Theory Paper on Contemporary Regulatory Models

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The Food Regulation Standing Committee

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Executive Summary

Australia's Food Regulation System (the System) is a joint regulatory model between Australia and New Zealand with broad objectives encompassing protection of the public health and safety of the community in consuming food. The System is complex and shares responsibility across all three levels of government whilst ensuring that international obligations are respected.

Despite this complexity, the System is remarkably good at collaboration, and is responsive when actioning bi-national responses to foodborne illness outbreaks. The System is recognised by stakeholders as a demonstration of scientific evidence-informed policy development and an effective means of ensuring confidence in the food supply. This in turn provides a platform for a vast range of food industries to operate and empowers consumers to make informed choices.

While the System and its enabling legislation have largely stood the test of time, its framework is over 20 years old and opportunities exist to reform it to become stronger, more robust and agile. Ministerial and stakeholder expectations of what the System should deliver have evolved over time. Change to date has been largely reactive, piecemeal and protracted and have led to:

- lack of clarity in relation to the scope of the System;
- inconsistent articulation of System objectives;
- lack of a strategic approach to balance the competing demands on the System;
- a mismatch between broad, multifaceted objectives and the narrow set of tools available to give them effect; and
- the underlying principle of national consistency being compromised.

Australia has initiated a program for the Modernisation of the System which aims to provide a revised legislative and institutional basis for the System, striving for international best-practice regulation and operation. While the program has several projects underway, one of these involves identifying and addressing opportunities for jurisdictional consistency.

In this context, Prism Institute was commissioned by Safe Food Production Queensland and the Queensland Department of Agriculture and Fisheries to provide recommendations to help modernize the System while focusing specifically on aspects of jurisdictional consistency.

Prism Institute experts have conducted a high-level review of the current System, obtained feedback on the System from various regulators through an electronic survey, and identified a set of eight recommendations that reflect current thinking and contemporary practices. These recommendations apply to the design of the regulatory framework and regulatory delivery by regulators. While these recommendations apply to the overall design and delivery of the food regulatory system, some (recommendation # 2,3,4,5 and 6) specifically address issues of consistency in decision making.

Overall, our initial assessment is that Australia and New Zealand are well placed to develop new approaches that would place them at the forefront of global developments and open up significant opportunities to reap commercial, trade and economic advantages that would considerably benefit national agriculture and food industries. The basic issues are to grasp a simplified structure, and a structure that supports public and private actors to work together to

achieve common aims. The structure would facilitate greater cooperative engagement between all actors, through mutual trust, based on consistent evidence from all parties that can be generated by digital systems. We suggest an Implementation Programme in the Conclusions section.

The seven recommendations are:

1. ***The Australia and New Zealand Ministerial Forum on Food Regulation (the Forum) shall ensure that the regulatory purpose/objectives address the increasing interconnectedness of supply chains and balance between social and economic outcomes.*** Food systems and supply chains serve different purposes for different stakeholders and society and carry different risks. The traditional purpose of regulation has typically focused on food safety. However, quite a number of other possible purposes might also be relevant and may also be regulated albeit differently. Examples may range from providing safe and healthy foods, supporting farmers or other parts of the production chain, securing an adequate level of national self-sufficiency in food, promoting trade etc. All of these purposes may be relevant, important and part of the regulatory objectives of one or many regulators. More importantly, the interconnected risks originating from different sectors of the supply chain can no longer be treated in silos as is evident from the aftermath of Covid-19. A simple example of this may involve the need to balance between social and economic outcomes. There is an increasing realisation that the purposes of individual regulatory authorities should be coordinated to achieve the fundamental goals of society and the state, to provide consistency and integrated focus as between different regulators, and to provide clarity for businesses and citizens. This paper includes reviews from jurisdictions including the UK, New Zealand and Canada that have tackled this aspect and provides some recommendations for consideration when multiple and sometimes perceivably conflicting purposes are at stake.

2. ***Policymakers and regulators in every jurisdiction should also explore the possible application of alternate governance models (e.g., primary authority model) that account for human/organizational behaviours and enable trust-based relationships between the various actors in the system.*** The functioning of a regulatory system for complex sectors such as food chains is dependent on effective governance structures that delineate the roles and accountabilities of the stakeholders and their relationships. More importantly, the governance structures should be built to support relationships that drive a culture of trust and cooperation amongst regulators and especially between regulators and the regulated. This would lead to consistency in decision-making and enhance credibility with consumers and society. While the current governance structure in Australia/New Zealand is well developed and mature, it will greatly benefit from modern behavioral science-based approaches such as Ethical Business Regulation (EBR) to deal with current and future challenges posed by evolving business models and expectations. One such structure that assists application of an EBR based approach is the UK's Primary Authority Model which provides a legal mandate to a single regulator to establish acceptable regulatory compliance framework with a business and for other regulators to adopt the agreed principles. This model drives consistency amongst regulators, provides a platform for agile responses to changes, increases a trust-based relationship amongst stakeholders among other benefits. Canada's delegated authority model, on the other hand, provides a

framework for the creation of regulatory authorities completely independent from government (with government oversight). These authorities, operating on fee-based models, are provided with the necessary tools that allow them to focus on regulatory outcomes without typical constraints in government such as budgetary limitations and are able to build partnerships with businesses and other similar regulators, increasing efficiencies and reducing bureaucracy. Both the described models do come with challenges including the need for major regulatory amendments, perceptions of industry capture, change management etc.

3. ***The Food Regulation Standing Committee (FRSC) in partnership with 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.*** While there are clear and obvious advantages with a national standards-based approach to regulating food, the standards setting process and the resulting codes have constrained regulators in Australia from dealing with industry demands and market innovations. While a majority of regulators do believe that they have flexible and nimble state regulations in place, the availability of additional regulatory tools would provide them with the ability to deal with ever changing industry innovations. Health Canada's regulatory sandbox approach to regulating advanced therapeutic products is an example of an innovative tool that allows the Minister to establish customized requirements to enable the authorization of an advanced therapeutic product with the ability to attach terms and conditions to each product authorization. The authorization requirements as well as any terms and conditions could be amended from time to time to allow for flexible oversight as new information and experience is gained. As more becomes known about a specific advanced therapeutic product, longer term regulatory requirements may be established, as appropriate, to set standard rules for a product type and remove it from the sandbox. The establishment of sandboxes or alternate rule setting methods will require legislative changes, but if carried out appropriately, will provide jurisdictions with the authority to deal with technical issues more efficiently and not having to wait for policy amendments or changes to standards.

4. ***The Implementation Sub-Committee for Food Regulation (ISFR) or an equivalent authority should ensure that 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 regulators and industry to ensure consistency in decision making.*** Regulators benefit from having a clarity and alignment between the overall regulatory purpose/objectives, the purpose of regulatory requirements, their individual and collective mandates. Regulators should understand and be able to communicate their purpose as not merely being compliance seekers but as trusted partner and influencers of good business practices in a manner that is consistent. UK Regulators' Code is a good example of a code of practice that provides guidance on developing the appropriate accountability structures, defining regulators' approaches to delivery and enforcement etc. The Regulators' Code is a framework for how regulators should engage with those who they regulate. New Zealand's Regulatory Stewardship which forms part of "Government Expectations for Good Regulatory Practice" is a statutory obligation for all departments to adopt a whole-of-system, lifecycle view of regulation, and taking a proactive, collaborative approach, to the monitoring and care of the regulatory system(s) within which they have policy or operational responsibilities and speaks to how regulators interact with each other. While the current Aus/NZ regulatory system has

designated IFSR's role to provide guidance and advice on consistent delivery of standards, the lack of clear accountability structures that include performance objectives lead to inconsistencies in regulatory delivery. Majority of regulators surveyed as part of this study believe that IFSR is designed to undertake this role and provides adequate support and guidance for the delivery of food safety requirements in a consistent manner while balancing stakeholder interests. However, they also feel that IFSR does not have the appropriate authority and structure to ensure consistency, flexibility and nimbleness in guiding the implementation of standards.

5. ***Regulators should use standardized risk assessment methods supported by innovative and collaborative approaches to data collection and use so as not only to gain an objective understanding of the overall safety system but also help better allocate regulatory resources.*** Risk assessment has become an integral part of the toolkit that regulators use in making a range of decisions including establishing priority areas of interventions, targeted use of resources, nature and levels of intervention including inspections and enforcement and measuring outcomes. Risk has become the "currency" of regulatory delivery. However, lack of consistent and harmonized standards on risk assessment, differing outcome measures largely driven by multiple and conflicting regulatory objectives, availability and quality of data, skills and competencies continue to create uncertainties in risk based regulatory decision making. Most surveyed regulators in this study have stated that they use of risk assessments for decision making but are seeking better standardized approaches. Canada is emerging as a strong leader in risk based regulatory decision making. In addition to establishing the first national guideline for regulators on risk-based decision making, several regulators including Canadian Food Inspection Agency have established innovative approaches to address the challenges and limitations posed by risk assessment and build better capacity and capability to support their decision makers. Australia, through its integrated multi-level regulatory system is uniquely positioned to adapt modern practices and develop an advanced risk assessment framework to support its regulators and advance ahead of the other developed countries.

6. ***In addition to leveraging technology, regulators should partner amongst themselves and with industry (e.g. data sharing agreements, joint inspections) for data collection, to help reduce uncertainty in risk assessments and increase consistency in risk-based decision making.*** Recommendation 6 refers to the need for appropriate and good quality data in conducting risk assessments and support regulatory delivery. Regulators have long relied on data solely generated through their own activities such as licensing, inspections, investigations and complaints to support their risk assessment models leading to large uncertainties in their risk estimates rendering them to either be limited and inadequate at best or irrelevant and flawed at worst. The proliferation of smart technologies and tools including Internet of Things, Machine Learning and Artificial Intelligence has created a unique opportunity for regulators to leverage these sources and significantly enhance the quality and quantum of data that would be required and beneficial for risk assessments. In Australia itself, regulators in Queensland and Victoria for example are leveraging smart technologies in the fisheries, food and dairy sectors to collect and utilize data. These efforts can be complemented by building partnership agreements between regulators, with industry and other players in the sector to collect, share and utilize data and increase consistency in risk-based approaches. Examples of emerging data agreements

and data hubs in the UK, Canada and elsewhere are included in this paper for Australia to consider.

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.*** Regulators typically achieve compliance by conducting inspections and audits and imposing enforcement sanctions after breaches of the rules, on the assumption that that will deter future non-compliance. However, extensive evidence from behavioural science and empirical studies now forms the basis of a different approach. Emerging studies, scientific evidence and insights into reasons for non-compliance suggest that regulatory responses should focus more so on changing human behaviour; how best to address the behaviour of individuals in regulated entities and the cultures of such entities. As such, an effective regulator needs to be able to have a (significant) number of means of intervening in how things are done, selecting intelligently from a well-stocked toolbox of intervention tools so as to fit the circumstances. Policy makers should ensure that regulators are provided with a wide range of interventions that can be used in conjunction with or as alternatives to traditional licence, inspection or investigation-based approaches. These might include for example, initiatives to raise awareness and understanding of requirements amongst those they regulate; oversight of industry compliance initiatives; incentive schemes to support and encourage good performance, and initiatives to empower the beneficiaries of regulation, particularly those most at risk. “Regulating through Culture” using tools such as ethical business regulations are becoming increasingly popular in countries including the UK and Canada. Many regulators in Australia have suggested that they have the flexibility and the culture of selecting intervention choices that are most effective for achieving outcomes. Among the interventions include proportionate response to compliance and enforcement and the use of risk-based decision-making. However, they have also expressed a lack of awareness of some of the modern and emerging tools like EBR and are very open to exploring new approaches to intervention and regulatory responses.

Chapter 2 of the report lays out our understanding of the current structure and functioning of Australia’s regulatory system and identifies opportunities for enhancement. Chapters 3 and 4 provide further details on contemporary practices in regulatory design and delivery including spotlighting the above-mentioned recommendations. In addition, Annex 2 provides an illustrative view of each of the eight recommendations and states the benefits and challenges associated with implementing the recommendations.

1 Introduction

Safe Food Production Queensland and the Queensland Department of Agriculture and Fisheries, on behalf of Australia's Food Regulation Standing Committee (FRSC) are exploring suitable regulatory models that could be applied to modernize Australia's food regulatory system. The purpose of this exploration is to modernize its regulatory system to provide greater certainty for markets, drive innovation while achieving four main objectives as follows:

- Create greater consistency in the implementation of policies and standards at national and bi-national settings and with imported food
- Shift from a highly prescriptive to an outcome-focused Model Food Provisions (MFPS)
- Explore the range of regulatory and non-regulatory tools that are available for intervention to complement the successful harm-focused risk-based approaches
- Bolster the current regulatory system innovations to respond to emerging trends and remaining at the forefront of best-practice regulation.

