Key areas of inconsistency in food regulation

Report

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mpconsulting™

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Chapter 1: Introduction

Background

Consistency in the regulation of food across Australia and New Zealand is important to reduce the regulatory burden on food businesses and government enforcement agencies, facilitate efficient trade and manage food safety risks. The current framework for food regulation in Australia and New Zealand supports consistency while providing each jurisdiction with the flexibility to implement, monitor and enforce certain regulations in the context of the local environment. There are a range of mechanisms aimed at supporting consistency in food regulation (see Attachment A).

Recognising the various roles that each level of Australian and New Zealand governments play in food regulation, and the sovereignty of New Zealand and each Australian jurisdiction, bi-national uniformity is not practical nor desirable. The current framework provides a level of bi-national consistency while acknowledging the sovereignty and distinct context of each country. It also supports national consistency within Australia while enabling each jurisdiction to regulate based on local issues or priorities, governance structures, resourcing and capacity. It also enables each country and jurisdiction to develop new and innovative approaches to regulatory practice, specifically for implementing, monitoring and enforcing regulatory requirements.

However, there are some areas where inconsistency can inadvertently and unnecessarily impact outcomes, create challenges for industry (for example, in terms of cost, compliance burden, market disadvantage, lost opportunity, uneven playing field, duplication of effort, etc.) and also for government (for example, undermining food safety objectives, causing reputational damage to the food regulatory system, challenges enforcing compliance, creating confusion for consumers, etc.).

Process

mpconsulting was engaged by the Food Regulation Standing Committee (the FRSC) to identify key areas of inconsistency in food regulatory approaches based on the impacts of these inconsistencies on industry and government. This is intended to support governments to identify priority areas for reform and make evidence-based decisions regarding the future of the food regulatory system.

As part of this process, mpconsulting:

- reviewed a range of materials including previous reviews commissioned by government and research undertaken by industry peak bodies
- sought public feedback on a Consultation Paper
- undertook targeted consultations with government regulators, food businesses and peak bodies
- reviewed relevant legislation (including the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act), the Food Standards Code (the Code), State and Territory food and primary industries regulation, the New Zealand Food Act) and guidance developed by Food Standards Australia New Zealand (FSANZ), regulatory agencies and industry bodies.

mpconsulting received 47 submissions from stakeholders, including:

- 24 food businesses, comprising associations, primary producers, manufacturers/processors, transporters/distributors, suppliers, retailers, importers, exporters, hospitality venues, health and community caterer
  - Sectors represented included independent grocery stores, primary producers of chicken meat, eggs, dairy and seafood, alcohol-based businesses, some food service businesses and some large, multinational manufacturers of packaged foods.
- 9 government agencies, comprising local, state and federal governments
- 14 others, including public health organisations and consumer advocates.

It is noted that the time period over which consultation was undertaken (during late 2020) likely impacted the number of stakeholders able to make submissions and the level of detail included in submissions. While stakeholders were invited to provide cost estimates of the impact of any identified inconsistencies, none of the stakeholders who made submissions chose to do this.

The majority of respondents were responding from Australia, with only four New Zealand-based respondents and six Trans-Tasman organisations.

Given the small sample size, no sectors were strongly represented and some of the issues raised were sector specific and only raised by one or two respondents.

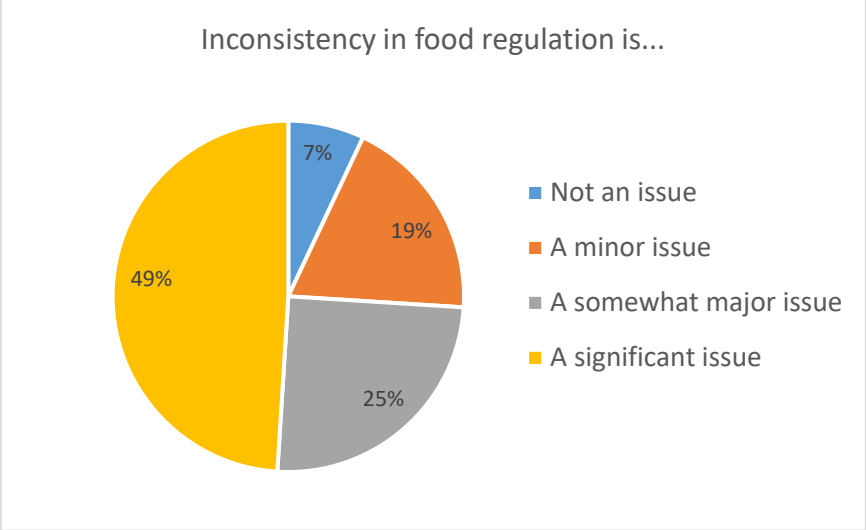
Stakeholder feedback

Stakeholders were asked a number questions relating to the consistency of food regulatory approaches (see Attachment B).

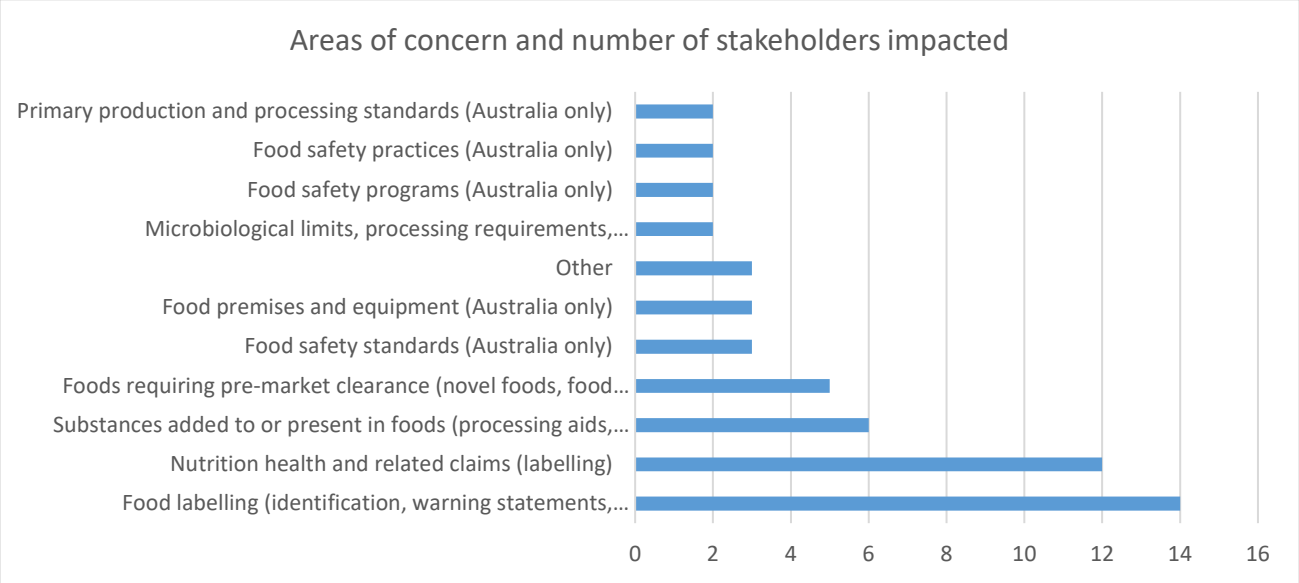
As anticipated, a range of issues were raised – some minor and very specific to a particular industry or business and some more significant.

Overall, stakeholders:

- felt that regulatory requirements are mostly consistent nationally within Australia and (to an extent) bi-nationally with New Zealand
  - Many stakeholders felt that there was strong consistency with regards to food safety matters ('where alignment is most important'). From an incident management perspective, strong consistency exists across jurisdictions in responding to food recalls, investigations of foodborne illness and decision making for these purposes.
  - Despite this, the vast majority of stakeholders considered inconsistency in food regulation to be a major or significant issue.



- highlighted that inconsistency has a more notable impact in some aspects of food regulation than others
  - For example, while there are some inconsistencies in the way certain requirements under the food safety standards and primary production standards are implemented across jurisdictions in Australia, the outcomes in relation to food safety are broadly consistent. Whereas inconsistencies in the application and enforcement of food composition and food labelling standards can result in notable differences between like products and create confusion for consumers.
  - Stakeholders were asked whether they had been impacted by inconsistent regulatory approaches (or inconsistent interpretation or enforcement of regulation) in any of the following areas and responded as below.



- described the different impacts of inconsistency, particularly on businesses that operate across jurisdictions.
  - Impacts on businesses included the increased costs/resourcing required to meet regulations across jurisdictions, market disadvantage for businesses based in certain

locations and limitations on capacity and incentives for innovation (including to improve food safety). Impacts on regulators included inefficient and duplicative monitoring and assessment of food businesses, challenges enforcing compliance, and more broadly, reputational damage to the food regulatory system.

- While quantitative information regarding the cost impact of any inconsistencies (particularly on food businesses) was sought from stakeholders, this was limited. Only one stakeholder provided an estimated (confidential) cost relating to the cost of relabelling products in response to changes to labelling regulations.

The subsequent chapter describes the range of areas of inconsistency identified by stakeholders. Following this, mpconsulting has identified a number of analysis and identification of possible areas for reform.

Chapter 2: Areas of inconsistency identified by stakeholders

Overview

Issues raised by stakeholders can broadly be grouped into the following areas:

- inconsistencies arising from the food regulatory system structure
- inconsistencies relating to labelling and claims
- inconsistent interpretations of standards
- inconsistencies with international approaches
- inconsistent approaches to the regulation of food premises across Australian jurisdictions
- inconsistencies arising from the interfaces between different regulators within Australia

This Chapter summarises stakeholder feedback in each of these areas.

Inconsistencies arising from the food regulatory system structure

While stakeholders were invited to provide advice on areas of inconsistency in food regulation and the impacts of this on businesses and regulatory outcomes, a number of stakeholders commented more broadly on some of the systemic or structural issues that they consider give rise to inconsistency, or more broadly, create complexity and unnecessary regulatory burden.

Navigating the regulatory framework

Industry stakeholders highlighted that food regulation is complex, making it difficult for owners of food businesses to understand their obligations. For example, stakeholders suggested that:

- requirements relating to one food industry may be spread out over hundreds of pages of legislation and described across multiple pieces of legislation (including both national and state level food and primary industry legislation).
- the structure of the Code itself makes it difficult to find information, which can lead to inconsistencies in interpretation. Stakeholders noted that, in addition, there is no searchability function in the Code to assist with finding information
- it can be difficult for businesses to interpret complex technical requirements and there is limited guidance available on how technical requirements should be applied in different industries
- there are many government agencies involved in the regulation of food. Owners of food businesses often don't know who to approach for advice or which agency is 'the source of truth'. Inconsistencies in how legislation is interpreted and applied across Australian jurisdictions further exacerbates this complexity (discussed below).

