



Ensuring Consistency across Australia and New Zealand's Bi National Food Regulatory System

Final Report

Prepared for:

**The Food Regulation Standing
Committee**

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1 Prism Expert Bios

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The first 25 years of his career was as a leading business lawyer in the City of London, assisting multinationals in various sectors. After his PhD on European regulation of consumer product safety systems, he became a full-time academic in 2004, leading a research team at the Centre for Socio-Legal Studies, Oxford. He was appointed Professor in Oxford in 2014 and has held an Erasmus Chair in the Netherlands and Visiting Chairs at ANU Canberra, Leuven, Beijing and Wuhan. He has written or edited 20 books and written many chapters and articles. He has chaired numerous committees on regulation and reform and was appointed OBE by the Queen in 2021.

Srikanth Mangalam is an internationally recognized expert in risk and outcome-focused decision making in areas of regulations, social impact and sustainable development with over 25 years of experience in North America, Asia, Africa, Australia, and Europe. He is considered as a visionary and a thought leader and has pioneered innovative solutions to addressing complex socio-economic and sustainability challenges including public safety, food security, gender equity, climate, health, youth employment and small-scale trade.

Prism Institute is a not-for-profit collaboration platform that conducts research, facilitates science-based dialogue between stakeholders and helps develop innovative policies and practical solutions to address risks to global sustainable development. Prism Institute has developed important research papers for the OECD and the World Bank on modern approaches to regulatory delivery including the use of emerging technologies. Prism Institutes advises governments and regulators in Canada, Europe, Australia, Africa, and Asia on regulatory reform in critical areas of socio-economic development including food, public health, global trade, infrastructure and public safety.

2 Executive Summary

Safe Food Production Queensland (SFQ) and the Queensland Department of Agriculture and Fisheries, on behalf of the Food Regulation Standing Committee (FRSC), are overseeing a project aimed at facilitating greater national consistency within the Australia New Zealand Food Regulation System (the System). The project forms a part of a larger initiative to modernise the System.

A previous study¹ commissioned by the FRSC identified that the lack of consistency nationally and at sub-national levels was largely induced by highly prescriptive legislative models. SFQ commissioned Prism Institute to assist in identifying and recommending best practices in regulatory design and delivery that would promote greater consistency in the implementation of policies and standards at the national and bi-national level and with imported food by:

- Making more use of an **outcome-focused, risk-based** approach and shifting the focus of the system away from a **highly prescriptive** legislative model.
- Exploring the **range of regulatory and non-regulatory tools** that are available for intervention to complement the **successful harm-focused risk-based approaches**.
- Bolstering the current regulatory system's ability to innovate **in response to emerging trends** and remaining at the forefront of best-practice regulation.

This work was carried out in two phases:

- **Phase 1** – Development of a 'Theory Paper on Contemporary Regulatory Models'.
- **Phase 2** – Selection of a preferred model, development of principles to guide implementation and an implementation roadmap.

Phase 1 involved the development and presentation of a regulatory theory research paper that explored and provided advice on suitable regulatory models that could be applied to a modernised Australian food regulatory system to facilitate national consistency. The recommendations are explained in depth in Prism Institute's report entitled '*Theory Paper on Contemporary Regulatory Models*'². They are also discussed in this report and a list of the recommendations is available at Annex 1.

Prism Institute's approach began with the premise that successful regulation depends as much on successful *design* as it does on *implementation*.³ This idea underpins the 'Regulatory Delivery Model' (RDM), a conceptual framework which proposes that certain conditions and practices must be in place for a regulatory system to operate effectively.

Prism Institute performed a review of the food regulatory system against the RDM, informed by a desk top analysis and feedback received from officials working within the System via a survey. Prism Institute identified several systemic gaps and developed a set of seven recommendations to address these.

The recommendations put forward a holistic, top-down approach to modernising the system and improving consistency. The approach goes beyond the idea that consistency is merely an

¹ MP Consulting, Feb 2021, "Key Areas of Inconsistency in Food Regulation".

² Mangalam S., Hodges C., & Sharpington L., Oct 2020, "Theory Paper on Contemporary Regulatory Models", PRISM Institute, Canada.

³ G. Russell and C., 2019, Hodges, "Regulatory Delivery".

attribute associated with the traditional delivery of regulation. Instead, the issue of inconsistency is understood to apply to the design, governance, culture and practices of the entire system. Prism Institute's recommendations outline a pathway for how these issues should be resolved and propose that all relevant parties working in the system should come together to agree *what* needs to be *done*, what needs to be *achieved* and *how* to do it.

Prism Institute also described features of contemporary regulatory practice to support the modernisation of the system and suggested how these could be adopted in the Australian and New Zealand system⁴. There is evidence to support that risk and **outcome-based, evidence-enabled, and trust-focused, cooperative** regulatory models are more likely to succeed in achieving regulatory objectives. This requires organisational change and a shift in the culture of the system, which will take time and sustained effort. Overtime, as more parties adopt the new way of working, greater consistency will be achieved, both within the broader food system and across jurisdictions.

Early adoption of the approach will assist in ensuring the system remains at the forefront of contemporary regulatory practice. Whilst the approach is innovative, the recommendations are informed by the RDM, as well as other emerging international best practice models, practices and approaches; including the Primary Authority Model, the Delegated Authority Model and Ethical Business Regulation. These contemporary practices can be seen in action by regulatory authorities around the world, including the UK Civil Aviation Authority, the Canadian Food Inspection Agency, the UK Office of Product Safety and Standards (previously UK Better Regulation Delivery Office) and the Government of Ontario (Canada).

Phase 2 of the work focused on prioritizing the recommendations and developing a strategy and roadmap for implementation. In Phase 2, a bi-national advisory group was formed consisting of representatives of the FRSC. Facilitated by Prism Institute, the advisory group deliberated on and prioritized the seven recommendations.

The group agreed that a voluntary code of practice co-created using a multi-stakeholder cooperative model would be the most effective way of ensuring jurisdictional consistency and facilitating the implementation of the recommendations. Through such an approach, regulators would benefit by having greater clarity and alignment between the overall regulatory purpose and objectives, the purpose of regulatory requirements, and their individual and collective mandates. Under a code, similar to the UK Regulators' Code, regulators would not only be compliance seekers but trusted partners and influencers of good business practices in a manner that is consistent. Such a code would:

- Provide clear guidance to regulators for implementing regulatory delivery frameworks and methods.
- Describe formal structures to hold regulators accountable to meeting overall regulatory objectives.
- Help develop meaningful performance and outcome indicators to achieve regulatory outcomes.

⁴ *Please note that this report makes reference to the 'bi-national system'. This reflects the Australia and New Zealand Food Treaty and the common market shared by the two countries. However, readers should note that it may be more appropriate for some of these recommendations to be implemented in Australia's food regulatory system only.

- Drive regulators to better understand business environments and establish relationships of trust.

The Code, together with a regulatory delivery governance and accountability framework, would clearly identify the roles and responsibilities of each regulator associated with the regulatory system, their interactions with other regulators and industry to ensure consistency in decision making.

To that effect, a draft Regulatory Practice Principles (RPP) document was developed with the following elements, which align with the RDM framework:

1. Regulatory Purpose and System Outcomes
2. Commitment to Ethical Values
3. System Governance
4. Responsibility, Accountability and Operating Practices
5. Measuring Performance
6. Continuous Improvement

The RPP document is currently in draft form, and it is intended to be finalised in collaboration with stakeholders. It will then provide the guiding principles which all participants in the regulatory system will be guided by as they work together to establish trust and cooperate to achieve the desired outcomes. Once finalised and fully implemented the RPP elements will:

- achieve a shared understanding of the common purposes and outcomes of the system
- achieve a commitment to ethical values that guide their activities
- determine governing structures for cooperating and achieving the outcomes
- describe regulators' commitment, responsibility, accountability and operating practices
- establishing appropriate evidence for demonstrating that the outcomes are being achieved and the system is working effectively, and
- build a culture of problem solving and constantly improving performance.