This paper prepared by Prism Institute experts presents options for Australia and New Zealand to consider in their endeavour to achieve the above objectives, on the basis of the contemporary practices advocated for by leading academics in the regulatory space and adopted by OECD and other countries globally.

The paper is built on evidence available through research publications by Prism Institute experts[1] and practiced by other institutions and suggest that **outcome-based, evidence-enabled, and trust-focused** regulatory models are more likely to succeed in achieving regulatory objectives. The methodology adopted in this paper is underpinned by this rationale and presented accordingly.

Historically, governments and regulators have placed greater focus on the design of regulations and overlooked the importance of delivery mechanisms in securing regulatory outcomes. While the paper discusses modern thinking and practices in regulation design[2], it's greater focus is on regulatory delivery **advocated through the "Regulatory Delivery Model" (RDM)**[3] which sets out a framework for regulatory delivery, comprising of three prerequisites (**governance, accountability and culture**) and three practices for regulatory agencies to be able to deliver societal outcomes (**outcome measurement, risk-based prioritisation, and intervention choices**). Various approaches including their benefits and limitations across the three prerequisites and practices are examined and reported.

The paper is structured into the following sections:

An executive summary that describes our recommendations on opportunities to modernize Australia's regulatory system in a matrix format such that it will help FRSC to achieve a quick

[1] Hodges C. and Steinholtz R., "Ethical Business Practices and Regulation"; Hodges C. Mangalam S. and Steinholtz R., "Regulating through Culture"; Blanc F., "From Chasing Violations to Managing Risks"

[2] OECD and Prism Institute, "Scoping Paper on Regulatory Future of Emerging Technologies", 2018.

[3] Russell G. and Hodges R., "Regulatory Delivery".

understanding of the choices available in priority areas as determined by the analysis, their benefits and limitations and levels of effort for implementation. The matrix is designed to allow FRSC to determine some concrete next steps in the review and modernization process.

Section I outlines our understanding of Australia's current regulatory system, its strengths, weaknesses and opportunities for improvement. This section also summarizes the findings of a survey of some of Australia and New Zealand regulators of the food supply chain on their views of the current regulatory system.

Section II provides a description of the contemporary thinking and practices associated with regulatory system design with a reference to food safety regulatory systems in general and applicability to Australia's existing structure.

Section III discusses the Regulatory Delivery Model and examines its applicability in the Australian context particularly with a commonwealth-state-local government delivery distribution system in place.

Section IV outlines the conclusions from the study and potential next steps for the FRSC to consider.

The paper also includes various annexes on Australia's current regulatory system, recommendations matrix, and one that provides a summary of the responses received from various Australian regulators on their views of the current regulatory system.

2 Section I: Understanding of Current Regulatory System

Food regulation in Australia and New Zealand is a joint system that involves the Australian and New Zealand governments, and Australian states and territories. The system is made up of the laws, policies, standards and processes that are designed to ensure food is safe for public consumption.

Food Standards Australia New Zealand (FSANZ) is established under the FSANZ Act to develop food standards. The Australian State and Territory governments and the New Zealand government implement and enforce the food standards developed by FSANZ through their respective laws. The Department of Agriculture, Water and Environment (DAWE) enforces the Food Standards Code at the border in relation to imported food through the *Imported Food Control Act 1992*.

Food laws are not legislated through parliament but developed, implemented and enforced by a strong cooperative joint system that specifies a range of safety issues including, labelling, food composition and food handling requirements. The joint system is overseen by the Australia and New Zealand Ministerial Forum on Food Regulation, also known as the Forum. The Forum is responsible for developing domestic food regulation policy and promoting a consistent approach to the implementation and enforcement of domestic food standards.

In addition to the policy element, government also plays the role of arbitrator and is required to balance the national interest with the potentially competing views from consumers, from industry and from itself.

Annex 1 presents a more detailed description of our understanding of the overall regulatory system. This section focuses on providing a summary of the system relevant for the purposes of reviewing and identifying opportunities for enhancements and modernization.

2.1 Summary of Roles and Responsibilities

All levels of Australian and New Zealand governments are involved and have responsibilities for parts of the system including the development of food policy, the making of food standards and implementation and enforcement of food regulations. Table 1 summarizes the roles and responsibilities of the various statutory entities in the food regulation system.

Process	Actor/ Committee	Role	Composition
	Legislative and Governance Forum on Food Regulation (Forum)	○ Develops policy guidelines for setting domestic food standards for Australia and New Zealand. ○ Promotes harmonised food standards within Australia and New Zealand. ○ The general oversight of the implementation of domestic food regulation and standards.	One or more Ministers with responsibility for food regulation from the Commonwealth and Australian states and territories and one Minister with responsibility for food regulation from New Zealand.

Process	Actor/ Committee	Role	Composition
Policy Development		○ Promotes a consistent approach to the compliance with, and enforcement of, food standards. ○ Plays the role of system arbitrator.	
	Food Regulation Standing Committee (FRSC) – a sub-committee of the Forum	○ Provides policy advice to the Forum. ○ Ensures a nationally consistent approach to the implementation and enforcement of food standards.	Commonwealth, New Zealand and Australian state and territory senior officials responsible for food regulation policy, Australian Local Government Association, and Chief Executive Officer of FSANZ as an observer.
	FRSC/IFSR Working Groups	FRSC can establish WGs for a range of reasons including responding to Ministerial policy development. ISFR can also establishment WGs, some time-bound and others on-going.	Commonwealth, New Zealand and Australian state and territory senior officials.
Standard Development	Food Standards Australia New Zealand (FSANZ) Board	The Food Standards Australia New Zealand Act 1991 (the FSANZ Act) established the FSANZ Board and its office. FSANZ develops food standards and has an established, accountable, consultative and transparent approach to stakeholder engagement. The steps undertaken by FSANZ and the Forum when developing or amending a food standard can be found here.	The Board has twelve members, appointed for terms and under conditions outlined in the FSANZ Act.
	Legislative and Governance Forum on Food Regulation (Forum)	The Forum can ask FSANZ to review an approved food standard; and following a review can amend or reject the standard. This step replaces the Parliamentary debate that normally occurs when laws are created.	One or more Ministers with responsibility for food regulation from the Commonwealth and Australian states and territories and one Minister with responsibility for food regulation from New Zealand.
Standard Implementation	Australian State and Territory and New Zealand Government Agencies	Adopt standards through state/territorial legislation, undertake implementation and enforcement .	N/A
	Implementation Subcommittee for Food Regulation	Develops and implements a nationally consistent approach to the implementation of food standards	Commonwealth, New Zealand and Australian state and

Process	Actor/ Committee	Role	Composition
and Enforcement	(ISFR) – a sub-committee of the FRSC	and regulations. Develops, or assists in developing, guidelines on consistent enforcement of food regulation. Consults with, and provides high level advice to, FSANZ. The ISFR terms of reference can be found here.	territory senior officials responsible for food regulation, FSANZ, and Australian Local Government Association
Emergency Response	Australian State and Territory and New Zealand Government Agencies	First point of contact for managing food recalls and incidents.	N/A
Support Services	Food Regulation Secretariat	The Secretariat provides administrative support to the Forum, FRSC and ISFR is located within the Commonwealth Department of Health and Ageing, but it operates independently in relation to its day-to-day functions.	N/A

Table 1. Roles and Responsibilities of the Various Statutory Entities in the Food Regulation System

A survey on Australia's policy regulatory governance structures and its regulatory delivery models was also carried out to gain an understanding of the regulators' views on the system and opportunities for improvement. The results of the survey are included in Appendix 3 of this report.

2.2 Opportunities for Enhancement

Australia and New Zealand have strong international reputations for safety and high-quality foods. This reputation is clearly demonstrated by the functioning of the joint food regulatory system. It is a complex system that involves all levels of the Australian and New Zealand governments and is administered by a mix of federal, state and local governments, as well as independent regulators. Since its inception as a prescriptive, rule-based regulatory scheme designed to prevent foodborne illness from microbial pathogens, the food regulatory system has undergone significant changes in response to government policy shifts and changing consumer expectations. Today, the food regulatory system not only aims to prevent foodborne illness, but also supports long-term nutrition and health, consumer choice and trade objectives.

While there are a number of strengths to the system, there are also opportunities for enhancement particularly in the face of changing business models, technological advancements and growing consumer expectations. This paper is not intended to review the adequacy of the current System or the operating models in different jurisdictions but to provide some recommendations for modernization based on contemporary practices. The authors of the paper acknowledge that some of the recommendations may already be in practice in certain jurisdictions and have been highlighted in the report. These recommendations were also compared against comments provided by regulators who participated in the survey (See Appendix 3 for details) to ensure alignment of needs and priorities with respect to the modernization efforts.

Some of the key areas of opportunities for enhancement identified include:

1. **Regulatory System Design: Purpose, Governance, and Regulations -** Given the complexity of the system including the range of regulations and standards representing the entire food chain and the different levels of government administering the regulations and standards, it is useful to re-examine and reset the purpose (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 clearly stated in the various pieces of legislation governing the food chain and may also be reiterated through the governance structures such as the **UK's Regulator's Code[4] as a means to state regulatory purposes and objectives as discussed later.**

   In addition to its role as the decision maker/overseer of the system, the Forum is also required to be the system arbitrator. To do this, the Forum must delicately balance its policy development role that involves addressing potentially competing interests from consumers, from industry and from itself with its oversight function. To enhance objectivity and deal with potential bias, it may be worth examining other accountability structures discussed in this paper wherein some of the operational and oversight responsibilities are delegated.

   In addition, there may be opportunities to modernize the regulatory design options that would allow regulators particularly at the sub-national level to be innovative and flexible in handling new and emerging technologies and business models. Examples such as **co-regulations, sandbox approaches, and adaptive regulations** are described further in this paper.

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, the paper describes alternatives such as codes of practice which would provide further guidance, accountability mechanisms, and feedback loops for continuous improvement.

3. **Regulatory Delivery: Practices** - The Regulatory Delivery Model presented in this paper advocates for three practices: A) Outcome Measurement, B) Risk Based Prioritisation, and C) Intervention Choices. The implementation of these practices involves modernization of practices that are both internal and external to the regulatory organizations.

   Internally, regulators should ensure that they have clearly defined and well-established outcomes to be achieved that are aligned with the regulatory purpose 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 currently lacking. Risk based approaches are heavily dependent on data. They should therefore identify and establish frameworks for collecting the relevant data and evidence to support risk assessments and the measurement of outcomes. The data should not only focus on traditional compliance indicators but should also increase emphasise on, and

[4] The Regulator's Code is proposed to be reviewed and likely updated in the next year.

enable, evaluating the culture and ethical practices of individual businesses and the sector as a whole. The available data combined with many of the modern technological tools will help regulators enhance their risk assessments and better prioritize their resources that is focused on enhancing the culture of the regulated sector.

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 to not only enforce regulations but, more importantly, educate, influence and reward regulated sectors. Examples of modernization practices including the emerging application of ethical business regulations from Canada, UK and elsewhere are described in this paper.
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. Examples of alternate delivery schemes that focus on behavioral sciences and help build better trusted relationships with industry, consumer groups and other stakeholders including UK's Primary Authority Model, Canada's Delegated Authority Model etc. will be discussed. The advantage of these models includes increasing the availability and quality of data/evidence for compliance assurance, shifting the responsibility for demonstrating compliance to the industry, and providing opportunities for growth in the sector.

The paper describes the three areas of opportunities in further detail and lays out the various options available and that are being used by other jurisdictions.

3 Section II: Regulatory System Design

3.1 Introduction

Well designed and delivered regulation plays a vital role in all modern societies, but whilst much attention has been paid to the design of regulation as the focus for effectively regulatory reform, authors and policy makers have historically overlooked the importance of regulatory delivery mechanisms in securing desired outcomes[5].

Governments typically establish rules to identify, measure and respond to risks. The range of responses to risk require co-ordination and possibly reconciling between differing policy objectives. Modern approaches to regulation explicitly acknowledge that the government cannot regulate to remove all risks and that regulatory action, when taken, should be proportionate, targeted and based on an assessment of the nature and magnitude of the risks and of the likelihood that regulation will be successful in achieving its aims. Regulatory responses are therefore to be informed by an assessment of harm expected to arise from the complex systems such as the food supply chain and for which regulations are the most appropriate instruments. As regulators begin contemplating the development of agile, flexible light-touch, multi-sectoral, forward-looking, neutral and transparent policy and regulatory approaches to respond to risk, several key questions arise including:

1. Have the regulatory purposes/objectives changed?
2. Does the current structure of the overarching system (system governance) help meet the objectives?
3. What are the options available to address any changes through regulations to the objectives?

The following sub-sections discuss these key questions in the context of Australia's current food system and provide suggestions that would help establish appropriate responses.