Governance of the food regulation system

A number of stakeholders emphasised that inconsistencies tend to arise from the complex and (sometimes) unclear roles and responsibilities of different actors within the system.

Stakeholders variously reported:

- The role of FSANZ in exploring changes to the Code is often duplicated by the FRSC and/or the Forum. Stakeholders felt that the assessment of applications and proposals is 'double-handled' by the FRSC/Forum and that the consultation process is often 'messy' due to the involvement of these bodies. Some stakeholders highlighted that this makes it challenging for industry (and public health and consumer bodies) to meaningfully feed into the development of regulation or changes to regulation.
- While the role of the Implementation Subcommittee for Food Regulation (ISFR) is to ensure food standards are implemented and enforced consistently, this body does not have the authority to effect changes to policy to promote consistency (this is the role of the FRSC). Some stakeholders noted that this lack of clarity regarding the role and scope of responsibility of various governance bodies means that even where issues are identified, it is challenging to implement changes to address these.
- The multiple bodies involved in food regulation can mean that industry bodies do not know where to source guidance on a particular matter. Some stakeholders considered that FSANZ should be the "source of truth" regarding the interpretation of certain requirements. Stakeholders suggested that FSANZ could make binding determinations of the Code and provide a central point of contact with which the public could raise issues and enquiries. It was also noted that FSANZ could develop advice and guidance for other enforcement agencies involved in food regulation, including the New Zealand Ministry for Primary Industries (MPI), Australian State and Territory Government regulators, the Australian Therapeutic Goods Administration (the TGA) and the Australian Competition and Consumer Commission (the ACCC), the New Zealand Medicines and Medical Devices Safety Authority (MedSafe) and the New Zealand Commerce Commission (CC).

Amending the Code

Stakeholders highlighted that the complexity, cost and extended timeframes for making changes to the Code mean that it is challenging to make necessary changes to keep the Code current. As a result, stakeholders highlighted that some regulations in the Code are quickly outdated and there are 'gaps' in the regulation of some industries or products. The impact of these gaps is that Australian and New Zealand food businesses are unsure how to ensure certain products are compliant with the Code, leading to inconsistent application of requirements.

Some specific areas where stakeholders suggested that the Code has not kept pace with industry and international practice are described under inconsistent interpretation of standards.

With regards to applications, some industry stakeholders highlighted that it can be 'prohibitively expensive for industry to seek sensible changes to the Code' and as such, 'only large companies likely to see a significant commercial benefit in changes can interact in the system'.

With regards to proposals, whilst the FSANZ Act requires FSANZ to finalise applications within certain timeframes, proposals initiated by FSANZ are not time-limited. This means that proposals are not always prioritised in the FSANZ work plan and can take considerable time to resolve.

Industry stakeholders identified two specific examples of proposals that have been delayed for several years:

- P1030 Composition and labelling of electrolyte drinks, which commenced in February 2014
- P1024 Revision of the regulation of nutritive substances and novel foods, which commenced in December 2012.

A number of industry stakeholders raised the ongoing delay and de-prioritisation of proposals create ongoing uncertainty for food businesses. Where adjustments to clarify the intent of certain standards are delayed, this results in ongoing ambiguity and inconsistency in the interpretation and implementation of standards and creates potential non-compliance by industry. Public health and consumer advocacy bodies also highlighted that the prioritisation of applications over proposals has the potential to put industry interests above public health and consumer interests.

> *Due to the burden of regulation within the Australian-New Zealand market it is often considered slow compared to other markets. This not only creates unnecessary cost, but also does not consider the realities of carrying out business in this market this includes interactions with retailers. There are only limited times during the year that retailers can consider ranging new products. If food businesses are not able to make these times, then they will not be able to sell their products in retailers' stores for some time. Any first mover advantage that could be gained is often lost in complying with regulatory requirements, which impacts the value that innovation could bring and dampens any desire to be the first to market with innovation.*

Consequential amendments to the Code

Some stakeholders also raised that there are some low risk areas of the Code that cross-reference international standards or the requirements of other countries/international bodies (e.g., with regards to food additives, methods of analysis, etc). There are also domestic matters such as changes to nutrient reference values (NRVs) that need to be kept up to date.

For example, some public health bodies noted that the NRVs used in the Code date from 2006. The National Health and Medical Research Council, (which sets NRVs based on currently available scientific knowledge) has updated a number of these since this date (e.g., fluoride in 2016 and sodium in 2017). It was suggested that this results in inconsistency between the NRVs referenced in the Code and those used elsewhere to inform public health policy. Stakeholders suggested it would be logical for the Code to be updated automatically in such circumstances, rather than requiring a proposal to be prepared by FSANZ and approved by the Forum.

It was suggested that the dynamic nature of the food industry is such that changes are frequently needed to keep the Code up to date and aligned with international technological and regulatory developments.

Coordination of regulatory changes

While not an area of inconsistency as such, many industry stakeholders raised that the introduction of new or amended regulatory requirements is not well coordinated. It was reported that 'as one major regulatory change is implemented, another one will emerge' placing burden (and cost) on industry to continuously review its practice to ensure ongoing compliance.

This was considered particularly impactful with regards to changes to labelling requirements.

Case study – labelling changes

One stakeholder raised the example of the recent changes to the Health Star Rating (HSR) system.

Many manufacturers are currently in the process of reviewing labels based on the outcomes of the Five Year Review of the HSR system. However, further labelling changes are currently being considered by governments, including Added Sugars Labelling, possible refinements to Country-of-Origin labelling within Australia and Plain English Allergen Labelling (Proposal P1044), which has recently been approved.

Stakeholders noted that the cost of labelling changes can be in the millions, and that the inability to plan for and coordinate changes to labels is inefficient. One stakeholder noted that 'the lack of alignment on timings has the potential to result in multiple label changes across all products, which is incredibly burdensome and costly to food industry.'

Stakeholders also highlighted that it is difficult for industry to plan for potential upcoming changes to regulations, as there is often 'no clear guide as to when the changes are expected to take place, if ever'. Some stakeholders referenced Proposals that have been on hold for years, making it challenging for industry to identify whether changes are likely to occur and what they need to do to comply with such changes. Industry stakeholders said they are required to 'try to anticipate' when changes might occur and try to align regulatory compliance internally.

Inconsistencies relating to labelling and claims

As noted in the previous Chapter, the majority of submissions focussed on inconsistency relating to labelling and claims. This was highlighted by all stakeholder groups across Australia and New Zealand, including government, industry and consumer advocacy and public health bodies, as a critical area of inconsistency in the food regulatory system.

The reasons for the inconsistency were variously described including:

- lack of clarity in the Code itself
- differences in interpretation within industry and between regulators
- inconsistent or absent enforcement by regulators, with some businesses taking advantage of this.

The impacts of this were described as:

- undermining confidence in the system
- creating an uneven playing field for industry (providing an unfair advantage to food businesses making inappropriate claims in jurisdictions that do not as actively monitor and enforce the requirements)
- limiting the ability of consumers to make informed choices.

While these impacts were not quantified by any of the stakeholders that provided a submission, they were variously described as having a significant impact across all stakeholder groups.

Labelling

Stakeholders raised various examples of inconsistent application of labelling requirements by food businesses. Some of these were attributed to unclear legislation or lack of guidance and some to inconsistent (or absent) enforcement by regulators.

In, relation to requirements under the Code, stakeholders raised the following examples:

- **Legibility of labels** – Standard 1.2.1 – Requirements to have labels or otherwise provide information (s24) specifies that if the Code 'requires a word, statement, expression or design to be contained, written or set out on a label—any words must be in English and any word, statement, expression or design must, wherever occurring: be legible; and be prominent so as to contrast distinctly with the background of the label'. Stakeholders have raised concern that these 'fairly general' requirements are not always rigorously applied by manufacturers and important information may not always be easy for consumers to read, particularly where consumers may be vision impaired. An example of this was provided for alcoholic beverages where the alcohol content and standard drink information was not obvious. FSANZ has published a Legibility Requirements for Food Labels User Guide (December 2013) however one stakeholder noted this is outdated and does not include sufficient examples of the effective display of information on labels.

- **Labelling of imported products** – Importers are responsible for ensuring the labelling on the food products that they import is compliant with the requirements of the Code. However, some stakeholders have highlighted that imported products regularly do not comply with some labelling requirements, creating an unfair advantage for those who do not comply. Stakeholders referenced products with no English on their labels or labels with non-compliant (or missing) NIPs, ingredients lists, mass declarations or allergen warnings.

Stakeholders also highlighted the following examples which currently sit outside of the food regulatory system:

- **Country of Origin Labelling** – Some stakeholders raised concerns about manufacturers incorrectly claiming their products are 'Australian made'. An example was provided where a manufacturer claimed a sports and nutritional supplement to be Australian made when the

product comprised of 100% imported ingredients that are dry blended in Australia. Advice by the ACCC's Country of Origin food labelling guidance specifies that products packaged in Australia using food from another country/countries should be labelled as 'Packed in Australia with ingredients from…'. Manufacturers have highlighted the competitive advantage (particularly in the current global climate) gained by claiming a product to be 'Australian Made' and the unfair disadvantage to manufacturers that are labelling their products correctly.

- **Container deposit schemes** – A number of Australian jurisdictions operate container deposit schemes, providing incentives to encourage recycling of used beverage containers. Some stakeholders highlighted that requirements to display certain information regarding container deposit schemes are not consistent across jurisdictions, particularly given there is not an operative scheme currently active in New Zealand (noting this is currently being developed).

- **Trade measurement requirements** – Trade measurement requirements differ between Australia and New Zealand. In particular, the Australian *National Trade Measurement Regulations 2009* specifies that tomato sauce must be labelled in volume, whereas the New Zealand regulations do not have this requirement. It was suggested that Australia also has stricter requirements regarding trade measurement text and positioning on a label, creating trade complexities between jurisdictions.

While the above requirements are not implemented through food regulation, they impact on food labelling and are not viewed as separate by a number of industry and consumer stakeholders.

General level health claims

Many stakeholders (across all stakeholder groups) commented on the inconsistent monitoring and enforcement of the nutrition, health and related claims standard, particularly with regards to self-substantiated health claims and the level of evidence required to demonstrate compliance.