Prism Institute also provided a high-level roadmap for implementing the recommendations using the guidance provided by the RPP as illustrated below:



This report provides more details on the two phases and demonstrates how the proposed recommendations and roadmap help to address jurisdictional consistency in implementing a modern collaborative food regulatory system.

3 Phase 1: Development of Recommendations

3.1 Context

The Conran Review

The Peter Conran report⁵ published last year suggests that “Australia’s federal structure, built upon reciprocal financial, legislative and policy responsibilities, requires intelligent cooperation on issues of strategic national significance. The recommendations of this review aim to ensure that Australians are served by a sustainable, effective, efficient and collaborative system of federal relations”.

The report was an outcome of a review with three key objectives; a) to enable national cooperation and consistency on enduring strategic issues, b) to address issues requiring cross-border collaboration; and c) to perform regulatory policy and standard setting functions.

The report highlights the importance of recognising the diversity between and within jurisdictions and the disparate nature of the challenges faced across the federation – where appropriate, decisions should be principles-based and allow individual jurisdictions to determine the best way to achieve agreed outcomes. The review also recommends reducing the number of fora to those necessary for intergovernmental policy collaboration and ongoing regulatory functions.

Consultation into key areas of inconsistency

Additionally, another study⁶ carried out on behalf of the FRSC in 2021 identified key areas of inconsistency in food regulatory approaches based on the impact of these inconsistencies on industry and government. Some of the themes of inconsistency that emerged through that study included:

- **Regulatory system governance** – Complex/unclear system governance including the roles and responsibilities of various bodies, interfaces between different regulators in food, medicines, and primary industry.
- **Regulatory delivery** – Challenges in navigating through the regulatory framework including identifying and interpreting technical requirements, difficulties in identifying government resources for assistance in navigation, inconsistent approaches to regulation of food businesses including the methods for registration and classification, audits and inspection arrangements including frequency/type of inspections, reporting requirements, inconsistencies in applying requirements, and inconsistencies arising from the interface between different regulators.
- **Standards Development** – Complex/slow processes for code amendments, lack of coordination in implementing regulatory changes, inconsistencies in the interpretation of standards, labelling requirement, and alignment with international approaches.

⁵ P Conran, October 2020, “Review of COAG Councils and Ministerial Forums”.

⁶ MP Consulting, 2021, “Key Areas of Inconsistency in Food Regulation”.

Theory paper on contemporary regulatory models – a systematic approach to improving inconsistencies

Using the inputs from the two above-mentioned reports as background, Prism Institute was initially tasked with carrying out a comprehensive research study and developing a theory paper that laid out various contemporary models and approaches to specifically address issues of jurisdictional inconsistencies in food regulation. To determine the appropriate models and approaches, Prism Institute set out to identify the systemic/root causes for inconsistencies across the system by reviewing contemporary research and practices, existing documentation (including the above-mentioned reports) on the Australia-New Zealand bi-national system and undertaking a survey across the various food safety regulators in the bi-national system. At the completion of this review, Prism identified that, while there are numerous strengths to the system, there are also opportunities for systemic enhancement that would take a top-down approach to modernization.

This report provides a summary of the recommendations made in the theory paper. To access the findings of the survey and detailed recommendations please refer to the full report⁷, available on the [Food Regulation website](#).

3.2 Recommendations

A focus on outcomes and shared responsibilities over the enforcement of rules

Delivery of regulation (Regulatory Delivery) has traditionally been based on models that assume the existence of a legal system and of rules, inspecting, checking, identifying non-compliance with the rules, and imposing sanctions or corrections. The legal system, therefore, relies on ideas like conformity with rules or standards, inspection, sanctioning and ultimately punishment and deterrence.

It is increasingly being realised that legal systems have limitations in affecting the behaviour or the outcomes that are desired—and in encouraging improvements in performance. In fact, as shown by the two previously mentioned studies relating to the bi-national food regulatory system, it is clear that they introduce inconsistencies leading to confusion amongst stakeholders, both in terms of expectations and desired outcomes.

In both business organisations and public regulatory systems, it is increasingly realised that more is achieved when everyone is aiming at the same shared objectives, has the same common purposes, and is making their own contribution to achieving the desired outcomes.

This can mean that purposes and outcomes that might conflict need to be discussed and balanced. For example, producing profit, prosperity and growth can conflict with protecting society (including workers, customers, investors, communities, and the environment) from harm. The MP Consulting report⁸ identifies examples such as “Country of Origin Labelling, “Nutrition

⁷ Mangalam, S, Hodges, C, & Sharpington, L, October 2020, “Theory Paper on Contemporary Regulatory Models”, PRISM Institute, Canada.

⁸ MP Consulting, 2021, “Key Areas of Inconsistency in Food Regulation”.

Claims” wherein the expected outcomes are in conflict across two separate regulatory systems creating inconsistency and causing social and economic impacts to consumers and industry.

Equally, some governments have required that their regulators not just ensure the goal of protection but also take into account the objective of business growth in everything they do. In the context of food systems in Australia and New Zealand, the MP Consulting report provides various examples of inconsistencies. These ranged from labelling requirements, business registrations, interfaces between regulations and regulators etc. The effect of these inconsistencies is unfair market advantages, restricted domestic growth opportunities, and increasing costs. All this whilst, not necessarily increasing protection to consumers.

The concept of the regulatory delivery model challenges legislators and regulators to focus on whether the purposes and outcomes of regulation—from protection to prosperity—are actually being delivered consistently and effectively. Consistency is therefore not merely an attribute associated with the traditional delivery of regulation but an expectation that the intended purposes and outcomes of all stakeholders will be achieved.

The core idea is to get all relevant parties together to work out not just *what* needs to be *done* but also what needs to be *achieved* and *how* to do it. Introducing the focus on purposes and outcomes from the start, and continuing the focus on achievement and delivery, will **drive consistency across systems and accelerate the outcomes**.

Enhancing trust and collaboration

Cooperative models⁹ drive consistency and help achieve desired outcomes when they have the following elements:

- A **trust-based system** that differentiates those who can be trusted to behave according to **ethical values in the achievement of agreed purposes and outcomes** from those who do not, with appropriate accountability and consequences.
- A system in which **all stakeholders work together to achieve the common purposes and outcomes**, avoid undesirable outcomes, and identify and resolve problems and reduce risk.
- **Co-creation involving all stakeholders**, such as government, industry, users, workers, and civil society. All stakeholders are **treated as responsible actors and encouraged to act through self-motivation with competence, autonomy, responsibility, accountability, and relatedness**.

Recommendations for a systematic approach

Advocating an approach based on cooperation and co-creation, Prism Institute provided a set of seven recommendations (described in detail in Annex 1) that aim to assist Australia and New Zealand in achieving greater consistency by using a broad-based systems/top-down approach to reform.

The recommendations, which fall under three broad themes, are discussed below:

⁹ C. Hodges, 2022, “Outcome Based Cooperative Regulation”.

1. Food Regulatory System: System Purpose and System Governance

Food systems¹⁰ are generally assumed to consist of various actors, their interactions and enabling policy environments and the cultural norms that exist along the food value chain. Food systems are broad, spanning from input supply and production of crops, livestock, fish and other agricultural commodities to transportation, processing, retailing wholesaling, and the preparation of foods, through to consumption and disposal. Ideally, the desired outcomes of a food system align with the broader goals of society, i.e. improved nutrition, health, safety, productivity, efficiency, environmental sustainability, climate-smart and inclusivity.