3.2 Regulatory Purpose

The world is currently facing the worst crisis it has witnessed in several decades in the form of the Covid-19 pandemic. The pandemic has demonstrated that it does not respect borders of any sort and has not only impacted the health of global citizens but affected poverty levels, economic losses, domestic or societal violence, restricted movements, access to goods and services, extreme weather events etc. as the world has relied upon complex, interconnected systems to deliver goods and services. Regulations and regulatory frameworks are rarely designed to tackle such interconnected systems and where social and economic outcomes are

[5] Russell and Hodges, "Regulatory Delivery".

a conscious collective choice[6]. The current situation therefore makes the need for regulations to be designed such that they are able to 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 instructive to view a 'food system' as a whole, rather than a '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?

The traditional purpose might be 'to ensure that food is safe'. But quite a number of other possible purposes might also be relevant. For example: to provide safe food (subtly different from the previous formulation); to eliminate food poverty; to support farmers or other parts of the production chain; to secure an adequate level of national self-sufficiency in food. All of these purposes may be relevant, important and part of the regulatory objectives of one or many regulators. However, there is increasing realisation that the purposes of individual regulatory authorities should be coordinated. The three main drivers for this are as follows:

- to achieve the fundamental goals of society and the state;
- to provide consistency and integrated focus as between different regulators;
- and to provide clarity for businesses and citizens.

The most familiar of such statements are perhaps the United Nations sustainable development goals (SDGs) that set out 17 Economic, Sustainable and Governance (ESG) goals. These could now be expanded to cover the development of all aspects of human, social, natural and economic capital.

The fundamental purposes are, indeed, fundamental because they drive the design of the regulatory system, the goals and activities of the regulatory bodies and officials, and the goals and activities of all involved in the food system.

It might make sense to undertake a national level debate around a restatement of the fundamental purpose(s) such as safe food; eradication of poverty; improvement of human, social and natural capital, as well as economic capital (business)? That would spark a debate on who has what roles in achieving this, whether business takes out too much, and others input is inadequate, and so on.

It is important to note that many private sector corporations and businesses are engaging actively in redefining their purpose in the larger social context and not limiting to meet shareholder values. The US Business Roundtable involving CEOs of many large corporations, for example, issued an open letter in 2019 stating that the purpose of their corporations was no longer exclusively to achieve shareholder value but to achieve stakeholder value: investing in employees, delivering value to customers, dealing ethically with suppliers and supporting outside communities are now at the forefront of their business goals. Similar practices are being

[6] OECD and Prism Institute, "Digitizing Regulatory Delivery using Emerging Technologies – A Review of Current Practices", 2020 (Forthcoming)

implemented by many responsible investors worldwide. Members of the United Nations sponsored "Principles for Responsible Investment"(UNPRI) have committed to ensuring the UN Sustainable Development Goals (SDG) form the forefront of all their investment strategies and decisions.

While this trend in the private sector is largely voluntary, regulators in some sectors are also beginning to take the larger purpose into account and affecting policy changes to cater to broader societal needs. For example, the UNPRI maintains a policy and regulations database that tracks regulations globally that require SDG related factors to be considered alongside investment decisions either mandatorily or voluntarily.

Australia's Food Regulation Agreement (FRA) is an inter-governmental document signed by all Australian governments in November 2000 committing to a national system of food regulation. with the following objectives:

- providing safe food controls for the purpose of protecting public health and safety;
- reducing the regulatory burden on the food sector;
- facilitating the harmonisation of Australia's domestic and export food standards and their
- harmonisation with international food standards;
- providing cost effective compliance and enforcement arrangements for industry,
- government and consumers;
- providing a consistent regulatory approach across Australia through nationally agreed
- policy, standards and enforcement procedures;
- recognising that responsibility for food safety encompasses all levels of government and a
- variety of portfolios; and
- supporting the joint Australia and New Zealand efforts to harmonise food standards.

There are two broad limitations in the way the objectives are set in the FRA:

- It does not account for interconnected risks within the food supply chain originating from the different sectors
- The need for balancing economic growth with social outcomes is not clearly outlined creating uncertainty in regulatory decision making that leads to inconsistencies.

The Commonwealth and the States and Territories also agree that there is a need to ensure that all sectors in the food supply chain manage their food safety risks but recognise that the mechanisms for ensuring that this happens will vary from sector to sector. The increasing interconnectedness of the supply chain and its associations leads to the creation and manifestation of interconnected risks something that has become starkly evident since the pandemic. It is our understanding that regulatory purpose will be re-examined as part of the Food System Modernization Review and more specifically with respect to the Food Regulation Agreement. In that context, it is important to note that there is no real precedence to regulatory objective setting and delivery that considers the interconnectedness of complex systems such as food chains. This may be a real opportunity for Australia and New Zealand to position themselves as a global leader in developing policy guidance that would not only reflect the interconnectedness but also set more holistic and integrated social and economic outcomes.

UK's Growth Duty is a recent example of how regulators can define and apply their regulatory practices to ensure that both social and economic outcomes are met. They can do so by

applying an understanding of the business environment, their business community and individual businesses that they regulate and the impact of their activities on businesses to ensure that they are acting where needed, and in a proportionate manner. The growth duty came into statutory effect on 29 March 2017 under the Deregulation Act 2015 and requires regulators to have regard to the desirability of promoting economic growth, alongside the delivery of protections set out in relevant legislation.

Canada's "Policy on Regulatory Development" is an example of guidance provided to determine the design of a regulatory system that is aligned with the overarching principles of the government's mandate to protect and advance public interest.

This policy is grounded in the following four principles, set out in the directive, to guide departments in developing, managing and reviewing regulations:

1. **Regulations protect and advance the public interest and support good government:** Regulations are justified by a clear rationale in terms of protecting the health, safety, security, social and economic well-being of Canadians, and the environment.

2. **The regulatory process is modern, open and transparent:** Regulations, and their related activities, are accessible and understandable, and are created, maintained, and reviewed in an open, transparent, and inclusive way that meaningfully engages the public and stakeholders, including Indigenous peoples, early on.

3. **Regulatory decision-making is evidence-based:** Proposals and decisions are based on evidence, robust analysis of costs and benefits, and the assessment of risk, while being open to public scrutiny.

4. **Regulations support a fair and competitive economy:** Regulations should aim to support and promote inclusive economic growth, entrepreneurship, and innovation for the benefit of Canadians and businesses. Opportunities for regulatory cooperation and the development of aligned regulations should be considered and implemented wherever possible.

New Zealand's "Government Expectations for Good Regulatory Practice" sets an expectation that their regulatory system should deliver, over time, a stream of benefits or positive outcomes in excess of its costs or negative outcomes. It sets out an intention not to introduce a new regulatory system or system component unless it will deliver net benefits for New Zealanders. Similarly, it seeks to remove or redesign an existing regulatory system or system component if it is no longer delivering obvious net benefits.

Principles under this expectation include:

The government believes that durable outcomes of real value to New Zealanders are more likely when a regulatory system:

- has clear objectives
- seeks to achieve those objectives in a least cost way, and with the least adverse impact on market competition, property rights, and individual autonomy and responsibility

- is flexible enough to allow regulators to adapt their regulatory approach to the attitudes and needs of different regulated parties, and to allow those parties to adopt efficient or innovative approaches to meeting their regulatory obligations
- has processes that produce predictable and consistent outcomes for regulated parties across time and place
- is proportionate, fair and equitable in the way it treats regulated parties
- is consistent with relevant international standards and practices to maximise the benefits from trade and from cross border flows of people, capital and ideas (except when this would compromise important domestic objectives and values)
- is well-aligned with existing requirements in related or supporting regulatory systems through minimising unintended gaps or overlaps and inconsistent or duplicative requirements
- conforms to established legal and constitutional principles and supports compliance with New Zealand's international and Treaty of Waitangi obligations
- sets out legal obligations and regulator expectations and practices in ways that are easy to find, easy to navigate, and clear and easy to understand, and
- has scope to evolve in response to changing circumstances or new information on the regulatory system's performance.

Any restatement of the purposes of parts of the regulatory system can be facilitated and made clear and consistent by being set out in a general Regulators' Code.

3.3 System Governance

Once the overriding purpose of the food system has been established and hence the food regulatory system, the next set of basic issues that arise are:

- Which *actors* have which *functions*? 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 *behaviour and culture*.

The answers to these questions give rise to a range of supplementary ones. What structures are required? Are there too many bodies with different responsibilities (which might overlap, conflict, or leave gaps)? Are all the bodies integrated well into a single system, or are they disjointed? What should be the arrangements for the governance and accountability of the different organisations? Who oversees others, who should be involved in consultation, and so on? What role is really relevant for all the existing actors? For example, should politicians be in charge of executive decisions, or do their essential roles lie with oversight of the system and its design, outputs and performance? Should consumers and other stakeholders be (more) involved in consultation, debate, governance? Does this point towards executive decisions being the responsibility of officials and businesses? Should the existing committee structure involving shadowing of a Ministerial committee by a separate committee of officials be simplified?

It is increasingly realised that societies, states and markets need to involve a high degree of cooperation between all the various actors. Achieving this internationally may still be a

challenge but important tools are already widely used within countries and in multinational businesses. Cooperation is facilitated where actors trust each other. Trustworthy actors can be relied on, whether to perform a contract[7] or to do the right thing in a regulatory context.

In democracies and not so much in authoritarian regimes, the idea has emerged of encouraging (and expecting) both those subject to regulation and regulatory authorities to build relationships of trust, based on their producing evidence that they can be trusted. The evidence will be ongoing and should emanate from various (maybe multiple) independent sources. Important evidence will relate to whether the culture of an organisation is ethical, as that will drive good outcomes in situations of conflict or uncertainty. The models are for a business (and regulators) to adopt Ethical Business Practice (EBP) and for the level of trust thereby generated between business and regulator to give foundation for a relationship that is strong enough to be characterised as Ethical Business Regulation (EBR)[8] .

EBP is the starting point and is equally valuable for commercial success and market health as for regulatory objectives. The essence of EBP is that a business strives to create and maintain a culture (or set of sub-cultures across a large organisation, perhaps differing in different functional or geographical areas) that is based on ethical values and produces all relevant evidence of this over time. Two Frameworks are specified for EBP: A Cultural and Leadership Framework and a Values-based ethics and compliance framework, which is now referred to as a Values-Based Integrity Framework although it includes elements associated with "compliance". EBP is not about perfection. It refers to a genuine, holistic and consistent effort to implement ethical business practices that maximise the ability of people to do their jobs and "do the right thing". The elements of EBP are aspects of achieving an effective ethical culture.

Leading businesses are increasingly focusing on ethical cultures as a fundamental mode of organising their activities[9]. One aspect is the adoption of social purpose.[10] A second element is the adoption of practices that will create 'no blame' open cultures, which have been shown to be essential in achieving the safety of high-risk activities involving multiple actors and organisations, such as safety in civil aviation.[11] All of this must be underpinned by consciously identified values specific to that organisation.

An EBP organisation will:

(a) have a clear and inspiring social purpose that motivates its people and drives its culture;
(b) be based on ethical values, as identified through a process of assessment and consultation with all staff (and potentially also other stakeholders);
(c) aim to provide long-term sustainability and stability (unless the nature of the business, e.g. a start-up, dictates otherwise, in which case this should be made clear);

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[7] See *Strengthening Trust in Business. OECD Business and Finance Outlook 2019* (OECD, September 2019).

[8] C Hodges and R Steinholtz, *Ethical Business Practice and Regulation: A Behavioural and Values-Based Approach to Compliance and Enforcement* (Hart, 2017).

[9] *Statement of Purpose of a Corporation* (U.S. Business Roundtable, 2019); JE Soeharno, *The Value of Oath* (eleven publishing, 2020) (in 2013, over 80,000 bankers in The Netherlands swore they would 'put the customer's interests first'); *Strengthening Trust in Business. OECD Business and Finance Outlook 2019* (OECD, September 2019).

[10] *The UK Corporate Governance Code* (Financial Reporting Council, July 2018); *Principles for Purposeful Business. How to deliver the framework for the Future of the Corporation* (The British Academy, 2019).

[11] 'Open and just cultures' are the foundation of civil aviation safety. See J Reason, *A Life in Error. From Little Slips to Big Disasters* (Ashgate Publishing, 2013); S Dekker, *Just Culture. Balancing Safety and Accountability* (Ashgate Publishing 2007). See also *Strengthening Trust in Business. OECD Business and Finance Outlook 2019* (OECD, September 2019).

(d) aim to deserve the trust of all stakeholders (owners, staff, suppliers, customers, communities, society, states);
(e) produce adequate evidence that supports such trust, on a transparent, consistent, ongoing and adequate basis;
(f) involve all stakeholders in discussions on the nature, operation, performance, culture and outcomes achieved by the organisation.

