activities:

- Generating compliance,
- Monitoring and assessing compliance, and
- Responding to non-compliance (enforcement). ¹

¹ Canadian Food Inspection Agency 2015, *Compliance and Enforcement Operational Policy*, <www.inspection.gc.ca/about-the-cfia/accountability/compliance-and-enforcement/operational-policy/>, CFIA, Canada.



In practice, food regulators are undertaking activities in support of all three areas on a continual basis and in an inter-connected manner. Food regulators conduct activities to generate and monitor compliance focusing on different topics or priorities as issues arise. At any point in time, food regulators will take action(s) to respond to non-compliance using a risk-based graduated and proportionate approach.

6. GUIDING PRINCIPLES

The following principles are used by food regulators in carrying out their regulatory functions:

- i. Regulated parties are responsible for understanding and complying fully with all relevant legislative requirements.
- ii. Food regulators assist regulated parties in understanding their relevant legislative requirements, for example, through provision of clear information and guidance.
- iii. Food regulatory activities across the compliance, monitoring and enforcement continuum will (the order does not identify any weighting):
 - apply a risk-based, graduated and proportionate approach with the emphasis placed on the objectives outlined in the applicable legislation;
 - involve the application of strategies most likely to generate compliance;
 - involve the application of multiple strategies in certain circumstances;
 - be applied in a way that is fair, impartial and transparent;
 - be carried out by trained, designated personnel in a manner consistent with the powers set out in the applicable legislation;
 - be carried out in a way that supports regulated parties to comply, including simple and straightforward ways for regulated parties to engage; and
 - be timely and coordinated.
- iv. The home jurisdiction rule will apply across the compliance, monitoring and enforcement continuum. The home jurisdiction is the state or territory in which a food business is based or, in the case of a national chain, where the home company's head office is located. The home jurisdiction is responsible for food regulatory activities across the continuum with that food business.

In taking a risk-based, graduated and proportionate approach, the harm or potential harm (as described in the objectives of the applicable legislation) associated with a food or an area of non-compliance is a key consideration for food regulators when making decisions about food regulatory activities, alongside practices in place to manage risks, risk factors that are not controlled for, marketplace deception or product misrepresentation.

Most regulated parties want to comply with the applicable law and will work towards compliance if appropriate support is provided. A graduated approach involves an increasing or 'step up' approach to identified non-compliance and normally starts with less severe actions to achieve compliance and increases in severity where non-compliance continues. A graduated and proportionate approach involves a weighing of relevant factors to determine the appropriate action to take in the circumstances. For example, it may not be proportionate to deal with severe noncompliance with an educative approach.

Food regulators will be open and transparent about the manner in which they undertake compliance, monitoring and enforcement activities. The action being taken will be clearly outlined and where necessary a clear distinction will be made between what is legally required and what is desirable but not compulsory.

Food regulators need to prioritise the food regulatory requirements and matters for which compliance, monitoring and enforcement activities are conducted. This prioritisation will be undertaken based on the guiding principles.

7. THE COMPLIANCE, MONITORING AND ENFORCEMENT CONTINUUM

The timing and timeframes for the regulatory activities and actions of food regulators is affected by a number of factors including: the risk, the magnitude of the issue, resources, capacity, and the level of co-operation of a business and is determined on a case by case basis. These factors are discussed further below.

Compliance is: A regulated party adhering to the requirements of laws.

The approaches used by food regulators to achieve compliance with the law across the compliance continuum are explained in more detail below.

7.1 *Generating compliance*

Generating compliance is: the activities of a food regulator that encourage and assist regulated parties to understand and comply with regulatory requirements.

Food regulators strive to achieve clear, implementable and enforceable laws. Clearly worded laws support compliance by making it easier for regulated parties and consumers to understand the requirements that must be met.

Regulated parties have an obligation to understand the requirements of the law. This includes existing, amended and new law.

Compliance management by food regulators begins with open and transparent communication with regulated parties and consumers about existing laws, changes to laws and new laws. Better compliance outcomes are achieved when the legislative requirements are clearly identified and accessible to regulated parties.

Food regulators provide information to regulated parties and encourage and assist compliance through various communication and education activities (see Table 1 of section 7.4 for examples).

Appendix 2 provides a detailed explanation of the activities available to food regulators to generate compliance.

7.2 *Monitoring and assessing compliance*

Monitoring is: observing and checking the progress or quality of compliance over a period of time; keeping compliance under systematic review; or maintaining regular surveillance of compliance.

Assessment is: evaluating the compliance of regulated parties against the requirements of law.

The monitoring activities done by food regulators are determined by the application of a risk based, graduated and proportionate approach. This targets activity and prioritises effort where it is most needed. Both pro-active and reactive activities are part of the monitoring approach.

A range of proactive planned monitoring activities are used to determine the level of compliance within a regulated sector.

Reactive monitoring is done in response to customer requests, complaints, incidents or other intelligence gathered. Complaints are prioritised based on the information received from the complainant and employing a risk-based approach consistent with the guiding principles. Complaints considered low-risk may not be actioned unless further complaints are received.

Food regulators monitor and assess compliance with legislative requirements through activities such as inspections, audits, sampling and surveys (see Table 1 of section 7.4 for examples).

Policies and procedural documents guide food regulators on how to conduct monitoring activities and the frequency of such activities. They describe detail about the place or thing to be assessed, the assessment criteria to be used and what constitutes compliance.