The current approach to self-substantiated health claims requires the business using the health claim to certify that the food-health relationship has been established by systematic review in accordance with Standard 1.2.7 – Nutrition and related health claims and to notify FSANZ. While FSANZ administers the notification process, it does not assess compliance of the notified food-health relationships, as this responsibility lies on the jurisdictions. FSANZ recommends that food businesses contact their local enforcement agency before notifying a self-substantiated food-health relationship to ensure that the jurisdiction is aware of the business's intentions, while avoiding unnecessary and inadequate notifications.

Case study – Verifying health claims

One organisation provided an independent review[1] undertaken of a number of specific health claims listed on the FSANZ website in 2017 (for companies based in Australia only) and found the majority could not be substantiated by an independent assessment of the available evidence. The organisation lodged 27 complaints about 100 notified relationships and found that only one

[1] Wellard-Cole L, Watson WL, Hughes C, Chapman K, 'How effective is food industry self-substantiation of food–health relationships underpinning health claims on food labels in Australia?' *Public Health Nutrition* 2019, 22, p.1686-1695.

jurisdiction took action to remove these from the FSANZ website. The review found that the time taken to investigate such complaints is often lengthy (up to 20 months) and complainants often do not receive responses notifying if the complaint has been investigated. The review also found that different enforcement agencies reached different outcomes in relation to similar health claims.

Stakeholders variously suggested that:

- there is a lack of clarity and transparency in the process for monitoring and assessing compliance of health claims used by some jurisdictions (referencing other public studies[2]).
- jurisdictions have varying capacity and capability to monitor compliance and proactively investigate claims, with some evaluating every notified health claim that is made, others relying on public complaints being made before acting and others choosing not to act. The process used by each jurisdiction to assess the compliance of general health claims is also variable, as this can be complex and costly, requiring scientific rigour and expertise
- Because claims do not need to be vetted prior to notification, the ability of food businesses to bring unsubstantiated health claims to market can undermine confidence in the food system, create an uneven playing field for industry (providing an unfair advantage to food businesses making inappropriate claims in jurisdictions that do not as actively monitor and enforce the requirements) and impact on informed choice for consumers
- in jurisdictions where health claims are more proactively monitored and assessed for compliance, it can be challenging for regulators to enforce compliance. For example, where a business is asked to remove a health claim that has been found to be unsubstantiated, the business may challenge this on the basis that it has been allowed in other jurisdictions and other companies may display similar claims in those jurisdictions.

While a number of stakeholders expressed their concern regarding this matter, others highlighted that given the majority of foods carry a low risk to public health, the implementation of more rigorous measures to ensure consistency and compliance across health-related claims would increase regulatory burden for food businesses and government alike 'that is non-commensurate with risk'. Stakeholders noted this may disadvantage small businesses who are unable to resource the implementation of additional compliance measures and is 'at odds' with the Australian Government's Deregulation Taskforce and the Modern Manufacturing Strategy, which are committed to reducing red tape, removing unnecessary regulation and reducing business compliance costs.

Nutrition claims (specifically 'Free' claims)

'Free' claims can be made about the absence of a substance in a food or beverage. These claims are regulated by both FSANZ (through the Code), the ACCC in Australia and the CC in New Zealand. The Codex Alimentarius also provides guidance on 'free' claims, which is adopted within many

[2] Wellard-Cole, L.; Watson, W.L.; Hughes, C.; Chapman, K. How effective is food industry self-substantiation of food–health relationships underpinning health claims on food labels in Australia? Public Health Nutrition 2019, 22, 1686-1695. Harvey, K.; Li, E.; Stanton, R.; Dashper, S. Kids' vitamin gummies: Unhealthy, poorly regulated and exploitative. Journal of the Home Economics Institute of Australia 2017, 24, 42-43.

international food systems. The Code permits 'free' claims when a component is not detectable, whereas the ACCC and the CC require that the absence of the substance must be absolute. This results in limitations to what claims can reasonably be made by companies. Some examples of this inconsistency that were raised by some industry and public health stakeholders include:

- **'Sugar free' claims** – It was noted that the ACCC and CC are not aligned with the Codex Alimentarius (EU Directive or US FDA which permit variations on Codex) which allows 'sugar free' claims on products with less than 0.5 mg/kg of sugars. A number of industry stakeholders noted that this limits the ability to innovate and reformulate to provide low and no sugar options where these options have 'minute, trace levels of sugar with no physiological impact'. It was noted that the ACCC and CC's approach prevents such products from being labelled as 'sugar free', whereas in other markets (such as the USA) these trace amounts would fall within the tolerance threshold, thus permitting the 'sugar free' claim.

- **'Fat free' claims** – Stakeholders advised that ACCC and CC are not aligned with the Codex Alimentarius which allows 'fat free' claims on products with less than 0.5 mg/kg of fats.

- **'Gluten free' claims** – Two main issues were raised in relation to gluten free claims:
  - Some stakeholders suggested that the Code, the ACCC and the CC are not aligned with the Codex Alimentarius which allows 'gluten free' claims on products with less that 20mg/kg of gluten. Applications were made to FSANZ in 2016 and 2019 to amend the Code to permit 'gluten free' claims where a product contains less than 20mg/kg gluten, in line with Codex Alimentarius. It was suggested that the application was unsuccessful due to FSANZ's assessment that there were gaps in the evidence that 20mg/kg is a safe level.
  - Others were concerned that some products claiming to be 'gluten free' also display a precautionary cross contact statement regarding wheat/gluten in the same product. This can be problematic for coeliac consumers who are uncertain whether to trust the 'gluten free' claim. While a 'gluten free' claim is defined in legislation, the use of a precautionary cross contact statement is voluntary – industry guidelines (published by the Australian Food and Grocery Council) are available to guide the use of cross contact statements. Stakeholders highlighted that some jurisdictions do not actively monitor and enforce this, while other jurisdictions require manufacturers to choose between the 'gluten free' claim or a precautionary cross contact statement.

Some stakeholders highlighted that this inconsistency can disincentivise product innovation and create confusion for Australian manufacturers and restrict consumer choice. It also makes labelling more complex, particularly for products that are traded internationally.

> *"Not allowing these claims with negligible and nutritionally insignificant levels of the claimed nutrient, as permitted by Codex, the US and Europe, denies consumer choice and innovation in the market, presents lost market opportunities and importantly market disadvantage and economies of scale. Products such as these invariably escape border inspection (as low priority surveillance foods) and once in the market jurisdictions do not take enforcement action given limited resources and other higher (food safety) priorities."*

Inconsistent interpretations of standards

Stakeholders (predominantly from industry and some from government) noted that inconsistent interpretation of standards between different regulatory agencies (and even by different individuals within regulatory agencies) can be frustrating and costly for food businesses.

Stakeholders broadly considered that inconsistencies arose from:

- 'gaps' in the Code where the Code has not been updated to keep pace with industry innovation and practice (and international approaches)
- a lack of clarity in the wording of some standards, that can lead to inconsistent interpretation and application, or
- different interpretations by different jurisdictions, which may be influenced in part by different risk appetites.

Stakeholders highlighted a number of areas where inconsistent interpretations arise. For example:

- **Beverages** – Standard 2.6.2 – Non-alcoholic beverages and brewed soft drinks describes the compositional requirements for certain types of beverages. However, there are now a wide array of water-based products available on the market that are not categorised within this standard.

- **Online food services**
  - Internet food orders are not considered in the Code and are consequently regulated as takeaway services. Stakeholders noted that this is challenging as the associated labelling exemptions are not always appropriate.

- **Iodised salt**
  - Standard 2.10.2 – Salt and salt products previously contained an editorial note specifying that salt manufacturers were to aim for 45mg/kg of iodine in iodised salt (based on FSANZ modelling) to help address mild iodine deficiency in Australia and New Zealand. This has since been removed, and while the Standard continues to provide a range in permitted iodine concentrations of iodised salt (25 – 65mg/kg), businesses are uncertain as to whether they should continue to aim for 45mg/kg of iodine in iodised salt.

- **Cadmium**
  - Schedule 19 – Maximum levels of contaminants and natural toxicants specifies the maximum permitted level for cadmium in 'chocolate and cocoa products' is 0.5 mg/kg. Stakeholders have highlighted that this regulation is intended to apply to finished retail products available to consumers to minimise potential adverse health impacts through dietary exposure and should not apply to ingredients used to manufacture cocoa products, however without this being clarified in the Code (or associated guidance), it was suggested that most manufacturers interpret this limit to apply equally to cocoa used as ingredient to manufacture cocoa products, which can restrict the sources of cocoa available to them and unnecessarily increase manufacturing costs.

- **Food safety practices**
  - Standard 3.2.2 – Food safety practices and general requirements specifies requirements for food businesses and food handlers to ensure food safety. Stakeholders highlighted that this standard is relatively high-level, and expectations of food businesses can be unclear. For example, section 7 requires a food business to 'use a process step that is reasonably known to achieve the microbiological safety of the food'. Some stakeholders highlighted that for people with limited understanding of food safety, such processes may not be well understood and non-compliance with this can be a key cause for outbreaks of foodborne illness.

- **Sanitation chemicals**
  - Standard 4.2.2 – Primary production and processing standard for poultry meat specifies that a poultry producer must 'systematically examine all of its primary production operations to identify potential hazards and implement control measures to address those hazards'. One primary producer highlighted that they trialled a new 'potentially improved, and internationally accepted' sanitation chemical in its processing operations. However, differences in approach and interpretation between jurisdictions meant that in one jurisdiction all chicken sanitised with the different chemical had to be discarded, which was a large financial loss for the company. However, a different jurisdiction was willing to work with the company to develop and implement a food safety plan for the new chemical and this product was able to be sold.

Industry stakeholders highlighted that different interpretations, approaches or risk-appetites between regulatory agencies limit the willingness and ability of industry to innovate to improve food safety management. Such examples also reportedly impact on decisions made by businesses as to which jurisdictions to establish and expand their operations.

Food businesses reported they spend significant resources trying to determine how to interpret regulatory requirements to ensure their compliance – highlighting that while large food businesses may have the resources to ensure their compliance with standards that are outcomes-based or less prescriptive, small to medium businesses don't always have the skills and knowledge to interpret standards and apply these requirements to their business effectively. It was suggested that more detailed guidance be provided for industry and for regulatory agencies, particularly around standards that are a common source of non-compliance or food safety issues.

Where the Code fails to keep pace with international practice, industry innovation is limited, placing Australian and New Zealand manufacturers at a disadvantage. This also impacts on consumers by limiting the availability of certain products in the Australia and New Zealand markets.