The EBP model builds on maximising the ability of an organisation to consider what its internal and external relationships are based on, and demonstrate, positive values in each of the seven levels of the maturity of an organisation.[12]

Strong evidence of the existence of an ethical culture will be available from the actions taken when things go wrong. An ethical operation (business or government) will seek to identify and respond to a regulatory problem (whether it has led to non-compliance or not) by taking the following steps (not necessarily in this order):

1. Constantly monitor all relevant sources of information to identify problems. This includes aggregated data feed back from staff, customers, suppliers, regulators, consumer groups, communities, investors and others.
2. React to information indicating the possibility of a problem in an immediate, risk-based and proportionate manner. Facts and issues will not be ignored, buried or denied.
3. Stop any continuing harm.
4. Apologise and explain the cause and the corrective steps taken to those affected.
5. Investigate the root cause of the problem, involving and cooperating with internal, external and regulatory expertise. The urge to ask, 'who's to blame?' will be firmly resisted.
6. Implement steps to prevent recurrence (reduce future risk).
7. Rectify any harm caused (redress or repair).
8. Agree any proportionate sanctions with regulators.
9. Monitor the situation to see if further modifications are needed.

A regulator will need powers to achieve all these functions and outcomes. It will need an extensive toolbox of powers and tools. However, a business that seeks to be trusted as ethical and EBP-compliant will take these steps spontaneously, or in cooperation with the regulator, without being compelled to do so.

It is also helpful to consider the entire system as a constant repeating model of problem solving. The core functions that are needed across the system are illustrated in the Figure below.[13] Versions of this list have been quoted with approval by the Irish Law Reform Commission[14] and the Australian Law Reform Commission.[15]

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[12] R Barrett, *The Values-Driven Organization: Cultural Health and Well-Being as a Pathway to Sustainable Performance,* 2nd ed (Routledge, 2017).

[13] C Hodges, 'Mass Collective Redress: Consumer ADR and Regulatory Techniques' (2015) 23 *European Review of Private Law* 829-874; C Hodges, 'Consumer ombudsmen: better regulation and dispute resolution' (2015) 15(4) *ERA Forum* 593.

[14] *Report on Regulatory Powers and Corporate Offences. Volume 1: Regulatory Powers* (Law Reform Commission, 2018), 51.

[15] *Integrity, Fairness and Efficiency—An Inquiry into Class Action Proceedings and Third-Party Litigation Funders. Final Report* (Australian Law Reform Commission, 2018), para 8.30.

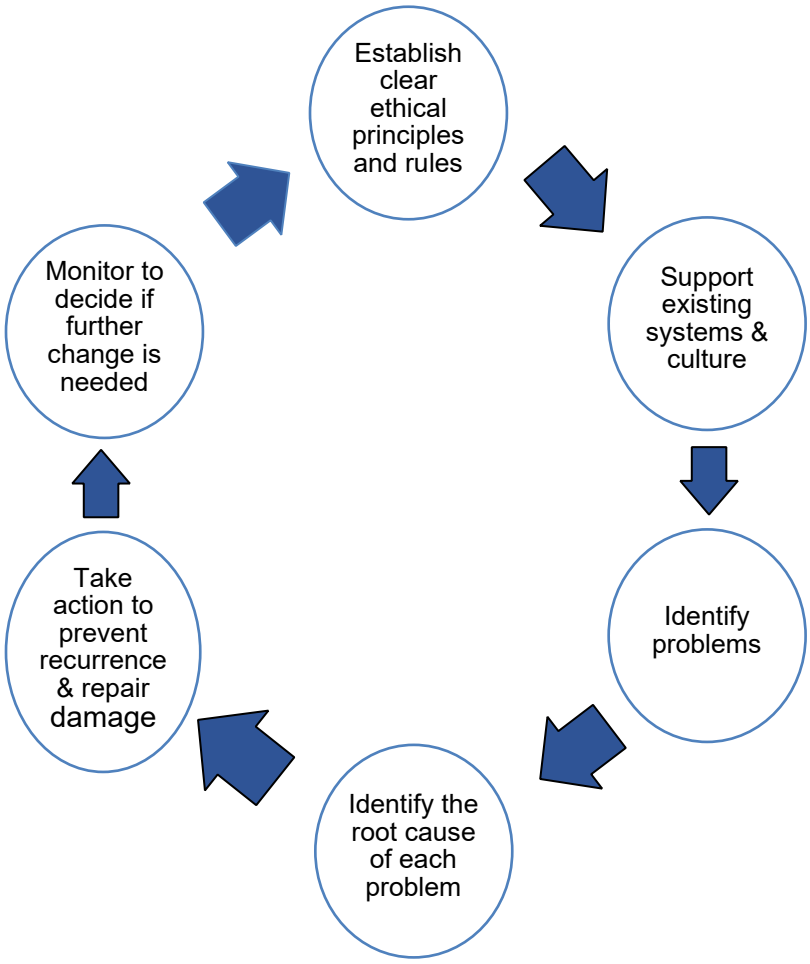

Figure 1: EBP Model

The core functions are, therefore, as follows:

1. **Establishing clear and shared ethical principles and rules.** The society should agree what its values and principles are. They should be seen to be ethical, that is in accordance with the consensus of individuals' prevailing rules of what is right and proper. Specific rules that apply to conduct should then be made that accord with the ethical principles and give specificity of what is required in particular concrete situations. This can be done in layers of subsidiary rules.
   It is an essential function of a legislator to specify the ethical values and principles. Detailed technical rules can be made at subsidiary levels, such as by regulatory or standards bodies, involving suitable consultation with all stakeholders. A Code (in many cases a Code that it is mandatory to observe) can be an effective model. The rules of the Code and any relevant guidance may be amended, updated and extended relatively quickly.

   Irrespective of how the principles and rules are made, they should be subject to open consultation between all relevant parties, allowing all stakeholders to have a voice in their consideration, and for all practical issues over delivery of the rules to be considered.

2. **Methods and systems to achieve effective economic performance and compliance with principles and rules.** All actors (public and private) should put in place and consistently operate relevant systems and culture to succeed in their legitimate endeavours. This will involve systems for operating (management, operations, feedback, evaluation and other systems) and controlling (regulation and ethical performance and compliance systems).
   In the case of regulatory bodies, the core model is the Regulatory Delivery Model (RDM)[16] that is discussed further below. In the case of commercial businesses, management and operational systems will be required. In both cases, it is fundamental to aim to observe the *ethical principles* rather than (just) the rules, and this is done by having frameworks that aim at achieving an *ethical culture* rather than just compliance with rules.

3. **Leadership development, behaviours and practices to create the conditions for ethical values and behaviour to prosper**. All organisations should focus on recruiting and developing leaders at all levels in the organisation with the character and skills required to nurture ethical cultures.

4. **The ability to identify problems.** Both commercial and regulatory bodies should strive to identify problems, rather than just focusing on breaches of rules. A problem might or might not be identified as a breach, and a breach might be considered to be serious enough to enable a real problem to be identified, so the risk-based aim is to take a wide focus and identify actual or potential problems.
   Various means of identifying problems should be in place, such as a culture of psychological safety[17] that facilitates the raising of issues, monitoring activities, tests, inspections and audits. A key advance is to adopt frameworks and practices that support and maintain an ethical culture in organisations and hence trust between them and the people involved.

5. **Analyse problems so as to identify their root cause.** This 'root cause' approach is now widely adopted in technical contexts. It aims to identify the real and often multiple and systemic causes of a problem, rather than just the proximate individual who 'caused' an incident or breach of a rule. The objective is to be as effective as possible in addressing the problem, rather than to sanction breach of a rule and hence fail to take more effective or widespread action.

6. **Taking action to prevent recurrence of the problem.** Action might be taken at 'ground level' by immediate actors, or more systemically at organisational level, or externally by a regulator. Whenever appropriate, relevant information and action should be notified to, and discussed and agreed between, responsible people at relevant levels, whether internal or external.

7. **Taking action to repair any damages caused**. The previous function is prospective, aimed at reducing future risk, and this function is retrospective, aimed at putting things right and back to balance. It may involve making repairs, recalling dangerous products, restoring the environment, paying compensation for loss or similar actions. Efficient systems should be in place to achieve these outcomes swiftly and economically.

[16] Set out in detail in G Russell and C Hodges (eds), *Regulatory Delivery* (Hart, 2019).

[17] AC Edmondson, *The Fearless Organization* (John Wiley & Sons, Inc., 2019).

8. **Monitoring the situation and action taken to see if any further or corrective action is needed**. Such corrective action might involve changes to rules (no 1 above) or to systems and approaches (no 2). It might involve cultural measurement over time to determine if cultural transformation efforts are succeeding. Thus, the model is circular, representing continuous activity (rather than activity just based on individual activities, such as inspections, identifying breaches and imposing sanctions).

The requirements are for a structure that:

- Is simple - that everyone can easily understand and can operate swiftly and efficiently.
- includes all relevant actors as active participants, each making their own contribution.
- Allocates clear responsibilities to certain defined actors, based on their purposes, functions and goals.
- Engages all actors as partners in the success of the whole enterprise, based on mutual trust and trustworthiness, based on relevant evidence of ethical behaviours and cultures.
- Encourages relevant issues to be raised, and data to be shared, on a partnership basis.

In more detail, the system would provide:

- a central primary communication channel and hub for data and decisions;
- delegation of responsibility for minor decisions and standard operational performance to the right level,
- with the ability for information and issues to be raised in any direction swiftly and in a no blame culture, but
- in the confidence that just consequences will be taken.
- An appeal mechanism.

Australia has a well-functioning and integrated regulatory system governance framework, but the structures are rule based and perceivably top heavy and the future requires a different approach. The Forum, for example, has the role of the decision maker/overseer of the system in addition to being required to be the system arbitrator. To do this, the Forum must delicately balance its policy development role that involves addressing potentially competing interests from consumers, from industry and from itself with its oversight function. To enhance objectivity and deal with potential bias, it may be worth examining other accountability structures to make the governance framework more resilient and nimbler to deal with the evolving sector by:

- Ensuring that the assigned responsibilities do not hinder or burden the system players (e.g. operational responsibilities for the forum may be delegated)
- Creating a more formal structure for engaging and consulting with the industry and other stakeholders and moving towards a trust-based relationship model (e.g. proactive engagement of industry may enhance their ability to take greater ownership of risk and increased transparency in sharing evidence of good practices).

Two example governance models implemented and practiced in the UK and Canada are discussed in the next sub-section.

3.3.1 System Governance Structure: The Primary Authority Model

Examples of successful system governance structure illustrating positive regulator-regulated relationships can be seen in many sectors. Each have individual characteristics. One example of a highly successful approach is the UK Primary Authority (PA) scheme.[18] This provides a structure for formal cooperation agreements between businesses, Local Authorities and some national regulatory authorities. It provides channels of communication between the contracting parties to identify and resolve issues of uncertainty over law or compliance.

The PA scheme includes the following elements:

1. formal agreements between a lead authority (the Primary Authority) and a business (or trade body);
2. a mechanism for any local authority to raise an issue of compliance or breach first with the PA and then for the PA to raise this with the business, rather than every local authority starting enforcement action itself;
3. a mechanism for the business to raise any issue of interpretation or compliance with the PA, and to receive 'assured advice' with which it should comply, with low risk of being prosecuted;
4. a mechanism for differences of opinion, especially between authorities, to be decided by a superior governmental authority (RD in the illustration).

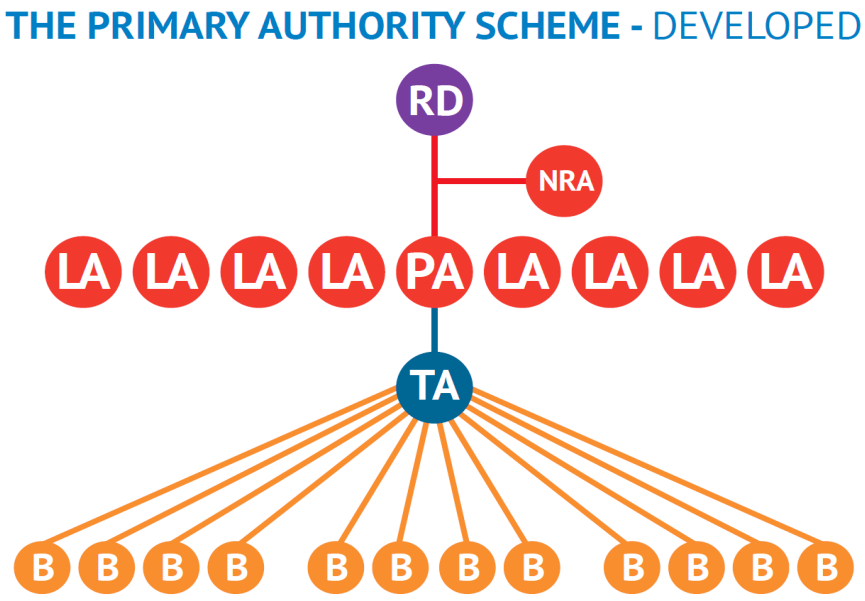

Figure 2: An illustration of the PA structure

RD = the Department for Business, which exercises overall supervision of the scheme.

[18] *Primary Authority Overview* (Department for Business, Energy & Industrial Strategy, 2019), at www.gov.uk/government/publications/primary-authority-overview.

