Australia and New Zealand's food regulatory system

## FINAL Report Aspirations for Australia and New Zealand's food regulatory system

Prepared on behalf of the Food Regulation Standing Committee 1 April 2021

### Context

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

The purpose of this report is to describe the aims, scope and aspirations for the system, as part of Stage 1 of the review of the <u>Food Regulation Agreement</u> (the FRA). This report will provide an evidence base regarding ministerial and stakeholder expectations for the system and provide strategic direction to guide other reform subprojects as indicated below.

Project Name	Project Objective
Review of the Food Regulation Agreement (FRA)	<ul> <li>Stage 1: describe aspirations for the food regulatory system to provide strategic direction for all reform projects, including Stage 2 of this project.</li> <li>Stage 2: review the FRA to create a new foundational document to underpin the food regulatory system.</li> </ul>
Jurisdictional consistency	Identify the key areas of inconsistency in food regulatory approaches based on the impacts on industry and government.
Operations	Develop and implement new operational processes to support the system's governance.
Review of the Food Standards Australia New Zealand Act 1991 (FSANZ Act)	Review the effectiveness of the FSANZ Act and the operations and responsibilities of FSANZ.

This report was informed by:

- review of the key challenges and opportunities facing the food regulatory system, including likely changes to the way that food is produced, distributed and consumed
- an examination of international approaches to food regulation and recent strategic documents guiding the modernisation of international food regulatory systems (see a brief summary at <u>Attachment A</u> and <u>Attachment B</u>)
- an understanding of the key features and principles of best practice regulation
- previous reviews of the Australian and New Zealand food regulatory system
- stakeholder consultation a <u>Consultation Paper</u> was released for comment on 23 November 2020; 66 submissions were received (see a summary of stakeholder feedback at <u>Attachment C</u>)
- discussions within the Food Regulation Steering Committee (the FRSC), across the agriculture, food and health portfolios.

The FRSC tested and considered a range of different approaches to this report. It was agreed that by describing the aims, scope and high-level aspirations for Australia and New Zealand's food regulatory system, this report will provide strategic direction to guide individual reform subprojects. Stakeholders will be further consulted regarding the detail of how each aspiration will be progressed as part of each reform subproject.

Further work under the reform subprojects will consider how best to describe the food regulatory system, particularly the use of the term 'collaborative' in highlighting the critical role collaboration may play in future-proofing the regulation of foods in Australia and New Zealand, including collaboration across governments and regulatory agencies and with external stakeholders. As part of a modernised approach to regulation, collaboration will be critical to ensure regulation is proportionate, effective and consistent.

Leading partnerships with other regulatory systems (including across Australia and New Zealand) and external stakeholders (including industry and public health organisations) will increase engagement with the System; encourage a safe and healthy food culture among industry and consumers; and enable the utilisation of a broader range of tools to achieve compliance outcomes.

Describing the System as collaborative promotes the resolving of issues by all involved in the System working together and provides the catalyst for change to reflect this future approach. However, it is not intended to signify collaborative decision-making for the System – this role is to remain the ultimate responsibility of Food Ministers as custodians of the System, supported by government agencies.

## Challenges and opportunities facing the System

While Australia and New Zealand's food regulatory system has largely stood the test of time, its framework is now over 20 years old. The food sector is rapidly changing, consumer expectations of food are changing, and we face a range of challenges and opportunities relating to:

- evolving science and new technologies, some with implications for food safety and changes to the way foods are offered to consumers
- poor nutrition and obesity continuing to impact on public health
- increasing use of digital tools providing visibility of supply chains from their point of origin through to the consumer
- responding to consumer expectations for improved product quality, environmental sustainability and ethical production
- ongoing changes to international trade relationships.

While Australia and New Zealand's food regulatory system is well placed to meet the challenges of the future, we need to make changes to future proof the system and continuously improve. There is also a need to clarify the role of Australia's food system and better position the food regulatory system in line with contemporary regulatory approaches.

Any changes made to Australia and New Zealand's food regulatory system will seek to:

- improve the responsiveness of the system
- enable better resolution of issues that are not strictly food safety issues and impact other portfolios
- make the system easier for stakeholders to understand
- expand the range of tools available to regulators and enable more risk-proportionate approaches
- ensure we have the right regulatory and non-regulatory tools to respond to the changing food system.