> *"Often the lack of clarity can result in products not being launched here or being prohibitively expensive. These are frequently products that provide specific nutrition benefits to compromised populations."*

Inconsistencies with international approaches

While the review is not focusing specifically on inconsistencies between the joint Australian and New Zealand food regulatory system and other countries, a number of industry stakeholders described areas where the bi-national regulatory requirements do not align with international standards and approaches.

Some specific areas that industry raised included:

- **Novel foods**
  - While it was acknowledged that FSANZ has regard to international standards (such as those developed by the Codex Alimentarius and the WHO's Joint Expert Committee on Food Additives) in its assessment and standard development processes, it was suggested that international evidence should be considered when FSANZ is assessing novel foods as this may 'help facilitate speed to market for innovation and reduce regulatory burden and duplication'.

- **Allulose status**
  - Allulose is widely used as a sugar substitute as it has 'the bulk and the mouth feel of table sugar with reduced caloric content' but contains fewer calories (approx. 0.4cal/gram)[3]. In Australia and New Zealand, allulose is considered a 'sugar' for the purposes of preparing nutrition information panels and ingredients lists. The FDA released *The Declaration of Allulose and Calories from Allulose on Nutrition and Supplement Facts Labels: Guidance for Industry* in October 2020 stating that it intends to 'exercise enforcement discretion with respect to the exclusion of allulose from the amount of "Total Sugars" declared on the label pending future rulemaking regarding amending the definition of "Total Sugars"'. Some stakeholders (particularly those in the beverage and confectionary industries) are seeking similar guidance from FSANZ, noting 'this uncertainty locally, and the complexity of making an Application to address this, continues to limit the beverage industry's ability to bring products to these markets as the size of the potential market does not justify the cost and delay in seeking an amendment to the Code'.

- **Maximum residue limits**
  - Schedule 20 – Maximum residue limits sets out the agricultural and veterinary chemicals, and their permitted residues, that may be contained in a food for sale in Australia. In New Zealand, maximum residue limits (MRLs) for agricultural compounds are set out in Food Notice: Maximum Residue Levels for Agricultural Compounds. For those not listed, it sets an MRL of 0.1 mg/kg. Other trading partners of Australia have also established a process for recognising default MRLs to manage low levels of residues occurring in foods which present no safety risk to consumers but do not have a specified MRL.
  - A number of industry peak bodies identified that:

[3] Mooradian AD, 'In search for an alternative to sugar to reduce obesity', *Int J Vitam Nutr Res*. 2019 Sep, 89(3-4), p.113-117.

- Australia does not have a process for recognising default MRLs, and importers are prohibited from importing ingredients/food containing chemicals that are not listed in Schedule 20 of the Code into Australia
- while FSANZ has adopted a risk assessment approach to establishing 'all other foods except animal food commodities MRLs', FSANZ has not determined a process or priority list for establishing MRLs for the remaining chemicals listed in Schedule 20 of the Code.
- these chemicals are frequently present at the lowest levels of detection and represent no incremental risk to consumers. Some industry stakeholders noted this has been an ongoing issue that can be costly to manage and makes it challenging for Australian manufacturers to participate equally in the global market
- the need for Australia to develop a more 'comprehensive, innovative and timely' approach to the management of low levels of agricultural and veterinary chemicals to better support industry to operate in the global market. It was suggested that Australia could adopt similar arrangements and default MRLs as New Zealand, Canada and other trading partner countries.

- **Formulated supplementary foods for young children**
  - Formulated supplementary food for young children (FSFYC) are defined under Standard 1.1.2 – Definitions used throughout the Code and Standard 2.9.3 – Formulated meal replacements and formulated supplementary foods as 'a formulated supplementary food for children aged 1 to 3 years'.
  - Codex stipulates this age range as '12 to 36 months'. One stakeholder suggested that as the Code does not specify the age range in months, this creates ambiguity as to whether it extends to immediately before the child's fourth birthday, or whether it stops at age 36 months. It was suggested that this inconsistency has potential to create challenges for businesses wishing to trade FSFYC internationally.

Stakeholders felt that such inconsistencies:

- acted as a brake on innovation
- presented a barrier to participation in world markets
- resulted in duplication of effort (for those applying for amendments to the Code and for regulators)
  - It was suggested that the lack of consistency with regard to reference of international standards and risk assessments means that FSANZ sometimes duplicates work that has already taken place overseas. Some stakeholders highlighted that this is not cost-effective or risk-proportionate and limits the ability of Australian and New Zealand industry to innovate.
  - It was also suggested that other countries (such as the US Food and Drug Administration (FDA), Health Canada and the European Food Safety Authority (EFSA)) have articulated processes for risk assessment in food regulation that could be reliably used as an evidence base for adopting standards or making changes to the Code

Inconsistent approaches to the regulation of food businesses across Australian jurisdictions

Registration and classification of food businesses

Food businesses and some Australian State/Territory and local governments raised the following issues in relation to the registration and classification of food businesses:

- **the process and fees for notifying or registering a food business differs between jurisdictions (and even within some jurisdictions), creating confusion for business owners and for some regulators**. For example:
  - In the Northern Territory, all food businesses need to be registered with the NT Department of Health. Registration can cost up to $217 and must be renewed annually for a fee of up to $175.
  - In Western Australia, food businesses are required to pay a one-off registration fee of $228 to register with WA Department of Health.
  - In Victoria, all food Class 1, 2 and 3 businesses must register with their local council and pay an annual registration fee. These differ significantly between local councils but can be more than $1,000. Class 4 businesses must notify their local council.
  - In South Australia, food businesses must notify their local council. There is no registration fee.
  - In Queensland, food businesses are licensed by local governments, with the fee structure varying across local government areas.
  - In Tasmania, Priority 1, 2 and 3 business must register with their local council and pay an annual registration fee, which differs between local councils. Priority 3N and 4 businesses must notify their local council.
  - In the ACT, most food businesses must be registered with the Health Protection Service. Registration can last up to three years and costs up to $828.
  - In New South Wales, food businesses need to notify either the NSW Food Authority or local government. Certain food industries need to apply for a licence through the NSW Food Authority. The fees for licenced industries are based on the business' number of fulltime employees, while the fees charged by local governments can vary.
  - In New Zealand, food businesses must register with their local council, or with the MPI if operating in more than one local council area.

- **different jurisdictions use different approaches to classify food businesses according to the level of risk their food handling activities pose**. It was suggested that this can result in businesses undertaking the same types of activities and selling the same types of food products being categorised differently in different jurisdictions (resulting in an increased compliance burden for some food businesses based on their location).
  - While many jurisdictions have adopted the national risk profiling tool and Risk Profiling Framework endorsed by FRSC (with varying degrees of modifications), others have a 'Class 1-4' system and others still use a 'High – Low' risk system.
  - The impact is that additional regulatory requirements may be implemented on different business sectors across jurisdictions and create inconsistencies, especially where a

business is a national organisation. Inconsistencies of this nature also reduce the ability for jurisdictions to share resources or systems and better manage limited resources.

- Where similar businesses are classified at a different risk level based on the jurisdiction the business is located, this can creates commercial disadvantage for businesses classified as higher risk (for example, where registration/audit fees might be higher, and the compliance burden may be greater).

Food safety programs and supervisors

The Code requires certain high-risk businesses to maintain a food safety program (to be developed in accordance with Standard 3.2.1 – Food Safety Programs). A Food Safety Program is a written document indicating how a food business will control the food safety hazards associated with the food handling activities of the business.

It was suggested that jurisdictions have different approaches to:

- **food safety programs** – For businesses with outlets in multiple jurisdictions, this can result in confusion and duplication of work – for example where a business is required to tailor food safety programs/plans to the requirements of each jurisdiction and must submit them to multiple regulators for review.

Case study – food safety programs

One stakeholder provided an example where their business employs staff in each of the states it operates with the sole purpose of maintaining the food safety program and government reporting for that state. The business owner noted that the inability to implement a single food safety program across all its operations 'due to the vast differences in how the jurisdictions interpret the Food Standards'. The business owner highlighted that if a single food safety plan was able to be implemented nationally, these staff could be redeployed to improving the business' food safety management. They also highlighted that the inability to implement a national food safety program/plan and different reporting requirements means that food safety management cannot be effectively compared between different operations, which limits a business' ability to identify areas for improvement in food safety management and adopt streamlined systems to manage food safety as the requirements differ jurisdictions.

- **food safety management statements** – Standard 4.1.1 – Primary production and processing standards – preliminary provisions specifies that certain businesses must have a food safety management statement (FSMS). It provides that a FSMS must be approved by a regulatory authority and is subject to ongoing verification by the relevant authority. The model food provisions do not cover primary production and processing. As such, some government stakeholders noted it can become problematic when primary processing standards stray into jurisdictional administrative arrangements in relation to primary production and processing (for example, by specifying the need for approval by a relevant authority). Regulatory agencies noted this can be problematic when undertaking monitoring and enforcement activities.

- **food safety supervisors** – Some jurisdictions require that businesses of a certain risk level/classification employ a food safety supervisor (FSS), which requires a food business to have employed a nominated person who has completed a food safety training course.
  - New South Wales, Victoria, Queensland and the ACT mandate the appointment of an FSS for businesses that serve ready-to-eat food, potentially hazardous food or food not sold and served in its original packaging. However, there are differences between the way this requirement is implemented in each State.
  - In New South Wales, an FSS is required for food businesses that prepare and serve food. The NSW Food Authority publishes a list of approved RTOs that can deliver FSS training and FSS certificates must be renewed every five years.
  - In Victoria, all Class 1 and most Class 2 food businesses must have an FSS, who must have completed specified minimum competency standards in food safety training for the food sector that they are currently working in through any RTO.
  - In the ACT, all registered businesses must appoint an FSS and provide the Health Protection Service with a copy of the completion certificate and proof of completing all training modules.
  - In Queensland, every licensable food business must have an FSS. Specified FSS training is recommended but not mandated and the FSS must be notified to the local government.
  - Western Australia, South Australia, Northern Territory and Tasmania do not mandate the appointment of an FSS. However, generally a food business needs to be able to demonstrate that someone employed in the business has the skills and knowledge to implement a food safety program.

These differing requirements can be confusing for business owners who have food businesses across multiple jurisdictions and make it challenging for employees to determine the level of training required to demonstrate that the skills and knowledge requirement has been met. FSANZ is currently progressing Proposal P1053 – Food Safety Management Tools (P1053) to explore food safety tools to support food service and retail businesses to better manage foodborne illness risks.