NRA = a national regulatory authority that is part of the scheme

LA = a Local Authority

PA = the Primary (local) Authority for the relevant business

TA = the national headquarters of the business, or a trade association or other partner

B = local outlet of the business or trade association

This model encourages responsible businesses to 'do the right thing' in all their activities. If they are unsure or identify a problem, they should raise it (for which they will be given credit in the Regulator's response).

It has been said:[19]

Numerous local authority-led projects in the UK over the past 20 years have demonstrated the potential benefits of a supportive approach. In an early example, a 2004 collaboration between Bolton Metropolitan Borough Council and Salford University aimed at improving food hygiene standards in ethnic catering businesses demonstrated that directed training support to businesses that had not previously responded well to a traditional inspection regime was very effective in raising compliance levels: 65 per cent of the premises targeted in the first phase of the project showed significant improvement.[20]

The Primary Authority like approach can also be applied in other jurisdiction where a national/sub-national regulator (e.g., energy) can be designated as the lead contact who would coordinate other regulators (e.g. health and safety, revenue, environment) with whom the business has to inter-relate.

The Primary Authority works alongside local Business Hubs that are intended to coordinate all local business activity (akin to Chambers of Commerce) in the prevailing local environment. A model for this in UK is the 'Better Business *for* All' (BBfA)[21] partnership between regulatory services and local businesses. The objectives of BB*f*A are:

BB*f*A Key Objectives

- Simplifying the local regulatory system and processes
- Providing advice and support to business
- Increasing the business awareness of regulatory officers
- Effective coordination across the regulatory system
- Establishing an ongoing dialogue between regulatory services and local business

[19] G Russell and H Kirkman, 'Outcome Measurement' in G Russell and C Hodges (eds), *Regulatory Delivery* (Hart, 2019).

[20] Improving the Public Image and Risk Assessment of Ethnic Minority Food Retail Businesses – the 'Bolt 'Project'. Presentation to Food Standards Agency workshop, 2004 (unpublished)

[21] Martin Traynor and Kathryn Preece, 'Better Business for All, an Approach to Building Local Capacity for Collaboration and Accountability' in G Russell and C Hodges (eds), *Regulatory Delivery* (Hart, 2019).

We do not suggest that the PA Model directly fits the Australian and New Zealand food requirements as it stands, but it forms a successful precedent that suggests appropriate solutions. The ANZ context would need to cover national, Territory and local actors, international actors, and other public Ministries and authorities that operate adjacent to food responsibilities (health & safety, environment, consumer protection, revenue and so on).

An example hypothetical scenario in the Australian context is provided in the text box for illustration purposes.

Future scenario: Woolworths wants to reduce operating costs, minimise the burden of demonstrating compliance, improve the ease with which it can deploy human resources across authority boundaries, and ensure that the standards and operating processes within and across its Australian stores are consistently complying with the law.

As part of its plan to achieve this, Woolworths seeks approval from the Forum to enter into a Primary Authority relationship with Safe Food Production Queensland.

As part of the agreement Queensland undertakes to consult supporting regulators where necessary, and all other regulators are bound by law to respect the advice and guidance provided by Queensland in regard to Woolworths compliance with food safety legislation.

Establishing the Primary Authority agreement between Queensland and Woolworths hinges on developing a strong relationship, itself based on mutual trust. Both parties agree to treat each other with respect, honesty and fairness, to raise all relevant issues promptly, to engage in discussions with the aim of finding solutions that are consistent with achieving the regulatory objectives and outcomes.

This process begins with the two parties working together to establish:

- what both parties expect to get out of the partnership
- what the objectives are, and how both parties will work together to achieve them
- how both parties will communicate with each other
- how regularly they intend to meet one another, and whether these meetings need to be formal or informal
- what kind of Primary Authority Advice is required
- whether an inspection plan is required (see below for more on this)
- whether any supporting regulator should be consulted, e.g. Safe Work Australia
- who the main contacts will be for both parties
- how the costs/fees will be structured, and what the overall cost will be.

The subsequent Primary Authority meets Woolworths needs in the following manner:

Benefit derived:	**Achieved through…**
√ **Complex business needs understood and addressed.**	Tailored and assured advice from a single regulator who invests in developing a deep understanding of its partner.

√	**Simplified business processes for operating with confidence across multiple authority jurisdictions.**	Legal relationship with a single authority, which provides assured advice that other authorities must respect. This means that if Woolworths follows the Queensland's advice: o it would not face enforcement action from any another authority that has a different view on whether compliance is being achieved. o Any other authority would need to notify Queensland of its concerns and intention to take enforcement action. o Queensland could block this activity if it conflicted with the advice it had given. o Any other authority would have to establish that Woolworths hadn't followed its Primary Authority Advice before it could take enforcement action.
√	**Rationalised time and resource spent on compliance activities.**	Eliminating unnecessary reviews and audits. For example, Queensland could provide Woolworths with an inspection plan that would govern the way it is inspected by officers from any other authority. This inspection plan would be approved by the Forum, and then made available to other regulatory authorities. Whilst Queensland would consult other regulators where necessary, its approved plan would take precedent.
√	**Improved engagement, communication with regulator, facilitating the development of trust and openness.**	A single, consistent point of contact with an authority.
√	**Enhanced business confidence that regulated activities and reduce your risk of contravening legislation.**	Provided that Woolworths follows the advice from Queensland, it can be confident that it is complying with the law. Moreover, provided Woolworths complied with any guidance from Queensland, it could disregard any conflicting advice from other sources

Another example of an alternate governance model is a legislated third-party approach called the Delegated Administrative Authority being administered in Canada. There are over 700 pieces of consolidated law with several thousand corresponding regulations in Ontario, province of Canada, covering many of the responsibilities administered by governmental and non-governmental authorities and agencies. Over the years, governments of Ontario have attempted

to cut unnecessary red tape, reduce burdens on businesses and create efficient and effective regulatory systems and continue to try new and innovative approaches as envisioned in the recently promulgated Burden Reduction Act of 2017.

In response to an early such initiative in 2000, Ontario established its first Delegated Administrative Authority (DAA)[22] as an alternative third-party approach to administration of public policies and regulations through the creation of private, not-for-profit corporations wherein services are provided on a cost recoverable, fee-for-service basis. There are fourteen such DAAs currently operating in Ontario most of which were created by moving existing government departments and agencies. The more recent DAAs were primarily created to either address existing gaps in the regulatory system or consolidate multiple portfolios lying within or outside government. Similar models are also being developed and implemented in other provinces of Canada including British Columbia, Manitoba and Saskatchewan.

Due to the flexibility provided, particularly from the fee structure and being considered independent of government public accounts, the DAAs can invest in resources and infrastructure for the purposes of delivering their mandates. Most of the DAAs use risk-based approaches to guide their inspection and enforcement efforts ranging from allocation of internal resources, making decisions on fees including licensing fees, administering non-compliance penalties and enforcement activities. Availability of funding also assists the DAAs in undertaking several activities that are not traditionally seen as enforcement such as investing in technology enabled delivery initiatives, consumer awareness campaigns, training and education programmes for regulated stakeholders, public education and internal staff training. While this model has several benefits many of which have been demonstrated, it requires major legislative changes and significant cultural shifts in thinking to implement. The long-term efficacy of the model is still under review and no clear evidence is available about its success.

3.4 Regulations

As systems such as those involving food supply chains get more complex, the risks associated with them become even more difficult to manage. Monitoring and responding to the integrity, reliability and safety of such systems would involve dealing with technical and human aspects. Regulators would require more tools and approaches than traditional compliance and enforcement instruments. As described in the previous section, regulatory approaches based on behavioural and social science will help focus more so on the culture of organizations (regulators and regulated) and not merely on traditional compliance and enforcement methods.

As a result, policymakers will require more operational flexibility in the way regulatory management tools are deployed. This may require adjustments to current legal frameworks to allow for experimentation and innovation in the way policy options are analyzed and implemented particularly for new and emerging business models. Organizational culture at all levels of government will need to adapt and change to allow policy makers and regulators to operate without fear of failure when experimenting.

[22] Srikanth Mangalam, “Canada’s Delegated Authority Model” in G. Russell and C. Hodges (eds), Regulatory Delivery (Hart, 2019).

Many countries around the world are in a similar position with rules-based regulatory systems. The ones that will really open up the opportunities of industry growth (agriculture, food, finance), fast economic recovery, exports, investment abroad will be those that fully engage with the new ways of working around cooperative engagement between business and government, trust, evidence, digitisation. Australia is well placed to grasp these opportunities on a world-leading basis. The new paradigm will enable innovation, selection of the best options (sandbox approach), early identification or risks and opportunities, adoption of effective implementation through full cooperative engagement of all actors.

The OECD[23] has undertaken research and identified some emerging approaches for policymakers to consider having in their toolkit as they begin to tackle disruption in traditional business models and supply chains. They include the following approaches:

- Performance or outcome-based regulations
- Regulatory Cooperation and Collaboration
- Co-regulations (Soft Regulations, Industry Codes and Standards)
- Regulatory Experiments (Regulatory Sandboxes, Adaptive Regulations)

3.4.1 Performance or outcome-based regulations

Performance or outcome-based regulations, which typically specify measurable outcomes (performance measures, risk thresholds etc.), allow businesses greater opportunities for innovation, as long it is easy to demonstrate that the desired performance has been achieved. They have had a long history dating back to the early 1980s particularly in the United States where the focus was to relieve the regulatory burden on governments and to limit its intervention. Various forms of outcome-based regulations have since been adopted in the United States and a number of other countries for the regulation of air and water quality, building and fire safety, energy efficiency, food safety, forest practices, nuclear power plants, pipeline safety, and work safety.

These types of regulations specify required outcomes or objectives, rather than the means by which they must be achieved. Firms and individuals are able to choose the process by which they will comply with the law. This allows them to identify processes that are more efficient and lower cost in relation to their circumstances, and also promotes innovation and the adoption of new technology on a broader scale. The focus of regulation is shifted to results or outputs, rather than inputs, and the degree of government intervention in markets is effectively reduced. Adoption of performance or outcome-based regulation can also simplify and clarify regulations, since they can be written in terms of underlying objectives, rather than requiring large amounts of detailed, prescriptive standards to be set out in legislative terms.

3.4.2 Regulatory Cooperation and Collaboration

[23] OECD and Prism Institute. “Scoping Paper on Regulatory Future of Emerging Technologies”.

Regulatory co-operation comes in many forms and types and can differ in geographical scope – from bilateral to regional or multilateral. Forms of cooperation may range from the most binding through harmonisation of rules via joint institutions to the lightest through exchange of information among regulators. International treaties and other formal legal agreements can impose identical legal requirements on participating nations, but these instruments have become increasingly difficult to negotiate and implement and therefore are often foregone in favor of more informal coordination approaches. The current Australia New Zealand Food Regulatory Framework is a great example of a multi-lateral framework that also address regional aspects.

The OECD's Mutual Acceptance of Data (MAD) program designed to address chemical safety globally is another example of regulatory cooperation based on exchange of information and mutual recognition through an international organisation that may prove an interesting reference. In the case of the MAD framework, member nations accept one another's test data for assessment of new chemicals as long as the data are generated following the OECD test guidelines and principles of good laboratory practice. The program facilitates testing harmonization among countries, and enables burden sharing in both the generation and evaluation of chemical test data. By working together on technical and policy questions, members and observers alike gain understanding of one another's positions on issues and learn how to apply technical approaches and policies to regulation collectively.

In the food sector, the Codex Alimentarius is an example of regulatory cooperation at a multilateral level in determining internationally adopted food standards and related texts for protecting consumers' health and ensuring fair practices in the food trade. The publication of the Codex Alimentarius is intended to guide and promote the elaboration and establishment of definitions and requirements for foods to assist in their harmonization and in doing so to facilitate international trade.

3.4.3 Co-Regulations

Co-regulation can be seen as being part of the continuum between industry self-regulation and government regulation. Industry self-regulation concerns groups of firms in a particular industry or entire industry sectors that agree to act in prescribed ways, according to a set of rules or principles. Participation by firms in the groups is often voluntary but could also be legally required. The groups can be wholly responsible for developing the self-regulatory instruments, monitoring compliance and ensuring enforcement, or they can work with government entities and other stakeholders in these areas, in a co-regulatory capacity. Self-regulatory schemes entailing some degree of government involvement are common; the level of involvement, however, can vary significantly among schemes.

Confronted by the regulatory challenges posed by disruptive technologies, examples of the emergence of an amorphous system of regulatory governance called "Soft law" are cited.[24] The

[24] Soft law regimes are those that lack "the mandatory, enforceable character of hard law," and are "understood to shape expectations of appropriate behavior more strongly than mere political or social undertakings." (Hagemann, 2018). These may include a wide array of policy vehicles ranging from principles and codes of conduct, policy guidance documents, best practices and voluntary standards,

flexible nature of soft law approaches makes them relatively easy to modify in response to changing circumstances.