Changes will build on the strong foundations of the food regulatory system to ensure it continues to meet stakeholder expectations, remains sustainable and best practice and is well-positioned to meet the challenges of the future. Changes will be made in partnership with stakeholders, informed by evidence and in a considered and planned way. Collaborative engagement is vital to navigating change, recognising there may not always be agreement among stakeholders regarding the extent and types of changes required.

### Aims and scope of the System

The high level aims of Australia and New Zealand's food regulatory system were endorsed by Ministers in 2017 and described in an <u>Overarching Strategic Statement (OSS)</u>.

These aims have been reviewed and affirmed by the FRSC, as remaining fit for purpose. In summary, the aims:

- were recently agreed and continue to align with government and stakeholder expectations
- align with those of international food regulatory systems, including those outlined by the Food and Agriculture Organization of the United Nations as the 'principal objectives of national food control systems' (see <u>Attachment A</u>)
- are broadly supported by internal and external stakeholders
  - The majority of stakeholders considered that the central aim of the system is to protect public health and safety.
  - While stakeholders had differing views about the relative priority of other aims (with some placing greater emphasis on supporting public health objectives and others emphasising the need to enable the existence of a strong, sustainable food industry), stakeholders broadly agreed that each of these aims remained relevant and accurately reflected the role of the system.

It is therefore proposed that the following aims (from the OSS) be included in a new FRA and be presented as the high-level aims of the food regulatory system – to:

- protect the health and safety of consumers by reducing risks related to food
- enable consumers to make informed choices about food by ensuring that they have sufficient information and by preventing them from being misled
- support public health objectives by promoting healthy food choices, maintaining and enhancing the nutritional qualities of food and responding to specific public health issues
- enable the existence of a strong, sustainable food industry to assist in achieving a diverse, affordable food supply and also for the general economic benefit of Australia and New Zealand.

Consistent with stakeholder feedback (and the OSS), the FRSC also proposes that the new FRA state that in pursuing these aims, the overriding priority will always be protecting public health and safety.

## Aspirations of the System

Through public consultation, the FRSC sought advice from internal and external stakeholders about the broad aspirations of Australia and New Zealand's food regulatory system.

While stakeholders agreed some of the proposals (such as the need for strong leadership, effective partnerships, improved responsiveness and continuous improvement of the system), stakeholder opinion diverged on some key aspirations. For example, stakeholders were polarised in relation to:

- the extent to which the system should actively support a strong and sustainable food industry or public health objectives
- the stakeholders who should play a key role in informing the system while some highlighted that the food industry has an inherent conflict of interest and should not be involved in contributing to policy and regulatory measures, others felt that the system did not adequately draw on industry expertise, including to ensure regulation is easy to understand, can be practically applied across a range of settings and is cognisant of emerging trends, issues and innovations
- the priority actions moving forward for example, some stakeholders felt that improving the consistency of how regulatory measures are implemented was paramount; others felt that improved responsiveness and transparency of decision-making were critical moving forward.

Noting that a consensus set of aspirations (agreeable to all stakeholders) is not possible, the FRSC focused on:

- building on the strengths of the existing system
- clearly articulating where things need to change in order to best position the system moving forward
- drawing on the outcomes of consultation to identify key areas of tension in the system and areas in which the system could be improved.

To maintain a robust food regulatory system to meet future challenges, we need to have effective controls in place to reduce and monitor risks and to actively respond to issues. Improved use of data and technology will be fundamental to enable regulators to actively monitor food safety risks, analyse the efficacy of individual interventions and better understand the performance of the system as a whole.

The aspirations also seek to promote and embed a safe and healthy food culture right across the food regulatory system (from primary production to the consumer's plate). This will require food businesses to understand their role in the supply chain, identify the risks associated with this role and take responsibility for actively reducing and managing these risks. By re-envisaging system objectives as shared objectives of all stakeholders, food businesses are more accountable for reducing risks related to food, ensuring consumers are able to make informed choices, promoting healthy food choices and enhancing the nutritional qualities of foods.

The following vision, aspirations and actions have been developed collaboratively by the FRSC (informed by the views of stakeholders) and are proposed to guide future reforms to the food regulatory system.