Food regulatory systems are part of the overall food system and facilitate the achievement of many of the desired outcomes of the food system via regulation. Typically, the objectives of food regulatory systems, such as the one in Australia and New Zealand, are primarily focused on protecting and improving public health and safety, whilst enabling informed consumer choice and supporting the existence of a sustainable industry¹¹. It is often the case that **not all the desired outcomes of a food system are covered under food regulatory systems**. Outcomes such as improved nutrition, productivity and efficiency, sustainability etc. may be achieved through other mechanisms such as advocacy, market-driven incentives, consumer activism etc.

Where those outcomes are covered under regulatory systems their delivery may be siloed, often conflicting and overlapping. For example, public health regulators may or may not share similar regulatory objectives as food safety regulators, or environmental regulators may impose requirements for climate adaptation that may not consider impacts on food access.

Regulations and regulatory frameworks are rarely designed to tackle such interconnected systems, and where social and economic outcomes are a conscious collective choice, this can lead to issues such as inconsistencies across the systems. Many of these regulatory systems are endeavouring to assist in achieving societal goals/outcomes (food security, informed choice, truth in advertising/labelling) but in isolation and without acknowledging the potential synergistic or antagonistic effects. As a result, inconsistencies and duplications across these systems are likely to occur unless the systems acknowledge the interrelationships between them and their contribution to the overall societal goals of the food system. The current situation therefore makes the need for regulations to be designed such that they can deal with the **complexity of interconnected systems and to deliver an acceptable balance between economic and social outcomes and delivered using a trusted, evidence-based, internationally co-ordinated approach**.

Under these circumstances, it is therefore ideally instructive to view a 'food system' as a whole when reforming the 'food regulatory system'. If one takes this wider perspective the questions that need to be asked include:

- What is/are the essential purposes?
- What goals are we aiming to achieve?
- What outcomes are to be delivered and how?

¹⁰ International Food Policy Research Institute, "Food Systems".

¹¹ Aspirations for Australia and New Zealand's Joint Food Regulatory System, 2017.

Given the complexity of the food system (representing the entire food chain) and the different levels of government administering the regulations and standards, it is **necessary to re-examine and reset the purpose(s) (if necessary) of the regulatory system**. This would help represent the current and future needs and the roles of the stakeholders including the industry, consumers and civil society. It is prudent to ensure that the **purpose(s) is/are clearly stated in the various pieces of legislation governing the food chain and may also be reiterated through the governance structures**. It should be acknowledged that **some of the actors, and by definition their roles, responsibilities and accountabilities, may not be addressed** using the food regulatory system and would therefore need to be managed.

2. Regulatory Delivery: Institutional Governance and Accountability:

One of the challenges with complex regulatory systems involving multiple regulators and various levels of administration is the ability to maintain consistency in decision-making that is aligned with the regulatory purpose and objectives. While the ISFR has the responsibility for ensuring consistency in delivery, **formal structures such as voluntary codes of practice, which would provide further guidance, accountability mechanisms, and feedback loops for continuous improvement, provide the ability to maintain consistency**.

3. Regulatory Delivery: Practices

Internally, **regulators should ensure that they have clearly defined and well-established outcomes to be achieved that are aligned with the bi-nationally established regulatory purpose/s and objectives**. While there is a desire to move more towards risk-based prioritization and intervention approaches, a **standardized approach to risk assessment and management is needed to provide businesses the certainty that they are treated fairly and consistently**. Risk-based approaches are heavily dependent on data. Regulators should therefore identify and establish **frameworks for collecting the relevant data and evidence** to support risk assessments and the measurement of outcomes.

Regulators should **ensure that they have a range of intervention choices and tools** that would allow them to effectively deliver their services and achieve the desired outcomes. In this context, the tools should provide the flexibility not only to enforce regulations but, more importantly, to educate, influence and reward regulated sectors. Externally, regulators should consider a **range of options to proactively engage industry, consumers and civil society so that achievement of regulatory objectives are co-owned by the stakeholders**. The advantage of these approaches is to increase the availability and quality of data/evidence for compliance assurance, shifting the responsibility for demonstrating compliance to the industry, and providing opportunities for growth and innovation in the sector.

4 Phase 2: Implementing Recommendations

Phase 1 laid out seven recommendations that present a systems approach to reform and modernization of the Australia New Zealand bi-national food regulatory system. It has been demonstrated that improving and ensuring consistency in regulatory delivery does not merely involve introducing or improving existing regulatory requirements and tools but it also requires a more holistic and collaborative approach to achieving broadly-established outcomes of the food system. Improvements in regulatory instruments and tools will be a natural output when undertaking such approaches.

An integrated, holistic, cooperative approach to reforming the food regulatory system based on the seven recommendations requires a multi-year, multi-disciplinary effort and therefore has to be carried out in several phases. To begin the process of reform and as part of phase 2, a bi-national advisory group was formed consisting of Program Leaders for Priority 1 and 2 areas, and project leaders of other modernisation projects. Facilitated by Prism Institute, the advisory group was tasked to:

- **Develop recommendations to define the purpose of the food regulatory system.**
- **Provide recommendations to enhance the current governance and accountability framework for the food regulatory System.**
- **Provide recommendations to improve consistency in regulatory delivery across the food regulatory system.**
- **Develop a strategic implementation plan and roadmap.**

4.1 Regulatory Purpose

As noted during a consultation to inform the development of aspirations for the food regulatory system, the aims of the food regulatory system that were updated in 2017 were deemed to remain fit-for-purpose by FRSC. The aims include:

- 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.

In pursuing these aims, the overriding priority has been identified to constantly be protecting public health and safety. It is evident from the aims that regulators are expected to deliver outcomes that create an acceptable balance between protection (of consumers and the public) and prosperity (industry, economy). In fact, many of the described aims of the food regulatory system may very well represent those of the overall food system. It became clear through discussions within the advisory group that there exists a potential misalignment between the aims of the food regulatory system noted above and regulatory mandates, which tend to focus primarily on protecting public health and safety. The advisory group agreed that there needs to

be a more broad-based consultation and review of the aims of the overall food system, it's similarities and differences with the aims of the food regulatory system and the impact on objectives of the food regulatory system.

In the absence of agreed broad aims for the food system and to reconcile the aims of the food regulatory system with the currently understood objectives of the regulatory system (individual mandates of regulators), **it was recommended that a common set of regulatory objectives across the bi-national and/or national system be established** by addressing the following key lines of inquiry:

- Are the objectives and desired outcomes of the bi-national food system established and if so, how do they relate to the aims of the food regulatory system
- Can the aims of the food regulatory system be met through regulatory delivery and if not, where are the gaps?
- Can the aims of the regulatory system be addressed through the proposed recommendations for reform?
- Can a broad-based consensus on the objectives and outcomes across key stakeholders in government, businesses, and civil society be achieved?
- Are measurable outcomes established to demonstrate the progress and achievement of these objectives? What are the outcomes?

The recommended action for future consideration is to **discuss and agree on the purposes and outcomes of the food regulatory system**. To summarise the main contenders for inclusion (allowing for some overlaps and even inconsistencies in this candidate list):

- to ensure that food is safe
- to ensure that safe food is provided and consumed
- to ensure that public health is maintained and improved through food
- to ensure that disease is reduced/morbidity is improved
- to ensure that (some/enough) food is available at affordable prices
- to eliminate food poverty
- to ensure improvement of human, social and natural capital
- to ensure consumers have choices and options about their food and sufficient information to exercise them
- to ensure an efficient food (safety) system
- to support production as a strong national sector
- to ensure that the sustainability goals are met (timing).