The International Standards Organization (ISO) and International Electrotechnical Commission (IEC) and other national standards bodies have jointly produced several international standards and guidelines covering Information technology including the specification, design and development of systems and tools dealing with the capture, representation, processing, security, transfer, interoperability and interchange, presentation, management, organization, storage and retrieval of information and data. Many of these standards cover a range of the disruptive technologies and provide “soft” but clear solutions to many of the regulatory challenges such as privacy, security, interoperability, data sharing and autonomous decisions. An example of good practices involves the powers of creating alternate rules and code adoption documents in Ontario, Canada.

For agricultural applications, especially where international trade disputes are the primary concern, harmonized risk assessment and risk management principles established by an international organization such as Codex are good examples of “soft laws”. Some of these requirements are also incorporated into regulations in some jurisdictions. For human gene editing, where medical tourism is the biggest international concern, scientific guidelines adopted by professional societies may be the best way to enforce common principles.

When faced with international governance of complex technologies that are constantly evolving, the current breed of soft law mechanisms serves as a foundational structure that can be built upon and the likes of which will continue to serve as new rules for emerging frontiers.

3.4.4 Regulatory Experiments

Examples of regulatory experiments that are being examined include:

- Enhancing flexibility through temporary regulation by using experimental legislation including sunset clauses to "define adaptable goals and enable the adjustment of laws and regulations according to the evolution of circumstances.
- Creating "regulatory sandboxes" to allow firms to "roll out and test new ideas . . . without being forced to comply with the applicable set of rules and regulations."
- Developing "anticipatory rulemaking" or adaptive regulations techniques that leverage feedback processes to enable "rule makers to adapt to regulatory contingencies if and when they arise because a feedback effect provides relevant, timely, decentralized, and institution-specific information ex-ante."
- Utilizing the iterative development of the common law to adapt rules to new technological contexts where possible and developing new specialist regulatory agencies where they are particularly needed.

white papers etc. Please note, that “soft laws” may carry a different meaning when developed by International governmental organizations such as the OECD.

- Using "legal foresighting" to identify and explore possible future legal developments, in order to discover shared values, develop shared lexicons, forge a common vision of the future, and take steps to realize that vision.
- Creating new multi-stakeholder fora to help overcome information and uncertainty issues that stifle innovation or inhibit effective regulation.

A couple of these approaches are discussed below.

3.4.4.1 Regulatory sandboxes

A regulatory sandbox generally refers to a regulatory "safe space" that creates an environment for businesses to test products with less risk of being "punished" by the regulator for non-compliance. In return, regulators require applicants to incorporate appropriate safeguards to insulate the market from risks of their innovative business. It typically involves a framework set up by a regulator to allow pilot testing of innovations by private firms in a controlled environment (e.g. exemptions, allowances, time-bound exceptions etc.) overseen by regulators. It was pioneered by the UK's Financial Conduct Authority has provided a new way to test a new idea outside the constraints of the full regulatory system and gain data on how well it works when applied to real scenarios[25]. Its application in fintech scenarios have been in place for a few years now and well documented.

As a non-financial sector example, Autonomous vehicle (AV) rules were introduced in Singapore in February 2017 providing rules for prospective trials of autonomous vehicles and automated vehicle technology, and prospective use of autonomous vehicles. Parties announcing trials included businesses looking at autonomous bus and truck technology, ride hailing applications and tourist services. The AV Rules and broader legislative framework give the Singapore Land Transport Authority the ability to effectively implement a regulatory sandbox in relation to any such trial or use. This allows the LTA, for example, to create bespoke licensing conditions and demarcated trial areas. The discretion provided to the LTA leaves it open for an applicant to engage with the LTA on the solution to be authorized. However, there are certain overarching conditions to authorization and duties of authorized operators prescribed under the Road Traffic Act and the AV Rules which have to be followed. A similar framework is also being adopted in Germany.

Most health products in Canada are regulated using existing rules under the Food and Drugs Act. Under exceptional circumstances, where current regulations cannot appropriately accommodate a product, a regulatory sandbox pathway has been made available. This pathway will be reserved exclusively for "Advanced Therapeutic Products," (ATPs) which are drugs or devices that are so novel, complex, and distinct that current regulations are not equipped to handle them. ATPs can offer tremendous health and economic benefits. As more companies make use of these new technologies, it became evident for Health Canada that a risk-based and flexible way was needed to authorize these novel products, while still protecting the health and safety of Canadians. The regulatory pathway can be tailored to the specific product, addressing its unique characteristics while maintaining Health Canada's high standards for

[25] https://www.fca.org.uk/firms/innovation/regulatory-sandbox

patient safety. Figure below provides a more detailed explanation of this new pathway, also known as a regulatory sandbox.

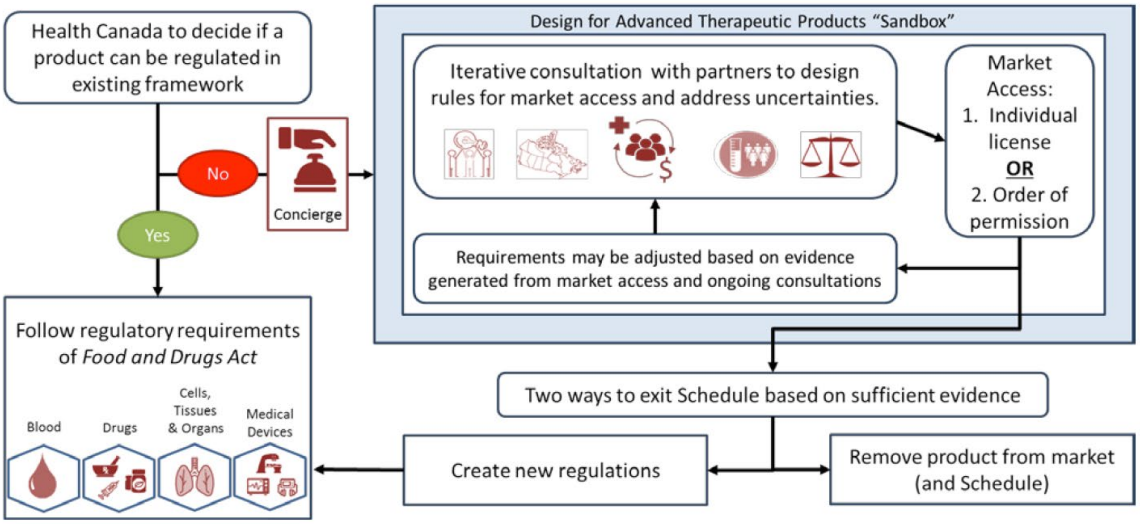

Figure 3: Health Canada's Regulatory Sandbox for Therapeutic Products

Another variation of a regulatory sandbox involves the ability to create alternate rules, exemptions or variation from adopted standards and code. Ontario's Technical Standards and Safety Act, which deals with the safety of technical devices and products, provides powers to the Ministers to make any order, alternate rules and exemptions to existing legislation in response to circumstances such as industry innovations. More specifically, Ontario's regulation on code adoption by reference allows the regulatory authority to adopt and amend codes and standards to address evolving expectations of its stakeholders and public.

A regulatory sandbox introduces the potential to change the nature of the relationship between regulators and innovators toward a more open and active dialogue. This trust built on evidence will also enable the regulator to revise and shape the regulatory and supervisory framework with agility. Regulators establish sandboxes to promote competition and efficiencies within markets through innovation. The success of a sandbox is dependent on how it is framed and, the effectiveness of the innovations amongst other factors. While the sandbox concept itself is easy to copy, its true value lies in the substance of the sandbox, which is the extent to which it can promote beneficial innovation based upon an in-depth knowledge exchange between innovator and regulator. Regulatory sandboxes are good examples of ethical business regulations.

Truly smart regulation will pair the sandbox with a strong, fact-based, research-driven dispensation and licensing practice that furthers innovation while minimizing risk. However, in markets where experienced regulators decide their cases, regulated entities already benefit from responsible dispensation practices, while avoiding the risks and uneven competition a sandbox creates. Some large and experienced regulators have therefore hesitated to adopt the sandbox approach and seek an efficient level of forbearance or dispensation by way of no-action letters, restricted licensing, piloting, and other tools. Risks and limitations with regulatory sandbox include sending negative signals to markets as the sandboxes are essentially "unregulated", lack of transparency and standardization, and perceptions of not creating level playing fields.

While there are clear and obvious advantages with a national standards-based approach to regulating the food, the standards setting process and the resulting codes have constrained regulators in Australia from dealing with industry demands and market innovations. While a majority of regulators do believe that they have flexible and nimble state regulations in place, the availability of additional regulatory tools would provide them with the ability to deal with ever changing industry innovations. Regulators in Australia with the ability to use regulatory sandboxes will be able to address market innovations and not have to wait for the standards setting process to make changes. A hybrid approach involving traditional sandbox models supported by legislative powers to create alternate rules or exemptions from codes/standards may be a way forward for Australia to consider when dealing with industry advancements and innovations.

3.4.4.2 Adaptive regulation

Adaptive regulation refers to design of institutions and processes to review and update policies in light of evolving scientific knowledge and changing technological, economic, social and political conditions. The pace at which technologies and business models are changing and globally evolving as described earlier, adaptive regulation may pose challenges for regulators, regulated parties and other stakeholders as periodic re-evaluation and revision might reduce the stability and predictability of rules, which could have the effect of discouraging investment and innovation. In response, the Institute of Risk Governance (IRGC) proposes, planned adaptive regulation (PAR) as an enhancement to handle this change with greater agility and predictability, through planned review and revision, rather than through a purportedly final decision that locks regulation in place and then grows increasingly out of step with the ongoing changes – yielding unintended consequences and rigid rules that inhibit innovation.

3.5 Summary

The design of the overall regulatory system sets the tone and direction for various functions and actors within the system. Regulators surveyed for this study feel that the current Food Regulation System adequately serves the purpose of developing policies and promoting a consistent implementation of standards and food safety requirements while believing there is room for improvement since implementation is not consistent across jurisdictions. In general, food standards have so far been focused on including scientific rules and, on system controls translated into a legal framework based on rules and deterrent enforcement. The next evolution of the regulatory system should factor in human behaviour, based on behavioural and social science and focus more so on the culture of organizations (regulators and regulated) impacting the overarching system.

Key recommendations for consideration with respect to the regulatory system design include:

- ***Need to ensure that the regulatory purpose/objectives are clearly defined and address current public interest and consumer expectations, business models and trade, and broader government policies***

- ***Explore the possible application of alternate system governance models (e.g., primary authority model) that account for human/organizational behaviours and enable trust-based relationships between the various actors in the system***
- ***Ensure availability of regulatory tools including regulatory experimentation methods like sandboxes to meet the needs and demands of current industry practices and supply chains***

4 Section III: Regulatory Delivery Model

Officials in the UK Office for Product Safety and Standards (OPSS), part of the Department for Business, Energy & Industrial Strategy, have developed a Regulatory Delivery Model (RDM) through working with governments and regulators across the world.[26]

The RDM comprises three *pre-requisites* for regulatory agencies to be able to operate effectively (governance framework, accountability and culture) and three *practices* that agencies need in order to deliver societal outcomes (outcome measurement, risk-based prioritisation and intervention choices.

These are summarised below.

4.1 Pre-Requisites

Pre-requisites for regulatory agencies to be able to operate effectively:

1. *Governance Framework* covers the basis on which a regulatory authority is formed, its powers, purpose, structures, the landscape within which it operates, and its powers and responsibilities.
2. *Accountability* covers the relationships and responsibilities of an authority towards its different audiences, what it is accountable for and to whom. It involves transparency and accountability mechanisms.
3. *Culture* covers the culture of the authority, emphasising the shaping features of leadership, values and competency.

4.1.1 Regulators' Governance, Accountability and Culture

Governance can be defined as the manner in which control is exercised; the influences over a person or organization; or the ways in which policies are delivered. In the RDM, Governance Frameworks are considered in terms of a regulatory agency's purpose, its structure, its operating landscape, and its powers and responsibilities.

The model set out here recognises that all stakeholders are involved in the governance and operation of the entire system, rather than compliance just being the responsibility of 'regulatees' and enforced by regulators. That shared involvement is illustrated by the figure below, which shows this communal involvement, albeit at differing levels of intensity, illustrated

[26] G Russell and C Hodges (eds), *Regulatory Delivery* (Hart, 2019).

by different shades of blue.[27] The model enables all stakeholders to be involved. Any governance framework set out under this model should be built with this in mind.