Subject to Food Ministers' agreement, these aspirations would be implemented through a number of different initiatives. While some examples of actions to deliver each aspiration are proposed below, these will be further developed and progressed through individual reform projects.

*Our vision: A world-class collaborative food regulatory system focused on improving and protecting public health and safety.* 

#### 1. Strong leadership and effective partnerships

#### Examples of actions to deliver this aspiration

• Establish efficient mechanisms to support Food Ministers to take a lead role in stewarding the system and resolving challenging policy issues (in collaboration with other government agencies, regulatory systems, policies and initiatives) to drive improvements to the system and achieve whole-of-government outcomes.

#### 2. Responsive, transparent decision-making

#### Examples of actions to deliver this aspiration

- Establish governance arrangements that enable effective and proportionate decision-making across all aspects of the system.
- Improve the way decisions and outcomes are communicated.

#### 3. Informed, engaged and accountable stakeholders

#### Examples of actions to deliver this aspiration

- Investigate pathways for collaborative stakeholder engagement to better enable expert advice to guide the system.
- Develop an effective system to proactively communicate advice to stakeholders, including to build greater understanding of the food regulatory system (amongst industry and consumers) and raise awareness of the responsibilities of key players in food safety.

#### 4. Proportionate and effective responses to policy and compliance issues

#### Examples of actions to deliver this aspiration

- Embed a safe and healthy food culture across the supply chain.
- Explore opportunities for adopting non-regulatory or co-regulatory approaches to achieve system aims (where this is appropriate and with oversight from government).
- Identify ways that technology and innovation can be harnessed to support system aims.



#### 5. Clear and consistently implemented food regulation

#### Examples of actions to deliver this aspiration

- Implement an effective regulatory delivery model to improve consistency.
- Review and increase clarity of food standards.
- Enhance the way inconsistency is resolved.

#### 6. Continuous improvement of the system

#### Examples of actions to deliver this aspiration

- Establish mechanisms to enable horizon scanning, risk analysis and emerging issues to better anticipate trends and influence future activities (such as reviews of food standards, policy development, setting strategic directions and priorities).
- Proactively monitor and regularly review the performance of all aspects of the system to drive continuous improvement.

## Attachment A: Aims of international food regulatory systems

Country/Organisation	Food system aims
Food and Agriculture	The principal objectives of national food control systems are:
Organization (FAO) of the	<ul> <li>protecting public health by reducing the risk of foodborne illness</li> </ul>
United Nations	<ul> <li>protecting consumers from unsanitary, unwholesome, mislabelled or adulterated food</li> </ul>
	<ul> <li>contributing to economic development by maintaining consumer confidence in the food system and providing a sound regulatory foundation for domestic and international trade in food.</li> </ul>
United States Food and Drug	Food Code: The purpose of this Code is to safeguard public health and provide to
Administration (US FDA)	consumers food that is safe, unadulterated, and honestly presented.
Health Canada	What are the Objectives for Regulating Health Products and Food?
	<ul> <li>Protect the public from sale and advertising of unsafe products</li> </ul>
	Support the safe use of products by transparently providing the information
	needed to help Canadians make informed decisions about their health
	Align lifecycle and regulatory system with health care and food safety systems
	Maintain appropriate and proportional regulatory oversight
	Incorporate international best practices
	Support science and technology innovation
	Ensure regulatory and operational sustainability and foresight
United Kingdom (UK) Food	Food Standards Act: "The main objective of the Agency in carrying out its functions
Standards Agency (FSA)	is to protect public health from risks which may arise in connection with the
	consumption of food (including risks caused by the way in which it is produced or
	supplied) and otherwise to protect the interests of consumers in relation to food."
	Where the interests of consumers is defined as: "Food is safe and what it says it is,
	and we have access to an affordable diet, and can make informed choices about
	what we eat, now and in the future".
European Union (EU) General	The stated aim of the General Food Law: "This Regulation provides the basis for the
Food Law	assurance of a high level of protection of human health and consumers' interest in
	relation to food, taking into account in particular the diversity in the supply of food
	including traditional products, whilst ensuring the effective functioning of the
	internal market. It establishes common principles and responsibilities, the means to
	provide a strong science base, efficient organisational arrangements and procedures
	to underpin decision-making in matters of food and food safety."