Audit and inspection of food businesses

Some food businesses and government regulators provided examples of differences between jurisdictions with respect to audit and inspection arrangements, frequency of audits/inspections and fees. For example, it was noted that:

- in some jurisdictions the **cost of surveillance audits** is part of the business registration cost and in others, food businesses are invoiced for each audit

- **arrangements for the use of third party auditors differ across jurisdictions**
  - Some industry stakeholders preferred the ability to have third party auditors undertake food safety audits, whereas some government stakeholders highlighted that this can carry risk (referring to previous examples where third party auditors have not undertaken audits in line with the government's regulatory requirements, resulting in outbreaks of foodborne illness).

- each jurisdiction has **different approaches to audit and inspection**:

- In New South Wales, all licensed food businesses are required to undergo regular audits or inspections. In general, an inspection activity looks at compliance with Standards 3.2.2 and 3.2.3 of the Code. A regulatory audit reviews an approved food safety program. The majority of councils in NSW inspect retail food premises using a standard checklist for compliance with the Code called the Food Premises Assessment Report (FPAR). Audits are conducted by an authorised officer of the NSW Food Authority or by an approved third party auditor. The NSW Food Authority has a Regulatory Food Safety Auditor System to enable third party auditors to conduct regulatory food safety audits of licensed food businesses in NSW.
- In the ACT, all registered food businesses must undergo regular inspections by Public Health Officers from the Health Protection Service. The ACT has developed a Food Business Inspection Manual to assist Public Health Officers adopt a consistent and transparent approach to food business inspections.
- In South Australia, most food businesses are not audited and only undergo an inspection by local council environmental health officers (EHOs). Vulnerable population businesses (e.g., hospitals, aged care facilities) are audited by approved SA Health and local council auditors through a second-party audit system. PIRSA accredited primary food production businesses are also required to be audited. PIRSA accepts specific third-party audits in lieu of additional government compliance checks in some cases.
- In Victoria, all Class 1 and some Class 2 businesses are required to have their food safety programs audited to register as a food business (and renew registration). The Victorian Department of Health and Human Services (DHHS) maintains a list of approved third party auditors. Class 2 business that use a department-registered food safety program require an annual desktop assessment by their Local Council. Class 3 and 4 businesses do not undergo regular audit/assessment. DHHS publishes a Food Safety Auditor Handbook to support auditors assess compliance.

It was suggested that these variable arrangements can be confusing for food businesses and can result in inefficiencies across (and within) jurisdictions. Stakeholders reported that, for business owners operating food businesses across different LGAs within the same jurisdiction or different jurisdictions, regulators may have different expectations regarding how a business demonstrates its compliance with certain requirements or 'what may be tolerated in one Council area may not be tolerated in another', which can result in both the inconsistent application of requirements and increased operating costs to businesses. A number of stakeholders highlighted that inconsistent assessment of compliance can also occur between different individuals within a single regulatory agency.

While it is recognised that audit is not the only monitoring tool available to regulatory agencies, stakeholders tended to focus on audit as having the most significant impact on food businesses.

Reporting of non-compliance

Stakeholders highlighted that there are inconsistent approaches to reporting information about business's non-compliance (or level of compliance) across jurisdictions. For example:

- in NSW, food businesses that have been prosecuted (as well as businesses that have received a penalty notice) have their names published via a public 'Name & Shame' list. Generally, prosecutions are published for 24 months and penalty notices for 12 months. NSW also operates a voluntary 'Scores on Doors' program for local government and businesses that displays the results of regular inspections of food premises.
- Victoria maintains a food safety register of convictions, where any breaches under the Victorian Food Act are published for 12 months
- while at the State level, Queensland does not publicly report non-compliance, certain local councils publish compliance information. For example, Brisbane City Council operates 'Eat Safe Brisbane' where licenced food businesses receive a star rating based on compliance with the *Food Act 2006*, the Food Safety Standards and good management practices and can publicly display their star
- in the ACT, a summary of businesses who are convicted of an offence against the ACT Food Act are published on the Register of Food Offences
- in South Australia, food businesses are rated based on the outcomes of inspections as part of the Food Safety Rating Scheme (but participation in this scheme is voluntary for local councils).
- in Western Australia, the names of offenders convicted in a court of law for breaches against food legislation are published in the food offenders list
- Tasmania does not appear to have a register of either kind.

While this may cause some confusion for food business (and consumers) operating food premises across jurisdictions (and some approaches may have more success at encouraging compliance), stakeholders did not describe significant impacts on food businesses beyond this.

Inconsistent application of regulatory requirements

A number of stakeholders raised examples of different jurisdictions regulating the same sector differently because of different regulatory frameworks and/or policy settings.

Differing approaches were described in the following areas:

- **businesses providing food service to vulnerable persons**
  - Standards 3.3.1 – Food safety programs for food service to vulnerable persons requires food businesses that process food for service to vulnerable persons to implement a documented and audited food safety program. This standard is generally applied in hospitals and healthcare settings, aged care services, community services and childcare centres.
  - Currently, New South Wales is the only jurisdiction in Australia that does not apply Standard 3.3.1 to the childcare sector. The NSW Food Authority provides a food safety program template for children's services businesses wanting to voluntarily enact a program. While a food safety program is not mandated, childcare centres must meet other food safety requirements in the Code undergo inspections by local government. Stakeholders have noted this inconsistency can create confusion for business owners and can make it more difficult for regulators to enforce compliance, for example, where a business has childcare centres across jurisdictions.

- **fast food and related businesses**[4]
  - Stakeholders noted that some jurisdictions have mandated kilojoule menu labelling for certain food businesses. To date, New South Wales, South Australia, the Australian Capital Territory, Queensland, and most recently Victoria, have introduced legislation for fast food menu labelling schemes.
  - Some stakeholders highlighted that the lack of clarity regarding whether this initiative will be rolled out nationally (and the staggered rollout across jurisdictions) creates inefficiencies and ambiguity for businesses.
  - Ministers have previously agreed that 'nationally consistent menu labelling is desirable both for the food industry, public health organisations and governments' and that the most effective way for this to occur would be to develop a food regulatory measure under the Code.[5]

- **school canteens**[6]
  - A number of stakeholders described the different policy approaches of governments to the sale of foods in school canteens and the impact this has on business (creating confusion and impacting the ability of some business to sell in schools in some jurisdictions and not others
  - While the Australian Department of Health has published National Healthy School Canteens Guidelines, each jurisdiction has developed additional detailed guidance, which outlines specific criteria that schools must use to guide all foods and drinks sold in canteens in that jurisdiction.

Case study – Unsweetened flavoured waters sold in school canteens

Jurisdictions treat products in different ways even within a setting. In school canteens, each jurisdiction has developed guidelines regarding what can be sold and how such products should be classified and 'promoted'. In relation to unsweetened flavoured waters in school canteens:

- the NSW Healthy School Canteen Strategy, the ACT 'Go for Green' Traffic Light System Guide and the Victorian Healthy Eating Advisory Service classify these products as green/everyday
- the Tasmanian School Canteen Association, the Queensland Healthy Food and Drink Supply Strategy, the Northern Territory School Nutrition and Healthy Eating Guidelines and the Western Australian Healthy Food and Drink Policy classifies these products as red/avoid.

Similar issues occur with flavoured milks.

Stakeholders note that this case study also highlights a lack of coordination across government initiatives. For example, where products that receive a high Health Star Rating are categorised as red/avoid, or vice versa.

[4] It should be noted that kilojoule menu labelling is regulated outside of the Code by State and Territory governments.
[5] Food regulation, Australia and New Zealand Ministerial Forum on Food Regulation Communique 6 August 2019.
[6] It should be noted that school canteen guidelines are regulated outside of the Code by State and Territory governments.

Industry stakeholders highlighted that different requirements placed on products or businesses based on the jurisdiction and the setting in which they are sold/operate means it is challenging for manufacturers to ensure their products meet all the relevant regulatory requirements. It also limits the ability of (and incentives for) manufacturers to innovate to develop products tailored for specific settings, as requirements are not necessarily consistent even within a setting.

Inconsistent thresholds for market entry

Market entry requirements are set by each jurisdiction as part of their processes for food business registration/licencing. A number of stakeholders reported that market entry thresholds can differ between jurisdictions, meaning that, based on the jurisdiction in which a business is located, it may or may not have to be registered (and meet the array of regulatory requirements associated with that registration).

Two specific examples of this were raised:

- **egg producers**
  - Standard 4.2.5 – Primary production and processing standards for eggs and eggs products defines an 'egg producer' as a business that 'involves the production of eggs whether or not the business grades, packs, washes, candles or assesses for cracks, oils, pulps for supply to the processor for pasteurisation or stores or transports eggs or egg pulp'. However, jurisdictions further define this term in different ways.
    - in Queensland and Western Australia, individuals or food businesses with one or more egg producing hens are considered egg producers
    - in New South Wales all egg food businesses need to meet food safety and labelling requirements and are categorised by business types covering the definition of 'egg producer' activities
    - in the Australian Capital Territory, individuals or food businesses with hen(s) that lay 240 or more eggs per week are considered egg producers
    - in Victoria and South Australia, individuals or food businesses with more than 50 egg producing hens are considered egg producers
    - in Tasmania, any individuals or food businesses that sell eggs to the public or businesses are considered egg producers.

- **businesses selling low alcohol beverages**
  - Under some State and Territory Liquor Licensing Acts, beverages with greater than 1.15% ethanol by volume are considered 'alcoholic beverages' or 'liquor', triggering alcoholic content labelling and the need for business stocking such products to hold a liquor licence. Under others, the threshold is 0.5% ethanol by volume. For example, while New South Wales and Western Australia specify a level of more than 1.15% ethanol by volume at 20°C, Queensland and Victoria specify a level of ethyl alcohol (ethanol) of more than 0.5% by volume at 20°C.

Stakeholders highlighted that these inconsistencies can create an unfair disadvantage in jurisdictions where regulatory thresholds are 'lower', subjecting those food businesses to increased regulation which necessarily increases the cost of compliance.

Inconsistencies arising from the interfaces between different regulators within Australia

Interface between food and primary industry regulators

In Australia, there are different arrangements between each State and Territory for the regulation of food and primary industries. Some States and Territories maintain discrete agencies responsible for regulating certain industries, while others have a single authority with primary responsibility for regulating food.