Examples of measurable outcomes may include:

- Reduction in the loss of healthy years of life (DALYs or disability-adjusted life-years) result from food safety risks
- Improvements in notifications and reporting of near-misses and supply chain failures
- Improvements in ethical practices of businesses (e.g., ESG ratings etc.)
- Reduction in prevalence of food insecurity, malnourishment, obesity etc.
- Increases in production/export of healthy foods, average incomes of SMEs
- Increases in women owned/indigenous food businesses
- Improvement in overall food safety ratings for businesses.

It is important that these outcomes be reflected as KPIs in strategic plans so that they can be measured periodically, and progress can be demonstrated over time. It is axiomatic that it may not be possible to achieve all outcomes at the same time and at the same pace, hence the need to set priorities and measure progress.

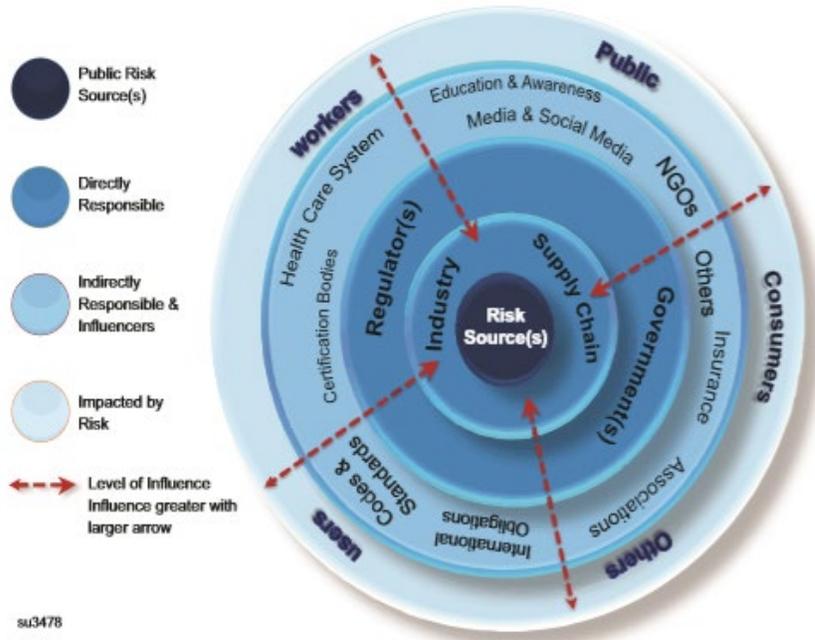
4.2 System Governance

The achievement of desired outcomes of the Australia-New Zealand food regulatory system, as laid out by its aims, requires active participation from a range of stakeholders across the system. As has been described earlier, many of the aims cannot be achieved by a traditional regulatory delivery method alone and would require a more holistic and cooperative approach.

Therefore, once the overriding purpose of the food regulatory system has been established, the next set of basic issues that arise are:

- Which *actors* have which *functions* in the system as a whole and in achieving the purposes and outcomes? Who has to do what?
- How do people interrelate? What *approach* and methodology underlies how they all act and work together? This is a matter of policy on cooperation, and of *behaviour and culture* in practice.
- How are these relationships structured and formalized?

Public Risk Management – Multi-Stakeholder Context



NGOs = Nongovernment Organizations

12

The illustration above provides an example of how the actors in the food system can be mapped. This approach not only assists in identifying the stakeholders but also the relationships and interrelations that are necessary to enable the system to function effectively. Further, it helps in determining their level of influence in achieving the objectives. The **roles, responsibilities and levels of accountability are generally directly proportional to the level of their influence on the system**. In order to define the roles and responsibilities of the various stakeholders and ensure that they are accountable, it would therefore be required to identify the various actors and the interactions between them across the food value chain.

It should be acknowledged that **some of the actors and by definition their roles, responsibilities and accountabilities may not be addressed** using the food regulatory system and would therefore need to be actively considered. In particular, their ability to positively or negatively impact the achievement of the desired outcomes should be taken into account while designing regulatory delivery options. For example, advocacy groups or educational institutions may be more effective in addressing unhealthy food practices and should therefore be recognized formally within the regulatory system.

The key lines of inquiry in establishing the system and its overall governance include:

- Are all the stakeholders who directly or indirectly influence the achievement of the system objectives, along with those who are impacted by the system, identified?
- Can the interactions and relationships between these stakeholders be defined?

¹² Underwriters Laboratories, UL 2984: Guideline for Managing Risks in the Public Interest.

- Are the responsibilities for the overall system (design, monitoring and continuous improvement using a problem-solving model) clearly defined and if not, is there a need?
- Are all the desired system objectives reflected in government policy?
- Are the regulatory objectives within the system objectives and their interdependencies well allocated and defined?
- Do the standards of performance and behaviour adequately reflect the desired regulatory objectives?
- Are the stakeholders of the system aware of, take responsibility for and able to be held accountable for those objectives that are mandated?
- Does the system currently operate based on clearly defined and shared ethical principles and standards, and do these principles and standards extend to beyond the regulatory objectives?

In addition to developing a representative system for Australia-New Zealand, it would also be useful to construct a matrix mapping the roles of the various players and their direct/indirect linkages to the desired outcomes. A sample matrix is provided as an example below:

| Aims | Stakeholder Group | Responsibility | Accountability | Regulators | KPI |
|---|-------------------|----------------|----------------|------------|-----|
| protect the health and safety of consumers by reducing risks related to food | | | | | |
| 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 | | | | | |

The creation of a matrix such as the one shown above will, at a minimum, help achieve the following:

- Communicate the various interventions and actors required to ensure a safe, healthy and sustainable food system including the role of the regulatory system.
- Develop an integrated approach to monitoring and measuring the effectiveness of the overall food system.
- An outcome-based approach to monitoring and measuring the functioning of the overall food system will help determine the effectiveness of the regulatory system and the need for improvements, if any.
- Establish opportunities for partnerships across stakeholder groups to ensure a common approach to achieve the desired outcomes.
- Help identify and address any inconsistencies in the understanding of the desired outcomes and the ethical principles and standards outlined to achieve them.

4.3 Regulatory System Governance

As evident from the functioning of the food system described above, many aspects of the system help achieve the desired objectives through regulation. It is also clear that **many of the desired objectives can be better achieved through other non-regulatory interventions, and the process of determining the balance between regulatory and non-regulatory interventions needs to be evidence based and continuous**. An appropriate, efficient, effective and sustainable governance structure needs to be in place to maintain this balance between regulatory and non-regulatory interventions. This **governance structure needs to be collaborative, evidence based, and built on a foundation of trust across all the stakeholders** identified as participants of the food system.