# Attachment B: International approaches to modernising food regulatory systems

Many countries have recently modernised (or are in the process of modernising) their food regulatory systems. Below is a summary of some of the regulatory reforms other countries have recently undertaken. While each country/regulatory system is different, the common themes or areas of focus in modernising food regulatory systems include:

- ensuring regulation is proportional, based in risk assessment and data analysis
- changing the way regulation is monitored and enforced to improve consistency and reduce unnecessary regulatory burden
- focusing on prevention, embedding a food safety culture across the supply chain
- improving traceability and responsiveness to food safety concerns, including through use of technology
- enhancing partnerships with stakeholders, including regulatory partners and regulated bodies.

#### **United States**

In 2011, the US FDA introduced the FDA Food Safety Modernization Act, which has been progressively implemented since 2011 and focuses on:

- Prevention including mandatory requirements for food facilities to document how they will prevent/minimise and monitor hazards, introducing produce safety standards and regulations to prevent the intentional contamination of foods
- Inspection and compliance including mandating inspection frequencies, powers to access records (including food safety plans) and food testing by accredited laboratories
- **Response** including authorities for mandatory recall, administrative detention of products, suspension of registration of a food facility, enhanced product tracing abilities, additional record keeping for high-risk foods
- Imports including explicit importer responsibilities, third party certification for foreign facilities, certification for high-risk foods, voluntary qualified importer program to expedite entry of foods from participating importers, authority to deny entry of food from a foreign facility.
- Enhanced partnerships including state and local agency capacity building, foreign capacity building including to build understanding of US food safety requirements, reliance on inspections by other agencies for domestic facilities.<sup>1</sup>

In July 2020, the US FDA announced the <u>New Era of Smarter Food Safety Blueprint</u>, noting:

<sup>&</sup>lt;sup>1</sup> United States Food and Drug Administration, 2020, <u>Food Safety Modernization Act</u> and United States Food and Drug Administration, 2020, <u>New Era of Smarter Food Safety</u>.

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The world around us is changing rapidly; many believe we will see more changes in the food system over the next 10 years than we have in decades. Foods are being reformulated; there are new foods, new production methods, and new delivery methods; and the system is becoming increasingly digitized. To keep pace with this evolution, FDA is taking a new approach to food safety, leveraging technology and other tools to create a safer and more digital, traceable food system. Smarter food safety is about more than just technology. It's also about simpler, more effective, and modern approaches and processes. It's about leadership, creativity, and culture.

The Blueprint outlines the approach FDA will take over the next decade to further modernise its food system and building on the Food Safety Modernisation Act. It 'represents the thinking of FDA food safety experts, consumers, the food industry, technology firms, federal and state regulatory partners, regulatory counterparts in other nations and academia'. It is centred around four core elements:

- tech-enabled traceability
- smarter tools and approaches for prevention and outbreak response
- new business models and retail modernization
- food safety culture.

Beyond food safety initiatives, the US FDA has also recently adopted new approaches to educate consumers and improve the information available to consumers to 'make it easier for you to make informed food choices that contribute to lifelong healthy eating habits'. Initiatives include the <u>New Nutrition Facts Label</u> and education campaign and the <u>Agricultural Biotechnology Education and</u> <u>Outreach Initiative</u>, which requires the <u>FDA</u> to work with other US Government regulators to share science-based educational information about GMOs to improve consumer understanding.

#### Canada

In December 2008, Health Canada released <u>Health Canada's Regulatory Modernisation Strategy for</u> <u>Food and Nutrition</u> (RMSFN)<sup>2</sup>, which presented a vision and objectives aimed at modernising Canada's regulatory system for health products and food, as well as proposed actions for moving forward. Health Canada noted that:

While Canada continues to have a strong food safety system, with many positive attributes, the current food regulatory system must modernize to keep pace with changes in science and technology, including food product innovation and new food technology applications. Health Canada must also make improvements to manage challenges posed by shifts in the organization, scale, and orientation of the food industry so that regulatory standards can continue to help protect and promote the health of Canadians.