For example:

- in Victoria, PrimeSafe is responsible for regulating meat, poultry, seafood and pet food, Dairy Food Safety Victoria is responsible for regulating the dairy industry, Agriculture Victoria also plays a role in regulating agriculture, biosecurity and food safety, and the Department of Health and Human Services Victoria works with local governments to regulate food safety
- in NSW the NSW Food Authority regulates all food businesses (including these industries) in partnership with local governments
- in South Australia, the Department of Primary Industries and Regions (PIRSA) is responsible for regulating businesses that are prescribed as undertaking all primary production and processing while SA Health and local governments regulate all other sectors.

Stakeholders raised some specific examples where the existence of different regulatory structures creates confusion or increased regulatory burden.

Case study – South Australia

In South Australia, a number of business types are subject to regulation by PIRSA, SA Health and/or local government environmental health officers. Stakeholders provided the following examples:

- supermarkets and retail outlets that sell ready-to-eat meats and have an onsite butcher
  - PIRSA only regulates supermarkets that have onsite butchers. Local government EHOs regulate supermarkets in general, including the deli section where there is no onsite butcher. SA Health can also be involved where a business undertakes high-risk processing and packaging of RTE meats.
- businesses that produce and process whole eggs, and pasteurise egg pulp
- butchers that sell both raw meat and smallgoods (noting that PIRSA regulators are now also authorised under the SA Food Act to assess foods other than raw meat and smallgoods with the aim of reducing regulatory duplication with local government EHOs).

Stakeholders (including governments and industry) variously suggested that in jurisdictions where all food businesses are regulated by a single entity, there is a reduced regulatory burden for businesses, which are only required to demonstrate compliance to one government regulator.

Some stakeholders suggested that a more integrated approach to regulation is adopted in jurisdictions with a single regulator as they monitor compliance across the whole food supply and '*are able to view each sub-sector as part of a greater food standards system, resulting in regulation more commensurate to risk*'.

Interface between food and medicine regulators

The 'food-medicine interface' refers to the potential regulatory overlaps between certain foods and therapeutic goods. Many stakeholders, including from government, industry and consumer advocacy and public health bodies, raised this as a critical area of inconsistency.

Within Australia, the approval process, permitted claims and composition of a product will differ according to whether it is classified as a therapeutic good or a food. FSANZ generally does not make determinations as to whether a product should be considered a medicine or a food. In collaboration with food regulatory agencies, the Therapeutic Goods Administration (TGA) (which regulates medicines and medical devices in Australia) has developed a Food-Medicine Interface Guidance Tool which can help businesses determine whether a product is a therapeutic good or a food. However, ambiguities remain particularly in relation to special purpose or supplemented foods.

Stakeholders reported that:

- this can result in frustration and increased compliance costs for businesses looking to comply with the correct requirements (for either foods or medicines). It can also result in businesses coming to different conclusions regarding which regulations apply, leading to inconsistent regulatory outcomes for similar products and potential non-compliance with regulatory requirements
- businesses 'take advantage of' this subjectivity and may choose to market a product based on the applicable regulatory requirements. Stakeholders highlighted that inconsistent outcomes can also occur across jurisdictions where some regulatory agencies take a more proactive approach to taking action against businesses that have incorrectly categorised their product
- it can be costly for businesses that incorrectly determine whether their product is a food or a therapeutic good, can create an uneven playing field where similar products are regulated and marketed under different regulatory schemes and is confusing for consumers trying to make an informed choice about products.

Some examples were provided:

- **Children's supplements in the form of gummy lollies** – some of these products have been listed with the TGA as complementary medicines, while others are classified as foods. For complementary medicines, there is a requirement to declare the presence, but not the quantity, of sugars on the label. In these situations, complaints about such products may be

interpreted differently by the different jurisdictions, or else not ruled on at all, instead being passed between the jurisdiction and the TGA.[7]

- **Collagen powder or powdered phenolics** – some businesses have classed these products as foods and display health claims (notified to FSANZ) such as 'stimulates and supports collagen production' and 'supports skin structure and health' which could be considered therapeutic in nature. Stakeholders reported that some businesses 'bypass the TGA, as the food regulatory system is cheaper and less stringent than the therapeutic goods regulations'.

- **Electrolyte capsules** – some businesses have marketed electrolyte capsules as formulated supplementary sports foods, which are not permitted to hold vitamin or minerals claims; others have marketed similar electrolyte capsules as therapeutic goods, which do hold vitamin and mineral claims.

Interface between domestic food regulators and regulators of imported foods

The Department of Agriculture, Water and the Environment (DAWE) is responsible for regulating imported foods at the border. All imported food must meet biosecurity requirements (specified in the *Biosecurity Act 2015*) to be allowed into the country. Once imported food has met these requirements, foods are monitored for compliance with the Code.

Food entering Australia is subject to the *Imported Food Control Act 1992*, which provides for the inspection and control of imported food using a risk-based border inspection program, the Imported Food Inspection Scheme (IFIS). FSANZ advises the DAWE on which foods pose a medium or high risk to human health and safety and these foods may be inspected under the IFIS.

This risk-based approach to inspection means that some non-compliant products may enter the Australian market. While this is also the case for domestically produced products (as these are not inspected before entering the market), some industry stakeholders suggested:

- it was more difficult for regulatory agencies to monitor and enforce compliance for imported products, or that regulatory agencies took a more 'lenient' approach with such products, creating market disadvantage for local manufacturers

- inconsistencies can arise when non-compliant parallel imports enter the market, go unchecked at the border and products compete on retail shelves alongside compliant local products. Stakeholders reported that small businesses are more likely to stock non-compliant imports and parallel imports than locally-based multinationals.

- common areas of non-compliance include colour additives, non-English labelling, allergens, nutrition information panels, country of origin labelling and the omission of the supplier's name or address details (which are important for product recalls).

[7] Harvey K, Li E, Stanton R, Dashper S, 'Kids' vitamin gummies: Unhealthy, poorly regulated and exploitative' *Journal of the Home Economics Institute of Australia* 2017 (24) p.42-43. Harvey K, Watson W, Stanton R, 'Where food meets medicine: reform needed' *MJA Insight* 2019.

  - One stakeholder provided an example where a product with no English labelling was imported by a third party. This meant, amongst other things, the allergen ingredients were not declared (in English), presenting a risk to public health and safety.

- local brand owners can be disadvantaged by this as it can result in reputational damage (and they may be required to take part in public relations and issue management) to limit this damage. It also disadvantages local producers who go to the expense of producing compliant products

- it can be difficult for local brand owners to challenge non-compliant imports, particularly where they are imported by retailers (for fear of negatively impacting their own commercial relationships with those importing retailers who they rely on to sell their products).

Interface between food safety and biosecurity

The *Biosecurity Act 2015* requires that all imports of food comply with the biosecurity conditions for their import.

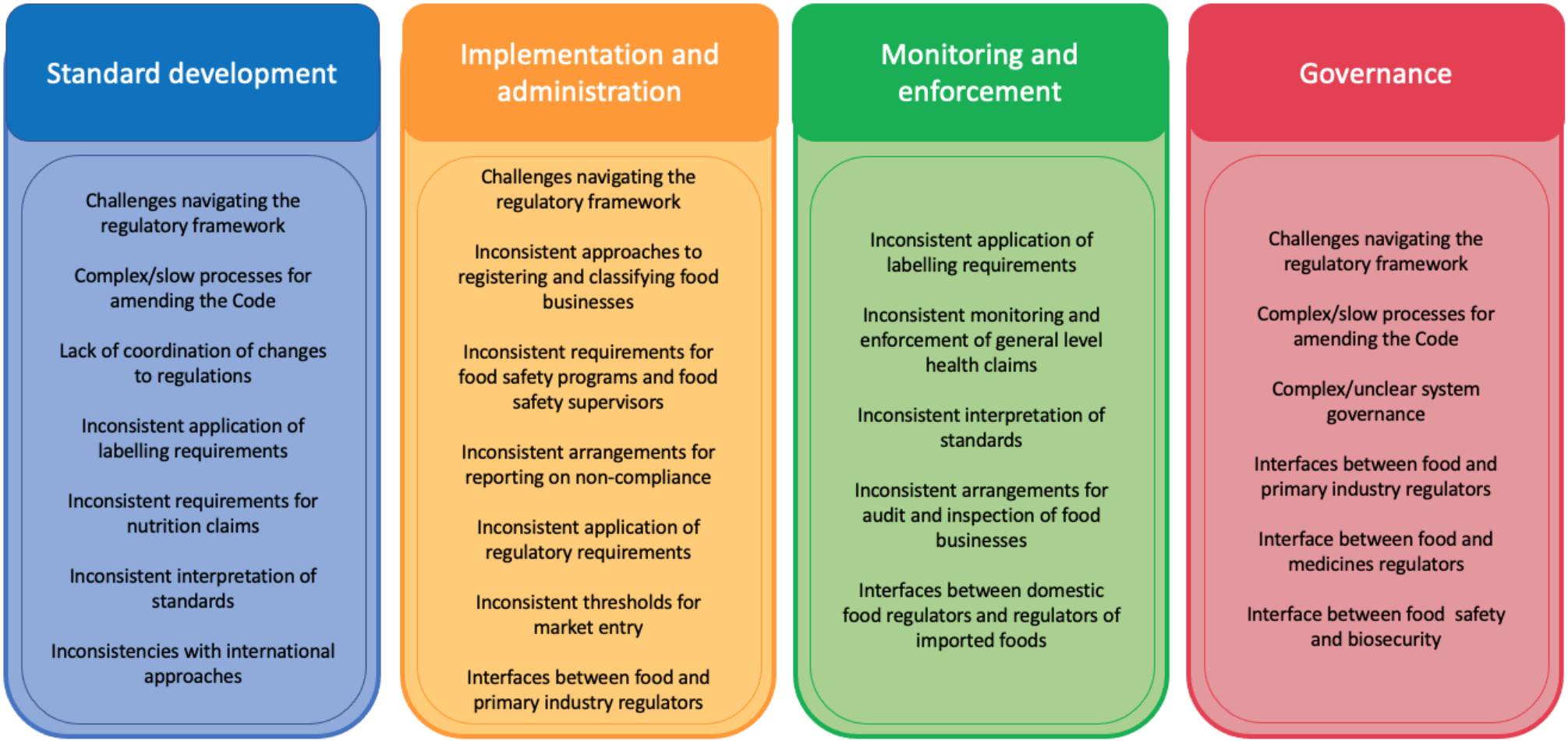
Stakeholders variously reported that:

- there are some areas of duplication between food safety and biosecurity legislation (as measures aimed at managing food safety and biosecurity risks are often connected)
- a focus on 'obvious' food safety risks, rather than the whole of food industry supply chain, risks creating gaps in the food safety system.
  - For example, while a food safety approach would require visitors to farms and processing plants to wash their hands, biosecurity requirements require this in addition to records of visitors being captured for traceability purposes.
- there can be a lack of coordination between regulatory agencies responsible for food safety and biosecurity leading to inefficiency and inconsistency. One stakeholder raised the chicken industry as an example, noting that food safety pathogens and bird health risks are closely related but regulation or management of these issues can be quite siloed.