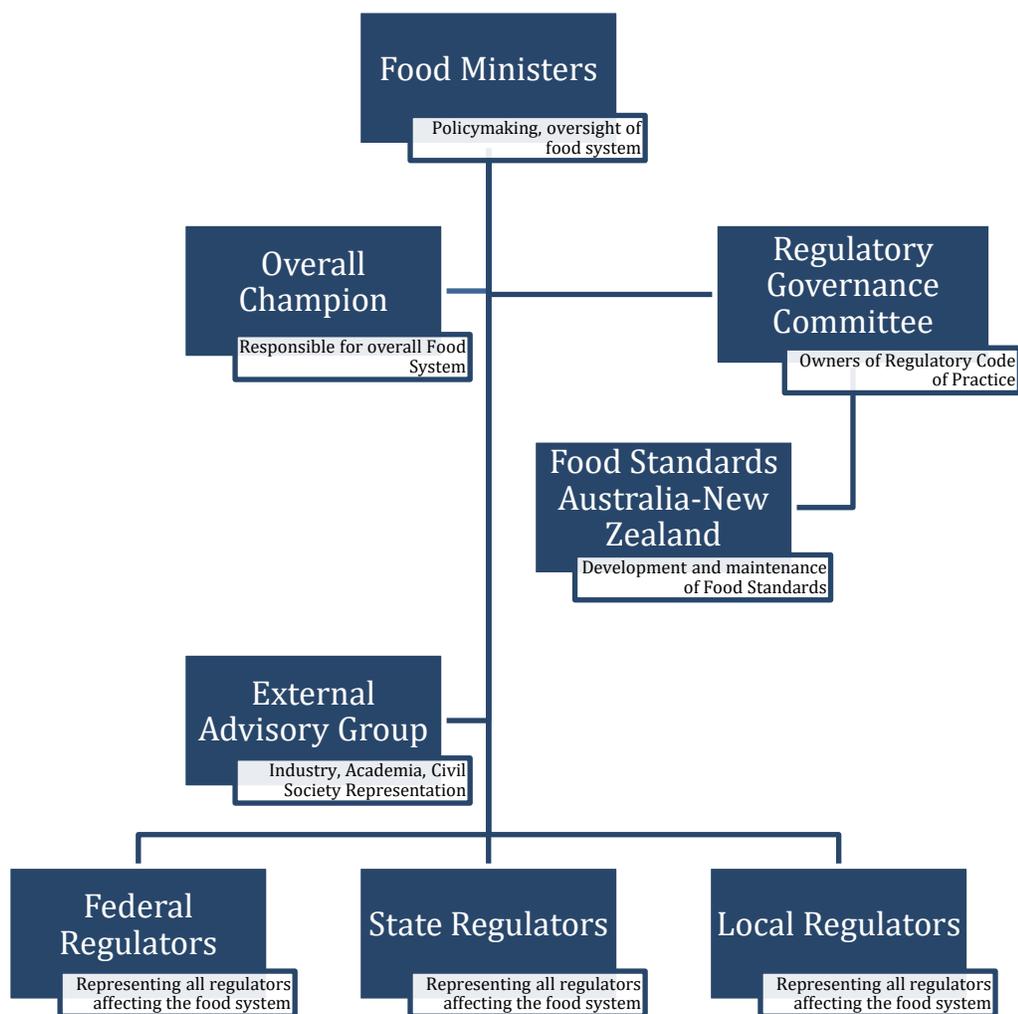
Currently, the governance structure in Australia and New Zealand is a joint system that involves the Australian and New Zealand governments, and Australian states and territories.

While the framework is well functioning and continues to serve its purpose, opportunities that make the processes more efficient, independent and less complex need to be explored. In this context, the following key lines of inquiry may be pursued:

- Does the structure adequately represent the desired objectives of the food regulatory system?
- Are the stakeholders of the food regulatory system adequately represented within the structure?
- Is there a formal framework in place that supports the interaction and interoperability between the stakeholders?
- Does the responsibility for the development and maintenance of the governance structure lie with policymakers (ministerial responsibilities)?
- Has the government established measurable outcomes to achieve the food regulatory system objectives?
- Are the operations and oversight of these agreements adequately delegated?

- Are the implementation agencies provided with the necessary independence, authority and flexibility to administer their responsibilities?

A simplified regulatory governance structure and a regulatory operating structure is provided below that broadly identifies the potential responsibilities and accountabilities associated with the actors of the governance structure. It should be noted that this proposed governance structure assumes the existence of a food system and recognizes a formal relationship between the food system and food regulatory system. In that context, Food Ministers and Overall Champion are expected to represent the interests of the overall food system.



The key features of the above structure include:

- **Elevating the role of the Food Ministers to primarily being responsible for developing and maintaining food policies and for the oversight of the food system; this would include their monitoring the achievement of desired outcomes of the overall food system.**

- **Creation of the role of a Champion who would be accountable for the overall food system.**
- **The role of the regulatory governance committee is to:**
 - **Seek advice and receive direction from the Food Ministers on the implementation of food policies.**
 - **Direct the development and maintenance of food standards through a process of cooperation and engagement with the stakeholders of the food regulatory system, which is formally represented by an external advisory group.**
 - **Develop and maintain a regulatory code of practice and associated regulatory/non-regulatory instrument that would be adopted and implemented by regulators at all levels of government who impact the food regulatory system.**
 - **Monitor the implementation of regulatory policies including reviewing the adequacy and effectiveness of regulatory delivery instruments.**

4.4 Regulatory Delivery Code of Practice

It has been established that consistency in regulatory delivery across the bi-national food regulatory system can only be achieved through a cooperative and collaborative approach between the variety of stakeholders interacting within the food system. Such cooperation could include development of new requirements, either in the food standards or food legislation, development of guidance material, scheduling audits or inspections. All of these activities should be aimed at achieving the set regulatory outcomes.

Approaches to cooperative engagement require the following elements:

- **A trust-based regulatory system** that differentiates those who can be trusted to behave according to ethical values in the achievement of agreed purposes and outcomes from those who do not, with appropriate accountability and consequences.
- A regulatory system in which all stakeholders **work together** to achieve the common purposes and outcomes, avoid undesired outcomes, and identify and resolve problems and reduce risk.
- **Co-creation** involving all stakeholders, such as government, industry, users, workers, and civil society. All stakeholders are treated as responsible actors and encouraged to act through self-motivation with competence, autonomy and relatedness.

The regulatory system can be configured to provide different approaches that differentiate between, for example,¹³

- a) those who produce continuous convincing evidence that they can be trusted (who should benefit from appropriate advantages);
- b) those who decline to do this but whose activities are regarded as legal as long as they comply adequately with the legal rules;

¹³ Examples include the Ontario Operating Engineers regulatory Alternative Paths, see <https://www.tssa.org/en/operating-engineers/resources/Application-for-the-Registration-of-a-Plant.pdf>; and the 'verified trust and accountability' model of the Essential Services Commission of South Australia, see *Inquiry into regulatory arrangements for small-scale water, sewerage and energy services Final Inquiry Report* (Essential Services Commission of South Australia, 2021).

- c) those who produce modules of relevant evidence of competence, resources, intentions, behaviours, and outcomes, which might be regarded as building blocks towards category (a): this may be particularly relevant for small businesses and start-ups.

Some of the practical steps in implementation include:

- Agreement on the core purposes, objectives and outcomes.
- Agreement on the functions, roles, responsibilities, objectives, outcomes, metrics and accountability mechanisms of each stakeholder in achieving the common purposes and outcomes.
- Agreement on the mode of engagement, such as a code of ethical practice governing the whole system, to which all actors should sign up, supplemented by all necessary subsidiary agreed rules on specific activities and behaviours, whether in law, standards or guidance.
- Agreement on relevant evidence that will demonstrate the extent to which an actors' activities achieve the desired outcomes and improvements in performance.
- Operating a performance monitoring system in which stakeholders account for their behaviour and contribution in achieving the desired purposes and outcomes, and cooperate in identifying problems, analysing root causes and implementing agreed responses prospectively to reduce risk and retrospectively to repair harm.
- Appropriate responses are made to failures or those who do not behave in the expected cooperative manner. Actors who make mistakes are supported to improve their performance, competence, behaviour and outcomes. Actors who behave unethically and anti-socially are subject to interventions of appropriate severity aimed at protecting society.