<sup>&</sup>lt;sup>2</sup> Health Canada, 2008, <u>Health Canada's Regulatory Modernization Strategy for Food and Nutrition (RMSFN)</u> and Health Canada, 2007, <u>Towards a Regulatory Modernization Strategy for Food and Nutrition: Health Canada Discussion</u> <u>Document</u>.

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The goals set out in this strategy included:

- improving predictability, effectiveness, efficiency and transparency of Health Canada's food regulatory system
- promoting regulatory responsiveness to food innovation and promoting consumer access to foods with assessed health benefits
- modernising the regulatory toolkit to address "food contributors" to chronic disease
- improving Health Canada's responsiveness to acute food safety health risks responding to new threats while managing ongoing risks
- promoting a sustainable and integrated system for food safety and nutrition in Canada.

For each of these goals, the strategy also set out a number of more specific objectives or actions. For example:

Goal	Modernising the regulatory toolkit to address "food contributors" to chronic disease
Objectives/	• Develop strategies to reduce the presence of trans fatty acids in Canadian diets to the lowest
actions	possible levels, consistent with the reduced levels of trans fats recommended by the Trans
	Fat Task Force.
	• Develop effective risk management approaches to reduce Canadian dietary exposure to low- level genotoxic carcinogens and other trace contaminants in food – whether these originate from environmental sources or are food processing-induced, examples include acrylamide, dioxins, furans, benzene, etc.
	• Develop effective strategies for the use of Health Canada's food regulatory levers to address the chronic medical conditions of vulnerable sub-populations and factors which contribute to these conditions. Early work should focus on:
	– Celiac disease
	<ul> <li>Food allergens</li> </ul>
	<ul> <li>Also see Goal 4 / Objective 4.2</li> </ul>
	• Contribute to the science base regarding risks of chronic disease development associated
	with incidental exposure to bacteria, protozoan, parasites, viruses, and prions.

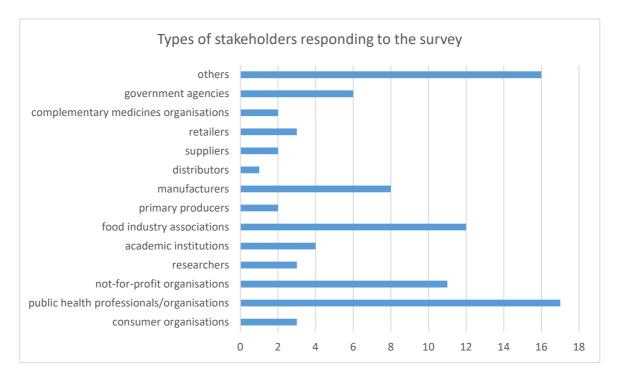
Health Canada has undertaken significant consultation on the different goals highlighted in the strategy (and the key components/actions under those goals) and published a more detailed <u>Regulatory Roadmap for Health Products and Food</u> in 2012. Health Canada has progressively reformed its food regulation system over this period, with the <u>Safe Food for Canadians Regulations</u> coming into force in January 2019 (and new requirements being progressively rolled out into 2021).



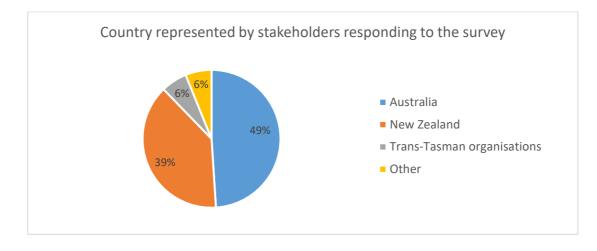
## **Attachment C: Summary of stakeholder feedback**

In November 2020, a consultation paper and online survey were published seeking stakeholder feedback on their aspirations for a modernised food regulatory system. The paper described some of the challenges and opportunities facing the food regulatory system over the next 20 years and set out the aims and scope of Australia and New Zealand's food regulatory system. It proposed a set of aspirations for the food regulatory system and some associated high-level actions on which stakeholder feedback were sought.

66 submissions were made from consumer organisations, public health professionals, food industry bodies, government agencies and others.



#### Stakeholders responded from across Australia and New Zealand.



Stakeholder feedback was more limited than anticipated, likely due to the timing of the consultation and the other, related consultation processes occurring in parallel.