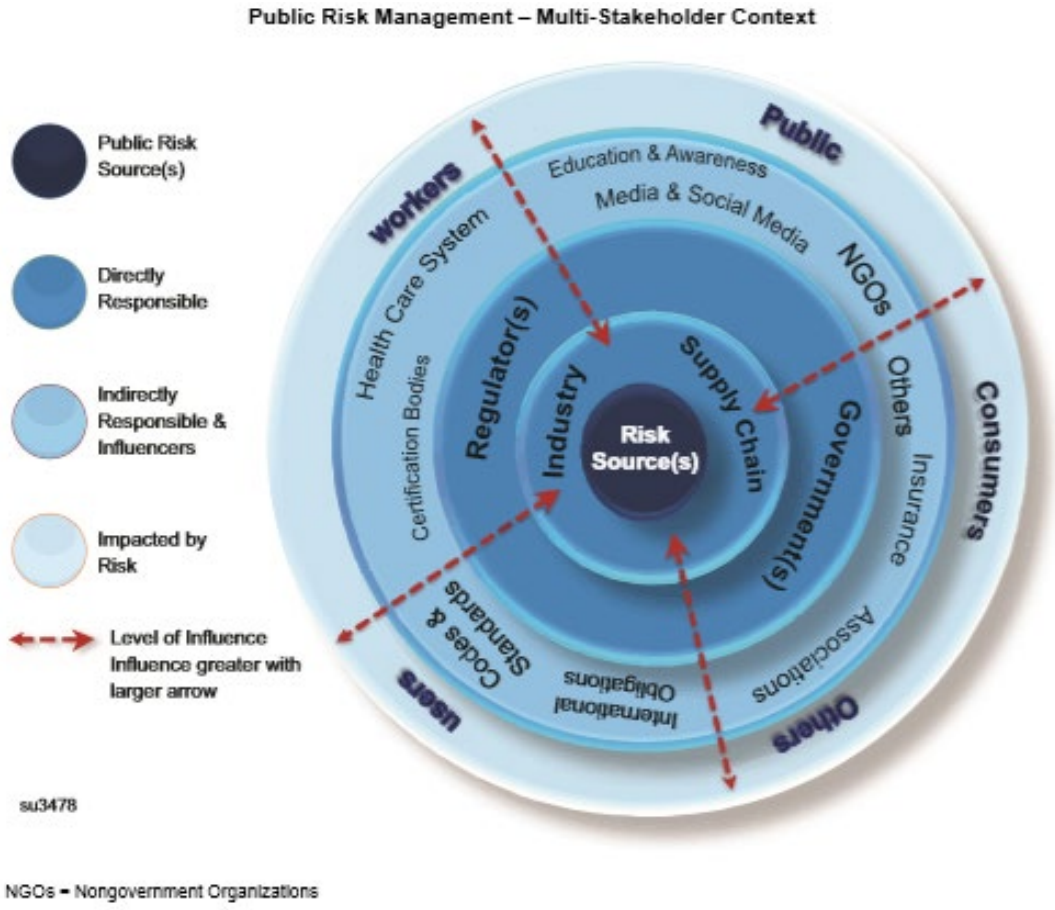

Figure 4: RDM Governance Framework

Accountability is understood within the RDM in terms of the empowerment of stakeholders to participate in the regulatory process and to challenge the regulatory agency. It is seen both as a constraint on the behaviour of the regulatory agency and as an enabler by strengthening the authorising environment through creation of confidence and utilisation of trust. While defining accountability, it is important to consider both what the regulatory agency should be accountable for and to whom they should be accountable. With respect to the latter, the RDM presents a simple representation of the accountability relationships between the key stakeholders of the system as shown in the figure below.

[27] CAN/UL2984:2019 National Standard of Canada: Standard for Management of Public Risks– Principles and Guidelines (Standards Council of Canada, 2019), Figure 2, p 18.

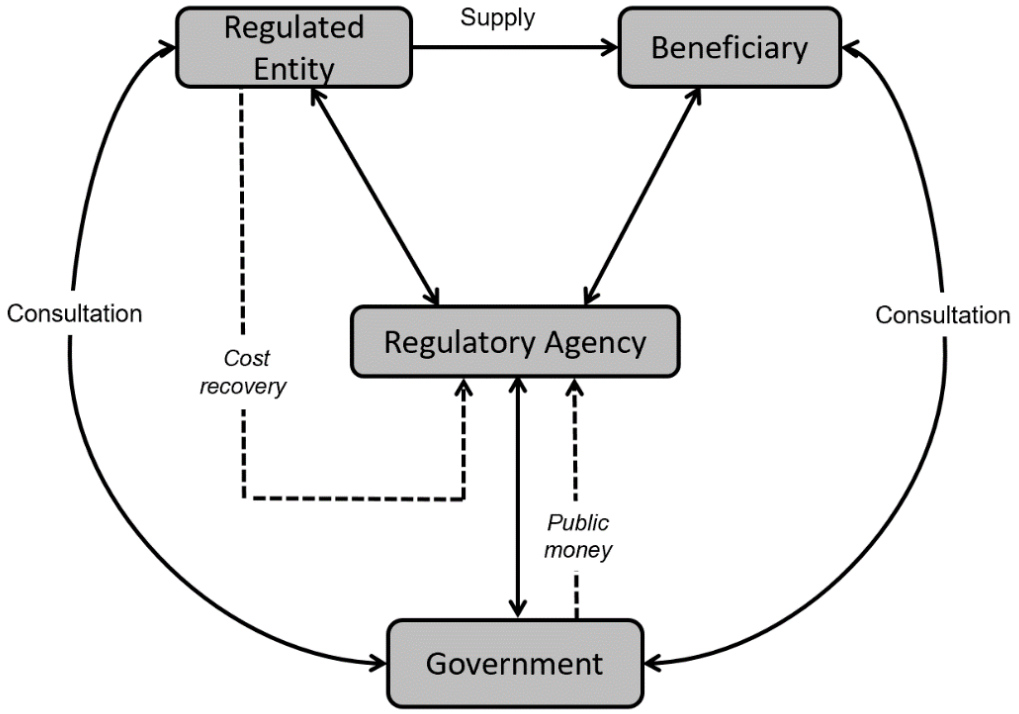

Figure 5: RDM Stakeholder relationships

Culture is considered within the RDM as a collective understanding and purpose that manifests itself in the visible behaviour of the regulatory agency. It will determine how the regulatory agency will respond to the forces of governance and accountability and support improvement.

The regulatory agency should, at a minimum, be able to establish, implement and demonstrate all the applicable ethical principles and standards described in the previous section as they pertain to ethical business practices and address the following key lines of inquiry:

- The agency's leadership should demonstrate the competence and capability of not only implementing EBP internally but in administering similar expectation of its regulated entities
- The agency's values are aligned externally with the regulatory objectives and internally with its pre-established principles and standards
- The agency's learning and development strategies are proportional to its purpose and that promotes a culture that focuses on the desired outcomes

The aspects of Culture explored within the Regulatory Delivery Model are:

1. The nature of the **leadership** of the regulatory agency, including the leadership drive to build an outcome-focussed culture.
2. The **values** of the regulatory agency, including their appropriateness to the regulatory task of the agency and the extent to which these are shared values.
3. The **competency** of staff to deliver the purpose of the regulatory agency, including whether knowledge, skills and behaviours are proportionate to the level of discretion.

The previous section provides more information and examples of practices involving the use of EBR and EBP approaches to addressing culture.

Some key lines of enquiry that should be addressed, when building a framework on governance, accountability and culture for regulators, would include:

- Clarity and alignment between the regulatory objectives, the purpose of regulatory requirements and of the regulatory agency – The agency should understand and should be able communicate its purpose as not merely being a compliance seeker but a trusted partner and influencer of ethical business practices
- The design and operational structure of the agency – The agency should have decision-making capabilities that are not limited to just inspections and enforcement but include broad range of toolkits that would allow it to become a facilitator of ethical business practices
- Governance landscape – As illustrated in the figure above, the agency should consider the entire system and have a clear understanding of the individual and collective responsibilities of the various actors within the system and especially other regulators
- Powers and responsibilities – The agency should have and be able to use a wide-ranging toolkit of regulatory and non-regulatory powers and instruments to primarily facilitate an enabling environment for ethical business practices and with a goal of meeting the set objectives
- Appropriate measures that demonstrate transparency of its functions and processes and that builds confidence and trust amongst its stakeholders
- Effective mechanisms that enable the regulated entities, governments and other stakeholders of the system to hold the agency accountable

UK Regulators' Code is a good example of a code of practice that provides guidance on developing the appropriate governance and accountability structures, defining regulators' approaches to delivery and enforcement etc. The Regulators' Code came into statutory effect on 6 April 2014 under the Legislative and Regulatory Reform Act 2006 and provides a clear, flexible and principles-based framework for how regulators should engage with those they regulate. The regulators and regulatory functions to which the Regulators' Code applies are specified in the Legislative and Regulatory Reform (Regulatory Functions) Order 2007, as amended in 2009, 2010 and 2014. Nearly all regulators, including local authorities and fire and rescue authorities, must have regard to it when developing policies and procedures that guide their regulatory activities. The Office for Product Safety and Standards works to support the effective implementation of the Regulators' Code.

The Regulators' Code is a framework for how regulators should engage with those who they regulate and provides the following principles: [28]

[28] www.assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/300126/14-705-regulators-code.pdf

The Principles of The Regulators Code[29]

1. Regulators should carry out their activities in a way that *supports* those they regulate to *comply and grow*.
2. Regulators should provide simple and straightforward ways to *engage* with those they regulate and hear their views.
3. Regulators should base their regulatory activities on risk.
4. Regulators should share information about compliance and risk.
5. Regulators should ensure *clear information, guidance and advice* is available to *help those they regulate meet their responsibilities to comply*.
6. Regulators should ensure that their approach to their regulatory activities is *transparent*.

New Zealand's Regulatory Stewardship which forms part of "Government Expectations for Good Regulatory Practice" is a statutory obligation for all departments to adopt a whole-of-system, lifecycle view of regulation, and taking a proactive, collaborative approach, to the monitoring and care of the regulatory system(s) within which they have policy or operational responsibilities.

This regulatory stewardship role includes responsibilities for:

- monitoring, review and reporting on existing regulatory systems
- robust analysis and implementation support for changes to regulatory systems, and
- good regulatory practice.

The efforts by Canada that resulted in the Safe Food for Canadians Act and the Safe Food for Canadians Regulations (SFCRs) is a recent example of an approach to modernizing the overarching food safety system. The legislation consolidates food provisions now administered and enforced by the Canadian Food Inspection Agency (CFIA) under four statutes into the Safe Food for Canadians Act to strengthen oversight of food commodities being traded inter-provincially or internationally. The Act focuses on three important areas:

- Improving food safety oversight to better protect consumers;
- Strengthening and streamlining legislative authorities;
- Enhancing international market opportunities.

The SFCRs are a series of outcomes-based regulations intended to make the whole food regulatory system agile, especially the monitoring and enforcement requirements. Supporting the SFCRs the CFIA is rolling out a series of non-regulatory initiatives over the coming years to consolidate the modernisation program. This includes an integrated risk-management scheme derived from greater use of data and surveillance, and a digitisation of the system to ensure that both regulators and the regulated are leveraging the best available technology.

Canadian Food Inspection Agency's move towards a more preventive and systems-based approach under the integrated Agency Inspection Model enables them and regulated parties to more readily adapt to emerging risks and global and scientific trend.

[29] The Regulator's Code is likely to be updated soon.

The CFIA's integrated Agency Inspection Model will apply globally recognized risk management concepts based on prevention. The guiding principles include systems-based, performance-based and risk-based approaches that are:

- founded on science and based on risk, and that use common inspection procedures and tools;
- aligned with international standards, such as those developed by *Codex Alimentarius Commission* (Codex), the International Plant Protection Convention (IPPC), and the World Organisation for Animal Health (OIE);
- based on the premise that industry is responsible for its products and processes and must demonstrate ongoing compliance with legislative requirements;
- flexible, to accommodate the complexity and size of an operation; and
- supported by information management / information technology (IM/IT) solutions that will facilitate planning, reporting and decision making.