The advisory group developed a set of **Regulatory Practice Principles (RPP)** that would be voluntary in nature and would guide the implementation of a consistent regulatory delivery model across the various jurisdictions in Australia and New Zealand.

The principles are grouped under six elements, which all participants in the food regulatory system must consider as they implement or advance the system at a national/binational level and State and Territory (jurisdictional) level.

These elements are:

- **Regulatory Purpose and System Outcomes**
- **Commitment to Ethical Values**
- **System Governance**
- **Responsibility, Accountability and Operating Practices**
- **Measuring Performance**
- **Continuous Improvement**

While the principles are intended to be voluntary in nature, they have been developed to support existing legislative requirements contained in jurisdictional Food Acts and other food related laws.

The principles are aimed at promoting consistency in regulatory delivery across the various jurisdictions, while supporting continuous improvement and the need for each jurisdiction to target interventions and resources towards individual areas of need. The principles and the elements are described in detail in Annex 2.

5 Roadmap for Implementation

Significant progress has been made in enhancing Australia and New Zealand's food regulatory system through various connected modernisation efforts and projects. With respect to achieving jurisdictional consistency, a phased approach has been adopted to consider and implement the seven recommendations made by Prism Institute. An advisory group consisting of various Reform and Priority leads has undertaken the task of reviewing the recommendations and, in coordination with Prism Institute, aiming to achieve the following outcomes as part of its first and second phases:

- Gaining a common understanding on the research and background on contemporary thinking and best practices in regulatory delivery.
- Understanding and agreeing on the relevance and context of the seven recommendations with respect to the Australia-New Zealand food regulatory system.
- Agreeing for the need to review and update to the purpose and governance affecting the overall food system in Australia.
- Accepting the need to identify and develop a code of practice that sets out principles for regulatory delivery based on cooperative approaches to achieving regulatory outcomes.

Through a series of consultations and discussions, the advisory group has worked through reviewing the recommendations and debated the nature of the modernisation of the regulatory system. In addition to accepting the need to review and update the regulatory purpose/s and the governance of the regulatory system, the advisory group has established an initial set of regulatory principles along the lines of what has been recommended in the previous section. These regulatory principles will guide the future design, testing and implementation of a regulatory system that is co-created, is values based and trustworthy, resilient, sustainable, and geared to addressing the future needs of food safety and security in Australia and New Zealand.

Assuming that there is broad based acceptance and approval amongst the FRSC and the Food Ministers on a cooperative approach to modernising regulatory delivery the roadmap for implementation would involve the phases as shown by the illustration below:



In Phase 3, using the recommendations generated by the advisory group in Phase 2 and involving a multi-stakeholder group, the purposes, objectives, desired regulatory outcomes, and bi-national key performance indicators shall be developed.

In Phase 4, the governance and accountability framework shall be modernized in two steps. In the first step, the range of stakeholder groups representing the food system shall be identified. Their roles, responsibilities, and accountabilities shall be defined. As a second step, the existing

regulatory governance and accountability framework shall be re-evaluated and restructured by considering the recommendations generated in Phase 2.

Selecting 1-2 key sectors in the food system, the regulatory practice principles shall be implemented and tested as part of a series of pilots in Phase 5. Using a co-creation approach, some of the essential elements in this phase that should be established include at a minimum:

- **Common set of ethical values and principles that the regulators and regulated can adhere to**
- **Development of a standardised risk assessment framework that can be replicated across jurisdictions and sectors and including the identification of various possible data sources, risk assessment methodologies, and criteria for decision making (e.g., frequency of inspections, selection of appropriate interventions, strategic planning etc.)**
- **Selection and testing of various operating models such as the Primary Authority, Delegated Authority etc.**
- **Selection and testing of various operating practices (e.g., risk based approaches to licensing, inspections and enforcement, risk based fee setting, alternate dispute resolution/compliance achievement strategies etc.)**
- **Selection of testing of sector/jurisdiction/agency specific KPIs and indicators alongside national KPIs and indicators to monitor system and regulatory outcomes**

These pilots will help improve the RPP, the ability to effectively implement them, and to scale them across the remaining sectors and jurisdictions.

Phase 6 will primarily involve developing a strategy for the full-scale implementation of the modernized food regulatory system.

The recommended immediate next steps would include:

- **Broad based consultation and engagement of stakeholders to deliberate on purposes of the overall food systems and its implications on the purposes of the food regulatory system.**
- **Establishing a clear and concise definition of purposes of the food regulatory system.**
- **Developing a common set of objectives and associated KPIs that help describe the purposes, measure, and demonstrate the outcomes.**
- **Sensitisation of stakeholders on the purposes, outcomes, KPIs and proposed reform using RPP as guidance and updating based on feedback received.**
- **Identify a sector or a combination of sectors to help design and pilot test the recommendations to modernise the regulatory system using the RPP as guidance.**
- **Undertake (or continue, as the case may be in some jurisdictions) a series of pilots to test the recommendations** that would include co-creating the following aspects at a minimum:
 - **Establishing a multi-stakeholder working group to help co-create a modernised regulatory system beginning with expanding the RPP to be applicable to all the stakeholders of the food regulatory system.**

- Develop a statement of ethical values that will underline the culture and operating practices of the entire regulatory system.
- Identify specific objectives and KPIs for selected sectors.
- Develop a standardized risk assessment framework that can be replicated across jurisdictions and sectors
- Develop the specifications for the operating model and operating practices based on recommended options and best practices.
- Implement the specifications for a defined period (typically 1-2 years), periodically monitor its performance and effectiveness, and enhance the framework based on feedback.
- Based on learnings, initiate scaling the framework across other sectors and consider whether legislative changes are required to support the framework.

Annex 1 – Recommendations for Modernisation

| Stage | Recommendation | Example Practice(s) | Benefit | Challenges |
|--------------------------|--|---|---|---|
| Regulatory System Design | <p>1. Need to ensure that the regulatory purpose/objectives address the increasing interconnectedness of supply chains and, balance between social and economic outcomes</p> | <p>1. UK Growth Duty Directive</p> <p>2. New Zealand Government Expectations for Good Regulatory Practice</p> <p>3. Canada's Policy on Regulatory Development</p> | <ul style="list-style-type: none"> ○ Builds national consensus on regulatory purpose and objectives of the overall food system ○ Assists in integrating broader social and economic outcomes associated with food systems ○ Ensure alignment of relevant regulations at national and sub-national levels with the regulatory objectives ○ Helps identify functions and actors across the food system, their roles and responsibilities, and their interactions | <ul style="list-style-type: none"> ○ May require amendments to legislation ○ Time-consuming process involving exhaustive stakeholder consultations ○ Change management to obtain buy-in from regulators ○ May require reassessment of the roles and responsibilities of regulators which could cause management issues such as job insecurities etc. |
| | <p>2. Explore the possible application of alternate system governance (e.g., primary authority model) that accounts for human/organizational behaviours and enable trust-based relationships between the various actors in the system</p> | <p>4. Ethical Business Practices and Regulations</p> <p>5. UK's Primary Authority Model</p> <p>6. Third-Party Assurance (Canada's Delegated Authority Model)</p> | <ul style="list-style-type: none"> ○ Enables a holistic approach to all activities. [Potentially very powerful.] ○ Guides swift and flexible response in new, unregulated or unclear situations. ○ Builds strong cohesion amongst all stakeholders on validity of purpose and intentions in outcome-focused risk management. ○ Differentiates between well-intentioned and other actors, hence driving them up or out ○ Encourages a trust-based relationship model between regulators and the regulated ○ Ensures consistency in the definition of compliance requirements for businesses (especially those operating in multiple jurisdictions) | <ul style="list-style-type: none"> ○ May require new legislation or amendments to existing legislation ○ Change management to obtain buy-in from regulators and businesses ○ May create perceptions and realities of “industry capture” especially amongst public and special interest groups particularly due to fee based regulatory delivery models ○ Small and medium businesses may not be challenged to satisfy expectations from such models ○ Needs wide understanding and commitment of stakeholders. ○ Requires transparent and some new types of evidence. ○ May need time and significant changes in management styles |