Stakeholders were asked a number of targeted questions:

- 1. What other key challenges and opportunities are facing the food system?
- 2. Do you agree that the focus of reforms should be on ensuring the system is set up to support interface management across regulatory systems, enables collaborative risk assessment and triage of issues and provides a range of (regulatory and non-regulatory) tools to support the system's objectives and empower consumers and industry?
- **3.** Is there anything missing from these aspirations and high level actions? Are there any aspirations or high level actions that you disagree with (and if so, which ones and why)?

Feedback was highly polarised between different stakeholder groups – particularly between public health and industry organisations.

Submissions from public health and consumer representative organisations emphasised:

- the growing public health crisis related to overweight, obesity and diet-related disease
- the need to utilise the food regulatory system to address public health matters that are intrinsically linked to the food supply, particularly the availability and promotion of highly processed foods
- the need for stronger regulatory approaches to protect consumers and manage the conflicting interests of industry (with some stakeholders expressing a severe mistrust of industry).

Submissions from industry representatives highlighted:

- that the food regulatory system is not well-placed to address public health concerns (or consumer values issues relating to environmental sustainability, ethical matter or animal welfare, etc.) – these are best addressed through targeted policy interventions or by individual companies seeking to meet consumer demand
- the need to reduce regulatory burden and improve global harmonisation of food regulation to support a strong food industry and international trade
- that regulatory measures must be risk proportionate, grounded in scientific evidence and measured for efficacy.

A number of submissions highlighted long-standing tensions between the views and priorities of different stakeholders and the challenges in all stakeholders working collaboratively towards solutions.

While stakeholder feedback was polarised in many areas, there were also some areas of strong consensus. The majority of stakeholders agreed there are an array of challenges (and opportunities) likely to impact the food regulatory system over the next 20 years, and that the broader food environment is experiencing a period of rapid change. Most stakeholders acknowledged that it is critical changes are made to the system to enable us to deal with these challenges into the future.

With regards to the key challenges and opportunities facing the system, stakeholders generally agreed with those outlined in the consultation paper and described a number of additional challenges:

- Public health stakeholders saw the proliferation of processed foods with limited nutritional
  value (and the impact of this on public health) as a key challenge for the food regulatory
  system. Public health stakeholders also highlighted a perceived power imbalance between
  industry and public health bodies when it comes to influencing changes to food regulation as a
  critical matter to be addressed.
- Industry stakeholders highlighted the need to support a strong, sustainable and resilient food
  industry in Australia and New Zealand, particularly to enable economic recovery following the
  COVID-19 pandemic and amidst increasingly globalised supply chains. Many industry
  stakeholders highlighted the need to harness technology and innovation to meet consumer
  demands and find different ways to demonstrate compliance with regulatory requirements.

While most stakeholders agreed that food safety must remain the ultimate priority of the system, stakeholders had differing views regarding the prioritisation of other aims (and how far the system should extend to address those priorities). For example, some public health stakeholders placing greater emphasis on "support public health objectives" and industry stakeholders emphasising the need to "enable the existence of a strong, sustainable food industry". New Zealand stakeholders noted that the scope of the system should not extend any further (i.e. to take a more active role in achieving any of these aims), given the need for each jurisdiction and country to respond to local priorities and circumstances as required.

The aspirations proposed in the consultation paper, for the most part, resonated with stakeholders, noting there were some different interpretations regarding the intent of some aspirations. While stakeholder feedback on the aspirations was wide-ranging and varied, some key themes included the need for:

- strong leadership and decisive decision-making
- transparency around how decisions are made and what is informing these
- improved engagement with all stakeholder groups to enable expert advice to guide the system and build stakeholder capacity to meaningfully engage with the system
- a range of regulatory tools to enable proportionate, risk-based decision-making (noting that some public health representatives perceived the use of non-regulatory or co-regulatory approaches as ineffective)
- harnessing technology and using data to monitor compliance and measure the effectiveness of regulation

- regulation that is easy to understand and consistently implemented across jurisdictions (and countries, where appropriate)
- proactive environmental scanning to inform the review of regulation and ensure it remains fit for purpose.

Overall, stakeholders sought further detail on the aspirations and associated actions and how these might be implemented in practice.