The information and evidence gathered during monitoring activities is used to make an assessment of the compliance of a regulated party with the regulatory requirements. The regulated party will be informed in a clear and timely way of the outcome of the monitoring activity and of the food regulators assessment of its compliance. Monitoring and assessment results are recorded and communicated to the regulated party and become part of the regulated party's compliance history.

The results of these activities also provide feedback to design and redesign, where applicable, programs and related policies to provide an effective and efficient enforcement continuum. Information gathered during monitoring assists food regulators to:

- determine the level of compliance across a regulated sector and trends in compliance;
- identify when, whether and what type of education responses or enforcement actions may be required;
- assess and prioritise risk and optimise an appropriate response, including developing compliance programs focused on the greatest risk;
- allocate resources according to risk;
- identify opportunities for improvement; and
- assess and review the overall effectiveness of their operations, education and programs.

Appendix 3 provides a detailed explanation of the activities available to food regulators to monitor and assess compliance.

7.3 Responding to non-compliance (enforcement)

Non-compliance is: a state where a regulated party is not adhering to the requirements of laws.

Enforcement is: a food regulator taking steps to require regulated parties to follow the law.

While the majority of food businesses comply with legislation voluntarily, some don't and food regulators need to take enforcement action to address any legislative non-compliance. There is a public expectation that contraventions of the law will be met with meaningful and appropriate action. Once non-compliance has been identified a food regulator must determine the most appropriate response to obtain compliance.

Factors considered in decision making

In making a determination about the most appropriate response to obtain compliance, regulators take a risk-based, graduated and proportionate approach and a number of factors are considered including:

Harm

The seriousness of harm or potential harm of the non-compliance is considered; including the potential impact on human health, likely exposure to the harm or potential harm, marketplace deception or product misrepresentation. Emphasis will be placed on the harm as established by the objectives of the legislation.

History

The compliance history of the regulated party is considered with respect to the existence of previous instances of non-compliance, the seriousness of past non-compliance, the timeframe of previous non-compliance and the responsiveness of the regulated party in taking corrective action in the past.

Intent

Food regulators consider the intent of the regulated party to commit a contravention or cause harm. There may be evidence that demonstrates the regulated party knowingly contravened the legislative requirements, including the intent to mislead consumers. On the other hand there may be evidence to demonstrate care and diligence to attempt to comply with requirements.

Approach of the regulated party

The co-operation demonstrated by the regulated party to initial investigations and food regulatory activities will inform decisions about any subsequent actions, should compliance not be achieved.

Consistency in enforcement response

There are two aspects to achieving consistency in responses to non-compliance. The first is that similar situations or incidents of non-compliance should be responded to with similar enforcement action. Notwithstanding that two situations rarely have exactly the same circumstances.

The second aspect is achieving consistency in approach between officers of one regulatory agency.

To assist with both aspects regulators may develop policies and procedures for use by officers which set generally expected/minimum action that would be taken when specific non-compliances are found.

Flexibility of response to non-compliance

There is a range of actions available to food regulators such as letters; the issuance of an Expiation Notice; and referral for prosecution (See Table 1 for examples).

Food regulators have the flexibility to select the appropriate action based on the severity of the non-compliance considering factors discussed above.

A food regulator may use multiple actions to obtain compliance. In addition, the action of a regulated party in response to enforcement action may lead to further action being necessary. For example failure to comply with a statutory notice may cause an additional offence, resulting in a food regulator taking further enforcement action, such as issuing an Expiation Notice or launching a prosecution, in addition to taking action to fulfil the statutory notice.

Enforcement actions should be chosen and used in the way that will best achieve compliance and the objectives of the legislation.

Appendix 4 provides a detailed explanation of the actions available to food regulators to respond to non-compliance.

Communication of a decision to a regulated party

The decision of a food regulator about the enforcement action that it will take should be communicated to the regulated party clearly and in plain language. Any actions required by the regulated party to achieve compliance and the timeframes for undertaking that action should also be explained.

Advice should also be provided on the process for seeking a review, or how to appeal against the decision.

7.4 Examples of activities for each part of the Compliance, Monitoring and Enforcement Continuum

Table 1 Examples of proactive and reactive food regulatory activities and actions across the Compliance, Monitoring and Enforcement Continuum

| Activities for generating compliance <i>Proactive & reactive</i> |
|--|
| Education |
| Information and Advice |
| Use of the Integrated Model in Standards Development |
| Mediation |
| Public disclosure e.g. register of prosecutions |

| Activities for monitoring compliance <i>Proactive & reactive</i> |
|--|
| Audits and Inspections |
| Sampling and Surveys |
| Trend analysis of data, including complaints and compliance data |

| Actions for responding to non-compliance <i>Reactive</i> |
|--|
| Warning / Corrective action request |
| Notice / Order |
| Conditions on / Cancellations of Registration |
| Seizure or Mandated Recalls |
| Enforceable Undertakings |
| Expiation / Penalty Infringement Notice (on the spot fine) |
| Prosecution |

8. LIST OF APPENDICES

Appendix 1: Application of the Strategy to Food Labelling

Appendix 2: Actions for Food Regulators for Generating Compliance

Appendix 3: Actions for Food Regulators for Monitoring and Assessing Compliance

Appendix 4: Actions for Food Regulators for Responding to Non-Compliance

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