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| | | | <ul style="list-style-type: none"> ○ Provides flexibility to regulators to test a range of regulatory tools to achieve outcomes without the need for government interventions ○ Encourages innovation amongst regulators especially with a fee for service model ○ Drives a more data and evidence focused model for regulatory delivery | <ul style="list-style-type: none"> ○ and upskilling and training of personnel. ○ Differing levels of commitment or achievement may confuse and undermine confidence. |
| | <p>3. Policymakers and regulators in every jurisdiction should ensure availability of innovative regulatory tools (e.g., regulatory sandboxes), that are flexible to deal with a constantly evolving industry that is also disruptive and, use them proportionately and fairly</p> | <p>7. Outcome-based regulations (Canada's Safe Food for Canadians Regulations)</p> <p>8. Co-Regulations (Ontario, Canada Alternate Rules and Code Adoption Regulations)</p> <p>9. Health Canada's Regulatory Sandbox for regulated Advanced Therapeutic Products</p> | <ul style="list-style-type: none"> ○ Provides flexibility to experiment with innovative and alternative regulatory strategies to address changes to business models and industry innovations ○ Allows regulators to more efficiently use their resources and not constrain them to ineffective regulatory instruments ○ Reduces barriers and burden on economic growth opportunities ○ Eliminates need for major legislative amendments to address technical changes in the food system | <ul style="list-style-type: none"> ○ Will require amendments to legislation ○ Extensive guidance will need to be provided to small and medium enterprise to comply with performance or outcome-based regulations ○ Clear guidance will need to be provided to regulators to ensure that they apply expected compliance outcomes consistently across the sector ○ Regulators will need assurance of a "no blame" policy when applying regulatory experimentation in the event of failures |
| <p>Regulatory Delivery Model - Prerequisites</p> | <p>4. The regulatory delivery governance and accountability framework should clearly identify the roles and responsibilities of each regulator associated with the regulatory system, their interactions with other</p> | <p>10. UK Regulator's Code</p> <p>11. Canada's Integrated Agency Inspection Model</p> <p>12. New Zealand Regulatory Stewardship</p> <p>13. OECD Guidelines on Regulatory</p> | <ul style="list-style-type: none"> ○ Provides clear guidance to regulators for implementing regulatory delivery frameworks and methods ○ Creates formal structures to hold regulators accountable to meeting overall regulatory objectives ○ Helps develop meaningful performance and outcome | <ul style="list-style-type: none"> ○ May need to be legislated ○ May require amendments to national and sub-national regulations ○ Change management to obtain buy-in from regulators ○ Differing levels of maturity across regulators may create implementation challenges |

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| | regulators and industry to ensure consistency in decision making. | Inspections and Enforcement | <p>indicators to achieve regulatory outcomes</p> <ul style="list-style-type: none"> ○ Drives regulators to better understand business environments and establish relationships of trust | |
| Regulatory Delivery Model - Practices | 5. Use of standardized risk assessment methods supported by innovative and collaborative approaches to data collection and use will not only help in gaining an objective understanding of the overall safety system but help better allocate regulatory resources | <p>14. UL 2984 Standard on Risk Management</p> <p>15. Canadian Food Inspection Agency's Establishment Based Risk Model</p> | <ul style="list-style-type: none"> ○ Provides guidance and confidence to regulators in defending risk-based decisions ○ Influences stakeholders of the system to arrive at a consensus on acceptable levels of risk ○ Improves the quality of information and evidence used for decision making ○ Provides flexibility to regulators to effectively and efficiently use resources ○ Promotes innovation amongst regulators such as the use of emerging technologies ○ Promotes innovation amongst regulated parties to create alternate methods to achieving compliance | <ul style="list-style-type: none"> ○ Events such as major incidents may put risk-based approaches under greater scrutiny ○ May create perception of "bowing to industry demands" especially if inspections become risk-based ○ Requires high quality data and evidence to reduce uncertainty in risk assessments ○ Requires specialised skill sets and competencies ○ Change management and upskilling training programs to obtain buy-in from operational staff particularly inspectors |
| | 6. In addition to leveraging technology for data collection, partnerships with industry and amongst regulators (e.g., data sharing agreements, joint inspections) will help reduce uncertainty in risk assessments and increase consistency in risk-based decision making | <p>16. UK FSA</p> <p>17. Data Trusts</p> <p>18. Canadian Food Safety Information Network</p> <p>19. Safe Food Queensland</p> | <ul style="list-style-type: none"> ○ Helps identify functions and actors across the food system, their roles and responsibilities, and their interactions ○ Allows regulators to more efficiently use their resources and not constrain them to ineffective regulatory instruments ○ Encourages a trust-based relationship model between regulators and the regulated ○ Drives a more data and evidence focused model for regulatory delivery ○ Helps develop meaningful performance and outcome | <ul style="list-style-type: none"> ○ Time-consuming process involving exhaustive stakeholder consultations ○ Change management to obtain buy-in from regulators ○ May require reassessment of the roles and responsibilities of regulators which could cause management issues such as job insecurities etc. ○ May create concerns regarding regulator 'capture' ○ Requires high quality data and evidence to reduce uncertainty in risk assessments |

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|--|--|--|--|--|
| | | | <p>indicators to achieve regulatory outcomes</p> <ul style="list-style-type: none"> ○ Provides guidance and confidence to regulators in defending risk-based decisions ○ Improves the quality of information and evidence used for decision making ○ Provides flexibility to regulators to effectively and efficiently use resources ○ Promotes innovation amongst regulators such as the use of emerging technologies ○ Use of intermediaries like data trusts help address data governance concerns and provides more channels for data sharing and collaboration, increases trust amongst stakeholders | <ul style="list-style-type: none"> ○ Requires investment in skills and technology by regulator and business |
| | <p>7. Regulators should ensure that they are equipped with a range of intervention choices and tools that allows them to address risk in a fair and proportionate manner focusing more on improving the culture of the regulated parties towards compliance; these choices should be designed to build and maintain trust with industry, consumers, governments and the public.</p> | <p>20. UK Civil Aviation Authority</p> <p>21. Canadian Food Inspection Agency Integrated Risk Management Framework</p> <p>22. Dairy Food Safety Victoria (Dairy RegTech)</p> | <ul style="list-style-type: none"> ○ Encourages ethical responses ○ Drives delivery of swift and holistic resolution of many issues: behaviour, redress (avoids litigation), monitoring ○ Supports trust relationships and cooperation ○ Allows regulators to focus on priority risks and efficient resource management | <ul style="list-style-type: none"> ○ May be criticized as soft or captured. ○ Needs wide toolbox of powers; legislation. ○ Needs discretion and flexible responses: approved written Enforcement Policy. ○ Ultimately needs consistent adoption across all regulators. |

Annex 2 – Regulatory Practice Principles

The principles have been separated into two sections, which together cover all elements of regulatory delivery. Section 1 covers elements and overarching principles for the system, while Section 2 covers elements and principles which focus on the roles and responsibilities of regulators.