Stakeholders suggested that a more cohesive approach to biosecurity and food safety would be more efficient for governments and industry and likely result in improved outcomes for human, animal and environmental health. It was noted that South Australia adopts a relatively cohesive approach to biosecurity and food safety requirements and in New South Wales biosecurity and food safety responsibilities reside within a single business unit.

Key areas of inconsistency and where these arise

Key areas of inconsistency in food regulation and where these arise



Note: some issues appear across multiple areas as there may be multiple factors contributing to the inconsistency

Chapter 3: Analysis and identification of areas for future focus

Analysis of stakeholder feedback

Focus of stakeholder feedback

Stakeholder responses to the online survey were more limited than anticipated – this is largely attributed to the timing of the consultation process and related consultation processes occurring simultaneously.

Stakeholders did not quantify the impact of inconsistencies and did not always describe the impact of inconsistencies well – for example, referring to inconsistencies causing 'confusion' and 'frustration' rather than attributing a cost figure or a tangible consequence. Industry stakeholders raised many very specific issues which, while these may be impactful to their business, were not necessarily widespread or representative of issues experienced by stakeholders more broadly across the system.

Issues outside the food regulatory system

A number of stakeholders raised issues that are not directly within the scope of the food regulatory system (i.e., matters that are regulated outside of the Code and are monitored and enforced by other regulatory bodies). While it is acknowledged that these are beyond the direct control of the food regulatory system, stakeholders do not identify these issues as separate.

Acknowledging the broader reform work currently occurring, this raises the issue of the scope of the food regulatory system, how far it extends and how interface issues are managed and communicated publicly. While some have suggested the scope of the food regulatory system could be expanded to cover all matters influencing the regulation of food, others have suggested stronger, more decisive governance and management of interface issues could address this.

Key areas for possible future focus

Identification of areas for future focus

mpconsulting has been requested to provide advice regarding the possible priority areas for reform, based on the outcomes of this project and taking into account the areas of inconsistency with the most significant impact on stakeholders.

Areas for potential focus by governments were identified based on:

- the number of stakeholder submissions raising the issues
- the veracity of these issues (i.e., where we have confirmed the issues exist) and where they have also been consistently described in other forums and through other reviews over the past few years

- whether the issues have impacts across different stakeholder groups (e.g., impact on governments, industry and consumers)
- the significance of those impacts (as described by stakeholders)
- whether the food regulatory system has the ability to influence/direct changes in those areas.

Based on the application of the above criteria, the following key areas have been identified for priority focus by governments:

- inconsistencies relating to the application, monitoring and enforcement of labelling requirements and health claims
- inconsistencies stemming from the food-medicine interface
- inconsistencies stemming from unclear or outdated standards, and consequential differences in interpretation of standards
- inconsistencies in approaches to the implementation of food safety standards on food businesses across Australian jurisdictions.

Each of the above areas of inconsistency have impacts across all stakeholder groups, including governments, industry and consumers.

Labelling

It is clear from stakeholder feedback (and from various reviews and consultative processes over the last few years) that:

- labelling is one of the more contentious and impactful areas of food regulation – as noted by one stakeholder, labelling is one of 'the most public-facing aspects of food regulation'
- different stakeholders often look to labelling to address broader issues not necessarily related to food safety or what has traditionally been captured in the food regulatory system. For example, to address consumer values issues such as palm oil or genetically modified foods, or to address broader public health matters, such as health ratings and added sugars
- interface issues between regulators is quite pronounced with respect to labelling because of the number of different regulators involved. For example, while food labelling plays part of the food regulatory system, it is also within the scope of the ACCC in Australia and the CC in New Zealand (overseeing country of origin labelling) and the National Measurement Institute in Australia and Trading Standards in New Zealand (regulating weights and measures labelling)
- labelling is likely to be a significant area of focus in future years, as consumer expectations continue to change regarding the matters on which they seek information, and as technology enables information to be provided in different ways.

Based on stakeholder feedback, there are two key issues with respect to labelling:

- **a lack of a consistent or predictable approach to resolving food labelling issues in a timely way**
  - There is currently no clear mechanism for determining which food labelling issues fall within the scope of the food regulatory system and which do not.

  - Further, there is no clear mechanism or criteria to support governments' decision-making around label regulation and limited coordination of regulatory changes relating to food labelling.
  - Both of these issues impact the food regulatory system and a wide range of stakeholders (industry, public health and governments).
  - Changes to labelling are costly, require lead time and have significant commercial impact across industry. Uncertain processes for resolving labelling issues can also create frustration and undermine confidence in the system (for industry, public health bodies, consumers and governments).

- **inconsistent approaches to monitoring and enforcement of food labelling**
  - Many industry stakeholders highlighted that some jurisdictions more actively monitor and enforce labelling compliance, which disadvantages manufacturers based in those jurisdictions (where manufacturers based in more 'lenient' jurisdictions can display non-compliant labels). This was also raised in relation to imported products, with some stakeholders reporting that regulatory agencies take a more 'lenient' approach to enforcing compliance with regards to imported products.
  - Stakeholders gave several examples of products with non-compliant labels available at retail stores, noting that missing or inaccurate information on labels can present a risk to consumer safety (particularly in relation to allergen information). Non-compliant labelling can also impact on informed consumer choice and create a culture of non-compliance.
  - Given the critical role of food labelling in communicating information to consumers and influencing purchasing decisions, it is important that food labelling requirements are actively and monitored and enforced.

General level health claims

While New Zealand has a clear process for assessing the veracity of self-substantiated health claims, Australian jurisdictions do not have such an approach.

More than a quarter of the stakeholders responding to the survey identified general level health claims as a significant area of inconsistency:

- From industry's perspective, the inconsistent monitoring and enforcement of health claims can create a culture of non-compliance and undermine confidence in the food regulatory. It can also create an unlevel playing field and add compliance costs for industry bodies who cannot determine whether a health claim will be considered acceptable or who go to lengths to ensure health claims are adequately substantiated.
- Consumers may select products on the basis of unsubstantiated health claims, which also creates market disadvantage for compliant manufacturers. Industry bodies highlighted that it can be expensive to adequately substantiate health claims (as per the Code requirements) and there is currently limited incentive to ensure health claims made are adequately substantiated or compliant.
- For government regulators, the current approach creates significant, duplicative regulatory effort. A number of government stakeholders noted that they have finite resources and

expertise and tend to prioritise critical food safety matters over matters that impact more on consumer choice.
- For public health bodies, the current approach risks consumers being misled about the health benefits of certain products. Some public health bodies highlighted that when complaints are made about a health claim, there is often no follow up or they are 'bounced' between different regulatory agencies that share responsibility for monitoring food labelling.

Food-medicine interface

A significant number of stakeholders (across all stakeholder groups but predominantly in Australia) raised issues relating to the food-medicines interface.

This is an important area for consistency moving forward because:

- it is expected the interfaces between the food regulatory system and other regulatory systems will continue to be blurred as innovation, technology and consumer choice evolve
- the rising medicalisation of foods and growth in foods with therapeutic properties means that the food medicine interface is becoming increasingly important
- any gaps or overlaps between the systems will continue to become more pronounced as new products continue to come into the Australian and New Zealand market.

This issue closely relates to labelling and health claims, as labelling requirements are a key point of difference between food and medicines regulations. Differences in what must, or may, be displayed on labels can result in consumers being misled about the relative benefits of like products. It creates challenges for regulatory agencies trying to enforce compliance and for industry in trying to determine the appropriate regulations to comply with.

Unclear or outdated standards

Unclear or outdated standards can lead to inconsistencies in the interpretation and application of regulatory requirements (including by both industry and regulatory agencies). The impacts of this include:

- unnecessary increases to the cost of complying with regulations where the Code is not clear
- some food businesses not fully understanding the regulations, leading to non-compliance with food safety requirements
- disadvantages to small businesses without the expertise/resources to interpret standards and effectively apply requirements to their business
- financial losses to food businesses where the way they have interpreted requirements does not align with that of regulatory agencies
- food waste, where non-compliant products are required to be recalled and/or destroyed
- restricting the availability of certain products to consumers in Australia and New Zealand (e.g., where these are not appropriately considered in the Code)

Inconsistencies predominantly arise from either 'gaps' in the Code where the Code has not been updated to keep pace with industry innovation and practice, or a lack of clarity in the wording or intent of the Code.

It is critical that the process for developing and amending standards is responsive, timely, risk-proportional and wherever appropriate, seeks harmonisation with international standards and regulations. This is important to enable the Australia and New Zealand food industry to innovate and compete on the world market. It is also important for public health and safety that standards are maintained in line with current, international scientific evidence.

Regulation of food businesses across jurisdictions within Australia

This issue was raised by a number of government bodies and food businesses – particularly in relation to the registration and classification of businesses, requirements around food safety programs and food safety supervisors and approaches to audits.

Inconsistencies in how food safety requirements are implemented and administered by each jurisdiction can result in an uneven playing field or market disadvantage based on the jurisdiction a business is located in. For food businesses with premises across multiple jurisdictions, it can also create significant duplication – with some stakeholders highlighting they require a specified person to manage regulatory compliance in each jurisdiction. Not being able to implement a single food safety program across premises located in different jurisdictions means food safety management cannot be effectively compared across premises, restricting the ability of food businesses to identify areas for improvement in food safety management and adopt systems and processes across the business. Given there are more than 95,000 food premises across Australia[8], the impact of this can be significant.

In New Zealand, food businesses with premises based in more than one local council area can either register each premise with the local council in each area or register all premises under one registration with MPI. A consistent food control plan or national programme template is available (based on the risk classification of the business) which can be used to demonstrate compliance regardless of the location of the premise.[9]

Inconsistencies between Australian jurisdictions also impact on the ability of government regulatory agencies to adopt a streamlined approach to monitoring sector compliance, collate consistent data across the sector, share compliance information and analyse trends.

[8] Australian Bureau of Statistics, 20 February 2020, Counts of Australian Businesses including Entries and Exits.
[9] Ministry for Primary Industries, 16 November 2020, Register a food business.