Section 1: Over-arching Principles for the System

Regulatory Purpose and Outcomes

A regulatory purpose statement reflecting the current thinking across the system shall be developed in a manner which ensures that:

1. The System shall be supported, at a national and jurisdictional level, by a set of well-defined outcomes and performance indicators that can demonstrate that the desired goals and objectives are met
2. Regulators can choose to expand or deviate from the Statement of Regulatory Purpose in their respective jurisdictions to address jurisdictional needs, commitments, or expectations, provided there is transparency in reflecting these deviations and appropriate processes in place to show the achievement of the System's purpose.

In addition to developing a broad set of outcomes and indicators at the national/bi-national levels, regulators and participants in the System are strongly recommended to establish, publish and regularly review jurisdiction specific outcome measures, including Key Performance Indicators (KPIs) for the System based on the regulatory purposes. The outcome measures shall:

- include measures that help demonstrate that participants are operating in accordance with the ethical values and principles of the System
- consist of, medium, and long-term KPIs (where appropriate) and leading and lagging indicators to demonstrate the performance within the System, and
- be meaningful, simple, and understandable.

Commitment to Ethical Values

An overarching statement of ethical values applicable to entire the system and all its players shall be developed and should note that:

- it serves as the foundational values and principles that guide the System and applies to all participants in the System
- for regulatory delivery to succeed, all participants in the system must understand their own cultures, what drives the culture, and what types of behaviours are generated.

Examples of values that can be considered to drive the system include:

- Purpose or contribution to society
- Collaboration, partnerships, community involvement

- Transparency, openness, integrity, creativity, trust, honesty
- Accountability, empowerment, innovation, continuous learning, autonomy, agility
- Quality, competence, efficiency, striving for excellence
- Customer satisfaction, respect, open communication
- Safety, health, financial accountability

In delivering their responsibilities within the System, participants shall commit to making decisions in line and operating in accordance with the ethical values.

Governance and Operating Practices

As described above, a system and governance structure ideally overseen by a senior champion shall be developed that ensures that an effective governance and active participation from stakeholders across the system. To facilitate this:

1. Strategic oversight of the System is to be maintained, to ensure the smooth functioning of the interactions and relationships between the stakeholders
2. The responsibilities for the governance and oversight of the System shall be clearly identified, allocated and communicated to stakeholders.
3. Stakeholders who directly or indirectly influence the achievement of the System objectives, along with those who are impacted by the System, shall be identified, with the interactions and relationships between these stakeholders mapped and acknowledged, at a jurisdictional and national/binational level
4. Each regulatory agency within the System shall issue a Responsibility and Accountability Statement. The statement will set out the regulator's functions, responsibilities, governance, accountabilities, transparency and policies aimed at achieving the purposes and outcomes.

Section 2: Principles for Regulators

The approach adopted by regulators and businesses will be integral to addressing the regulatory purpose/s and achieving the desired system outcomes. The need for a consistent and cooperative approach across regulators and between regulators and businesses is critical. The principles governing such approaches shall be co-created by these stakeholders in the future. In the interim, regulators shall consider the following elements:

Responsibility, Accountability and Operating Practices

In delivering their responsibilities within the System, regulators and businesses shall commit to making decisions in line with good regulatory and corporate governance practices and operating in accordance with the pre-defined ethical values.

Specifically, regulators shall commit to:

- being open, impartial, cooperative with regulated entities and other stakeholders

- being collaborative with other regulated entities and other stakeholders who have demonstrated a commitment to the ethical values and principles and purpose of the System
- producing relevant evidence to build trust and strive constantly to improve their performance in achieving the agreed outcomes
- acting independently and create the necessary governance, capacity and infrastructure to do so
- collaborating with each other to reduce redundancies, eliminate inconsistencies and make it easier for businesses to comply with regulatory requirements
- prioritising their resources and actions to meeting the purpose of the System, and
- demonstrating transparency in their decision-making approach and actions.

Responsibility and Accountability Statement

In developing their Responsibility and Accountability Statement, each regulator shall map of all functions, all participants and their responsibilities and responsibilities for each function. In doing so, each regulator shall ensure:

- the functioning structure of the regulator adequately represents the desired aims of the System
- the stakeholders of the System are adequately represented within the structure
- measurable outcomes are established by the higher levels of government to achieve the desired objectives
- the regulator is provided with the necessary authority and flexibility to administer their responsibilities, including developing the most appropriate regulatory operating models.

Operating Model

Regulators shall be provided with the flexibility and authority to develop and implement operating models that allow them to use modern evidence-based ethical and risk-segmented approaches to administering their responsibilities and achieve the desired objectives.

Regulatory operating models shall eliminate or reduce inconsistencies, minimise duplication of efforts, be developed using a cooperative approach with stakeholders and targeted to optimise resource, reduce costs, and create greater efficiencies.

Regulators, when establishing its regulatory operating model/s, shall ensure the model:

- provides both consumer and business community confidence in the System
- is risk and evidence based, proportionate to risk, reflects international best practices and is adaptable
- can adapt to deal with innovation, disruption and the changing nature of industry practices
- promotes greater cooperation and collaboration amongst System participants, and can enable regulators to develop and implement cooperative monitoring arrangements with System participants

- encourages regulated entities to adopt risk-based standards, surveillance and compliance approaches
- ensures noncompliant businesses become compliant, and persistent non-compliance is managed effectively.

Operating Practices

A regulator's operating practices shall be based on the chosen operating model/s, shall be informed by the desired outcomes and be subject to the values and principles that guide its decision making.

The operating practice shall consist of three primary elements - risk based prioritisation; selection and application of intervention choices; and monitoring and measurement

In developing and implementing the three elements of their operating practice, regulators shall issue policies and procedures to demonstrate that they:

- adopt and apply standardised risk-based approaches to decision making
- apply consistent standards in identifying, collecting, and utilising evidence to support their risk assessments
- encourage the use of innovative approaches internally, and with their external partners, to collecting, processing and utilising data for risk-based approaches
- have a regulatory toolkit that is broad and encompasses mandatory and voluntary methods of intervention
- have the powers (mandatory and discretionary) to apply these tools commensurate with the overall risk (including culture risk) posed by businesses
- have the authority and ability to collect the necessary evidence to measure risk posed by businesses (including data sharing agreements with other agencies, businesses etc.)
- deploy their interventions proportionate to risk, evaluate the effectiveness of interventions and makes changes if necessary
- are able to drive cultural change within their agency, including reskilling, capacity building and training operations personnel

Planning and Performance Measurement

Regulators shall publish a strategic plan or subordinate plan (which if applicable supports a wider departmental organisational strategic plan), that reflects the regulatory purposes and:

- identifies the activities, outputs, expected outcomes and impacts, the linkages between them, and the balance as can be shown through a balanced scorecard
- clearly demonstrates and articulates alignment with the regulatory purpose and objectives
- demonstrates the commitment to the ethical values, and
- establishes appropriate KPIs that describe the outputs and demonstrate progress on the outcomes.

Regulators shall establish performance measurement plans that:

- are aligned with their strategic plans and associated KPIs and link directly to their interventions and actions
- apply consistent standards in identifying, collecting, and using evidence to support risk assessments
- encourage the use of innovative approaches, internally and with their external partners, to collecting, processing and utilising data for risk-based approaches
- can be verified through independent methods and reported to System participants

Continuous Improvement

A continuous improvement framework will be developed and implemented to monitor the functioning of the System, which:

- Focuses on a problem solving/causal analysis approach to identify gaps and limitations in the regulatory system and to prioritize correction actions
- provides flexibility to adapt and modify the governance, accountability, functionality and operating models and practices of the System, to meet with the needs and challenges identified as part of the continuous improvement cycle, and
- ensures that changes to the System shall be based on evidence, cooperative and consultative, transparent, and proportionate based on risk