Chapter 4: Next steps

In March 2020, the Australian New Zealand Forum on Food Regulation (the Forum) endorsed an implementation plan for an ambitious reform agenda for the food regulatory system aimed at ensuring the system remains strong, robust and agile into the future. The reform agenda is being progressed through a number of interconnected projects, including:

- the review of the Food Regulation Agreement (FRA)
- the implementation of new operational processes to support the system's governance
- the review of the *Food Standards Australia New Zealand Act 1991*.

It is expected that outcomes from this work will feed into the above projects to assist in informing priority areas for reform. This will enable governments to make evidence-based decisions regarding the future of the food regulatory system.

It is acknowledged that, in a bi-national and federated system, there will necessarily be different approaches to administering regulations and to monitoring, assessing and enforcing compliance based on the systemic differences and different regulatory priorities between countries and jurisdictions.

However, this report identifies a number of areas of impact where government attention could be focused to help improve consistency while maintaining food safety outcomes.

Attachment A: Existing mechanisms to promote consistency in food regulation

There are currently a number of mechanisms aimed at supporting national and bi-national consistency of food regulation:

- One of the objectives of the **Food Regulation Agreement** (the FRA) is to provide a consistent regulatory approach across Australia through nationally agreed policy, standards and enforcement procedures.

- Likewise, the **Joint Treaty** with New Zealand aims to reduce unnecessary barriers to trade between the two countries, including through a joint system for the development and promulgation of food standards.

- The **Code** describes standards or requirements relating to food and food production. Chapters 1 and 2 (relating to labelling, food additives, contaminants and chemical residues, foods requiring pre-market clearance, microbiological and processing requirements, and food standards) apply in both Australia and New Zealand. Chapters 3 and 4 (relating to consumer food safety and primary production and processing) apply in Australia only; New Zealand has separate standards covering these matters.

- The **Model Food Provisions** provide a legislative basis for a 'substantially equivalent' national food safety regime and are used by each State and Territory as a basis for their food acts. Model Food Provisions are split into Annex A, which are to be applied consistently and Annex B, which may be varied by each jurisdiction as required.

- The **FRSC** coordinates policy advice to the Forum and aims to ensure policy decisions can be consistently applied nationally and bi-nationally.

- The **Implementation Subcommittee for Food Regulation** (ISFR) provides a forum for Australian and New Zealand food regulators to determine common approaches to implementing and enforcing food standards. The ISFR also produces guidelines to support consistency, for example the Australia New Zealand Regulation Compliance, Monitoring and Enforcement Strategy, National regulatory food safety auditor guidelines and policy and Principles for inspection of food businesses.

Attachment B: Stakeholder survey questions

Guidance for Respondents

This survey has been divided into:

- Questions for Food Industry Stakeholders
- Questions for Government Stakeholders
- Questions for Other Stakeholders (e.g., third party auditors, general public, consumer organisations, public health professionals).

We encourage you to respond to the questions that best represent your sector.

All respondents should respond to the 'Introductory Questions' and are encouraged to respond to the 'Other General Comments' section of the survey.

A supporting Consultation Paper has been developed to assist stakeholders in responding to the online consultation.

Please note that you should respond to this survey in the format most appropriate for you and your organisation. You may respond to any of the survey questions or provide a written submission. You are also invited to provide case studies, examples, reports and any other evidence regarding the impact of inconsistencies. You can upload these in the 'Other General Comments' section of the survey.

All information provided as part of this survey will be treated as confidential and will only be used to inform the identification of potential areas for reform. If we wish to use any of the information or examples you provide as part of your submission, this will be de-identified, and we will contact you to seek permission first.

Introductory Questions (Required)

1. **What is your organisation?**

2. **What is your name?**

3. **What is your email address?**

4. **What is your phone number?**

5. **Do you give us permission to contact you to seek further details about any of the information included in your submission?**

   - ☐ Yes
   - ☐ No

6. **What sector do you represent?**

- ☐ Food industry - respond to the questions for 'Food Industry' stakeholders
- ☐ Government - respond to the questions for 'Government' stakeholders
- ☐ Third party auditor - respond to the questions for 'Other' stakeholders
- ☐ Other - respond to the questions for 'Other' stakeholders

7. Which country are you responding from?

- ☐ Australia
- ☐ New Zealand
- ☐ Trans-Tasman organisation
- ☐ Other (please specify)
- ☐ Prefer not to say

8. What jurisdictions do you operate in?

- ☐ NZ
- ☐ ACT
- ☐ NSW
- ☐ NT
- ☐ QLD
- ☐ SA
- ☐ TAS
- ☐ VIC
- ☐ WA
- ☐ Other (please specify)

9. Is there any information about your organisation you would like to provide?

An opportunity to provide any other information about your organisation.
(Upload file here)

Questions for Food Industry Stakeholders

1. What food industry sector do you represent?

- ☐ Association
- ☐ Primary Producer (e.g., agriculture, farming, fishing)
- ☐ Food processing and manufacturing (e.g., flour mills, canneries, bakeries, breweries, wine makers)
- ☐ Transport and distribution (e.g., water carriers, warehouses, food delivery vehicles)
- ☐ Supplier (e.g., wholesale supplies to cafes and restaurants)
- ☐ Retail (e.g., supermarkets, delicatessens, convenience stores)
- ☐ Imports
- ☐ Exports

- ☐ Hospitality (e.g., restaurants, cafes, hotels, take-away stores, events)
- ☐ Health and community (e.g., hospital catering, meals on wheels, nursing home catering)
- ☐ Complementary Medicines
- ☐ Other (please specify)

2. What size is your organisation?

- ☐ Micro (1-4 employees)
- ☐ Small (5-19 employees)
- ☐ Medium (20-199 employees)
- ☐ Large (200+ employees)

3. Has your business been impacted by inconsistent regulatory approaches (or inconsistent interpretation or enforcement of regulation) in any of the following areas:

- ☐ Food labelling (identification, warning statements, statements of ingredients, date markings, directions for use)
- ☐ Nutrition health and related claims (labelling)
- ☐ Foods requiring pre-market clearance (novel foods, food produced using gene technology and irradiation)
- ☐ Substances added to or present in foods (processing aids, vitamins and minerals, food additives)
- ☐ Microbiological limits, processing requirements, contaminants and residues
- ☐ Food safety standards (Australia only)
- ☐ Food safety programs (Australia only)
- ☐ Food safety practices (Australia only)
- ☐ Food premises and equipment (Australia only)
- ☐ Primary production and processing standards (Australia only)
- ☐ Other – please specify
- ☐ No

If yes – go to Question 5

If no – go to Question 7

4. What was the nature of the inconsistency?

5. What was the impact on your business?

Please provide examples or case studies of the impact this issue has on your business and where possible, try to quantify the impact (in terms of the associated cost, compliance burden, market disadvantage, lost opportunity, duplication of effort, etc.).

6. Are there any other areas of food regulation (law or practice) that are inconsistent between States and Territories, or between Australia and New Zealand, that adversely impact your business?

For each identified area, please describe the issue and how it impacts on your business. Provide examples or case studies and where possible, try to quantify the impact (in terms of the associated cost, compliance burden, market disadvantage, lost opportunity, duplication of effort, etc.).

7. **Are there any areas of duplication between the food regulatory system and related regulatory systems?**

   Other regulatory systems could include consumer affairs, biosecurity, agriculture, therapeutic goods, etc.

   Please describe these below.

8. **Inconsistency in food regulation is:**

   - ☐ Not an issue for my business
   - ☐ A minor issue for my business
   - ☐ A somewhat major issue for my business
   - ☐ A significant issue for my business

Questions for Government Stakeholders

1. **What level of Government do you represent?**

   - ☐ Local Government
   - ☐ State Government
   - ☐ Federal Government

2. **Identify any areas of food regulation that are inconsistent between States and Territories, or between Australia and New Zealand, that you consider adversely impact food businesses and/or regulatory outcomes. For each of these, please describe:**

   a) **the nature or source of the inconsistency**

   b) **the impact of the inconsistency**

      Please provide examples or case studies and where possible, try to quantify the impact.

      Impacts might include undermining food safety objectives, challenges in monitoring and enforcing regulation, poor regulatory outcomes, reputational damage to the food regulatory system or adverse outcomes for food businesses (in terms of cost, compliance burden, market disadvantage, lost opportunity, duplication of effort, etc.).

3. **Are there any areas of duplication between the food regulatory system and related regulatory systems?**

   Other regulatory systems could include consumer affairs, biosecurity, agriculture, therapeutic goods, etc.

   Please describe these below.

4. **Are there any other areas of the food regulatory system that could be adjusted to improve the way regulation is implemented, monitored and enforced?**

   Consider for example, changes to the Food Standards Code or the Model Food Provisions, providing additional guidance to regulators/industry, improving coordination across regulators, better using data and technology to regulate food businesses, etc.

5. **I consider inconsistency in food regulation to be:**

   - ☐ Not an issue for government
   - ☐ A minor issue for government
   - ☐ A somewhat major issue for government
   - ☐ A significant issue for government

Questions for Other Stakeholders

1. **What other sector do you represent?**

   - ☐ Third party auditor
   - ☐ General Public
   - ☐ Consumer Organisation
   - ☐ Public Health Professional
   - ☐ Public Health Organisation
   - ☐ Not-for-Profit Organisation
   - ☐ Researcher
   - ☐ Academic Institution
   - ☐ Consultant
   - ☐ Other (please specify)
   - ☐ Prefer not to say

2. **Identify any areas of food regulation that are inconsistent between States and Territories, or between Australia and New Zealand, that you consider adversely impact food businesses and/or regulatory outcomes. For each of these, please describe:**

   a) **the nature or cause of the inconsistency**

   b) **the impact of the inconsistency**

Please provide examples or case studies and where possible, try to quantify the impact.

Impacts might include undermining food safety objectives, challenges in monitoring and enforcing regulation, poor regulatory outcomes, reputational damage to the food regulatory system or adverse outcomes for food businesses (in terms of cost, compliance burden, market disadvantage, lost opportunity, duplication of effort, etc.).

3. **Are there any areas of duplication between the food regulatory system and related regulatory systems?**

   Other regulatory system could include consumer affairs, biosecurity, agriculture, therapeutic goods, etc.

   Please describe these below.

4. **I consider inconsistency in food regulation to be:**

   - ☐ Not an issue
   - ☐ A minor issue
   - ☐ A somewhat major issue
   - ☐ A significant issue

Other General Comments

An opportunity to provide general comments on the consistency of food regulatory approaches.

1. **Do you have any other general comments on the consistency of food regulatory approaches?**

2. **Please upload any additional examples, case studies or other supporting evidence here.**