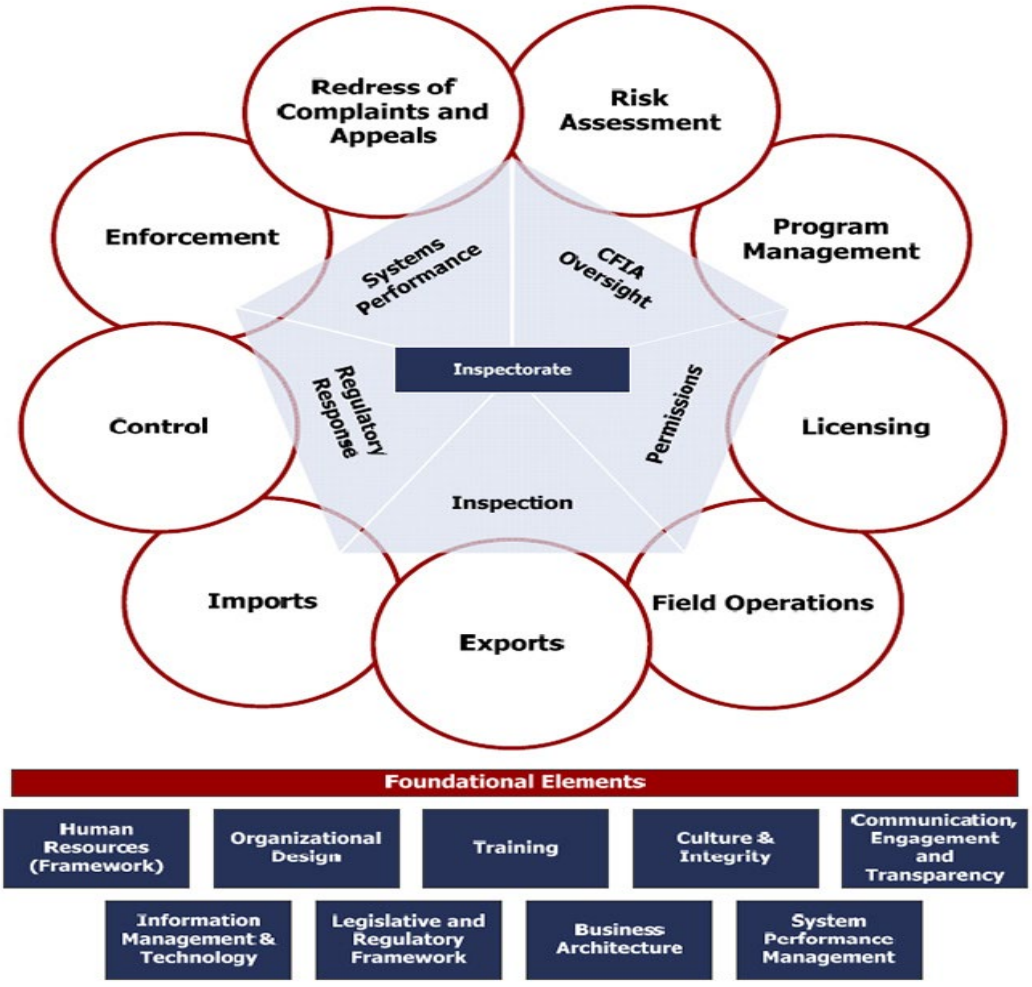

Figure 6: CFIA's integrated Agency Inspection Model

The Organization for Economic Cooperation and Development (OECD) has developed a guideline for Regulatory Enforcement and Inspection and is an overarching framework to support initiatives on improving regulatory enforcement through inspections, making them more effective, efficient, less burdensome for those who are inspected and at the same time less resource-demanding for governments. The principles address the design of the policies, institutions and tools to promote effective compliance – and the process of reforming inspection services to achieve results. The principles include:

- **Evidence based enforcement** - deciding what to inspect and how to inspect should be grounded on data and evidence, and results should be evaluated regularly
- **Selectivity** - Promoting compliance and enforcing rules should be left to market forces, private sector and civil society actions wherever possible: inspections and enforcement cannot be everywhere and address everything
- **Risk and proportionality** - the frequency of inspections and the resources employed should be proportional to the level of risk
- **Responsive regulation** - inspection enforcement actions should be modulated depending on the profile and behaviour of specific businesses
- **Long term vision** - clear objectives should be set and institutional mechanisms set up with clear objectives and a long-term roadmap
- **Co-ordination and Consolidation** - less duplication and overlaps will ensure better use of public resources, minimise burden on regulated subjects, and maximise effectiveness
- **Transparent Governance** - Structures and policies should support transparency, professionalism, and be results-oriented. Execution should be independent from political influence, and compliance promotion efforts should be rewarded
- **Information Integration** - Information and communication technologies should be used to maximise risk-focus, coordination and information-sharing – as well as optimal use of resources
- **Clear and Fair Process** - coherent legislation needs to be adopted and published, and clearly articulate rights and obligations of officials and of businesses
- **Compliance Promotion** - use of appropriate instruments such as guidance, toolkits and checklists
- **Professionalism** - Inspectors should be trained and managed to ensure professionalism, integrity, consistency and transparency
- **Reality Check** - should deliver the performance that is expected from them – in terms of stakeholder satisfaction, of efficiency (benefits/costs), and of total effectiveness (safety, health, environmental protection etc.).

In the Australian context, the Implementation Subcommittee for Food Regulation (ISFR) is a subcommittee established by FRSC to support it in its purpose of ensuring a nationally consistent approach to the implementation and enforcement of food standards. Its primary task is to promote and facilitate consistent, bi-national (where applicable) approaches to implementation of compliance with and enforcement of the Australia and New Zealand Food Regulation System. While ISFR has produced several guidance documents for the implementation of standards, they are product/technology specific. The regulators can certainly benefit from the creation and administration of codes of practices outlined earlier which would provide guidance on regulatory delivery methods and approaches.

Surveys conducted with the regulators suggest several bureaucratic challenges with the governance structure of the System. For example, queries raised during ISFR implementation of standards at times require policy considerations and referral to FRSC and when this happens, there is a delay in the time it requires to resolve issues and at times issues may fall off the radar due to FRSC's crowded agenda. IFSR being a volunteer group may not be adequately equipped and structured to administer its role and responsibilities fully.

ISFR does not have direct access to the stakeholders and while IFSR support and guidance has been found to be appropriate but not consistent as a result of it not having direct access to the stakeholders. From a roles and responsibilities standpoint, many regulators feel that FSANZ is best placed to provide guidance on the interpretation of standards. However, they believe that FSANZ should provide interpretations of the Standard, in association with ISFR, to meet the needs of industry and regulatory stakeholders and effectively administer its responsibilities.

Australia has the distinct advantage of an already established and functioning governance structure designed to develop and maintain regulatory codes of practice. In this context, ISFR could play a greater role in providing guidance and direction in that regard without necessarily dictating the powers and responsibilities of jurisdictional regulators. A framework for consistent implementation of standards can be agreed at ISFR the implementation of which can ultimately be the responsibilities of jurisdictional regulators.

4.2 Practices

Practices that agencies need in order to deliver societal outcomes:

1. *Outcome Measurement* covers the need to identify the outcomes on which the agency is focused and to monitor and report against them.
2. *Risk-based Prioritisation* is the mechanism for allocating (scarce) resources to priority areas at strategic, operational, tactical and targeting levels, using risk as the ‘currency of regulation’.
3. *Intervention Choices* involves the ability to select and implement appropriate means to mitigate risks including through understanding of the awareness, capability and motivation of the regulated and of the beneficiaries.

4.2.1 RDM Practices - Outcome Measurement

Measures such as the number of inspectors; inspection levels or frequencies; the numbers of prosecutions or other sanctions; when taken as proxies for outcomes, have a perverse effect. They encourage a focus on quantity over quality and incentivise poor choices.[30]

The OECD, in its best practice principles for regulatory enforcement,[31] suggests that 'improvements in the number of businesses that are "broadly compliant" with the requirements should be used only as a complement to outcome indicators'.

The UK Office of Product Safety and Standards provides an example of a logic modelling approach for measuring outcomes and impacts as shown in the figure below.

Inputs	Activities	Outputs	Outcomes	Impacts
Legal mandate: **Powers to enforce**	Advice and guidance activities	Information and guidance documents	Improved compliance	Stronger market for 'sustainable' timber
Competent staff	Developing compliance tools for businesses	Tailored advice delivered	Confidence and certainty in business community	Reduced illegal logging and deforestation
Technical expertise	Training businesses	Businesses trained	A level playing field for UK businesses importing timber	Improved governance in timber supplying countries
Funding	Verifying licences for timber imports	Licenced timber enters the country	More responsible business practices in sourcing timber	Conservation and safeguarding of biodiversity
Data and intelligence	Inspections and other checks on compliance measures	Sanctions for non-compliance	Consumer confidence in UK timber products	Reductions in CO2 emissions

[30] G Russell and H Kirkman, 'Outcome Measurement' in G Russell and C Hodges (eds), *Regulatory Delivery* (Hart, 2019).

[31] 'Regulatory Enforcement and Inspections, OECD Best Practice Principles for Regulatory Policy' (OECD, 2014).

-	Receiving allegations of non-compliance	Regulatory reports	-	-

Figure 7: Office of Product Safety and Standards logic model for measuring outcomes and impacts

Whatever be the approach selected by the regulatory agency, the key lines of inquiry should consider:

- Impacts and outcomes that are appropriate for the set regulatory objectives
- Measure the culture of the regulators and regulated entities
- Measure its direct and indirect impact on the performance of the regulated entities
- Reflect the entire food system including the supply chains

The importance of setting appropriate regulatory objectives has been discussed earlier in Section 3.2.1.

4.2.2 RDM Practices - Risk Based Prioritization

Risk is defined as combination of the probability of harm and severity of harm (ISO Guide 51). Regulatory agencies are generally understood to be the overseers and custodians of public risk which is understood as the full range of potential public harms, arising from voluntary or involuntary activities, from which the public expects protection while ensuring public good (UL 2984) (See Figure 7).

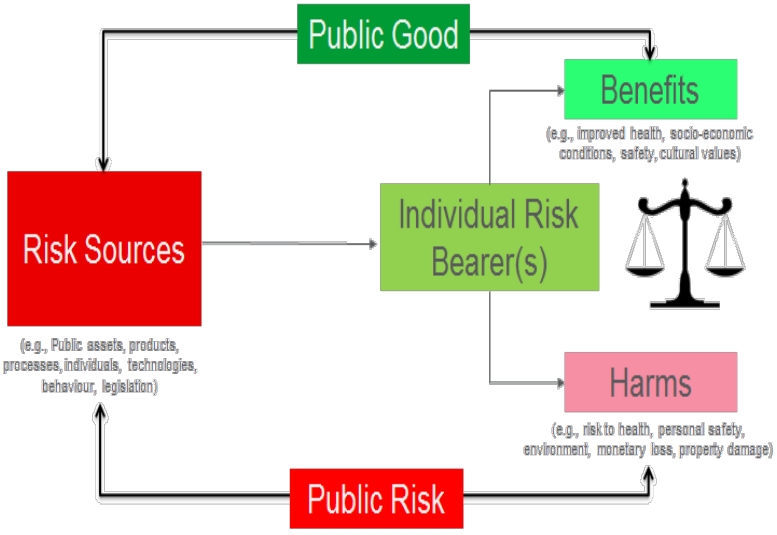

Figure 7: Risk assessment model

In the regulatory delivery context, risk-based decisions include:

- setting rules and expectations (e.g., laws and regulations);
- determining the degree and level of regulation
- Priority setting (e.g., identifying government priorities/policies);
- Resource allocation (e.g., inspections, audits);
- Oversight and enforcement (e.g., compliance management);
- Prosecutions;
- Public reporting (e.g., independent audits, third-party reviews, public interest watchdogs); and

Organizations such as regulatory agencies whose primary responsibility is public risk management should demonstrate that their resources are focused on addressing identified public risks for which they are responsible.

In addition to traditional approaches to conducting risk assessments, it is important to consider culture risk as part of the overall risk assessment. Culture risk is the likelihood that individuals and teams in a business will behave ethically (or not) and as discussed in Section 5 can arise in many ways. This is relevant not just on a daily basis in a 'steady state' but especially when the circumstances give rise to pressures on the humans or organisation involved, such as financial distress or to obtain what is perceived to be a short-term gain at the risk of unethical action and possibly long-term damage.

Several methods for risk assessment are available and are being used by regulatory agencies worldwide but when applying it to the proposed model, some of the key lines of inquiry should:

- Include evidence and data that measures "culture risk" and that reflects the culture and business practices of the regulated entities and their impact on both the components of risk (likelihood and consequence)
- Involve analysis that represents an appropriate balance of compliance risk and culture risk
- Account for the presence and effectiveness of not only its own intervention choices but also those of the regulated entities
- Assess the amount and types of "Cultural Entropy" or dysfunction in the organisation.

CAN/UL2984:2019 National Standard of Canada: Standard for Management of Public Risks–Principles and Guidelines also provides guidance for regulators to develop and implement standardized risk-based prioritization methods. Using standards such as UL 2984 will ensure that risk assessments are applied consistently by both national and sub-national regulators. Several regulatory agencies in Canada are beginning to formally adopt and apply UL 2984 as means to ensure such consistencies.

CFIA's integrated risk management model is a good example of how data, reports and surveillance are used to identify trends, allowing them to focus on risk and support program design, planning, compliance and enforcement efforts. In particular. CFIA's peer reviewed Establishment-based Risk Assessment (ERA) model for food establishments is a tool developed to evaluate food establishments based on the level of risk they represent to Canadian consumers. The ERA model uses data and a mathematical algorithm to assess the food safety risks of food establishments under CFIA jurisdiction. It takes into consideration risks associated with a specific food commodity, operation or manufacturing process, mitigation strategies

implemented by the industry to control their food safety risks, as well as establishment compliance information.

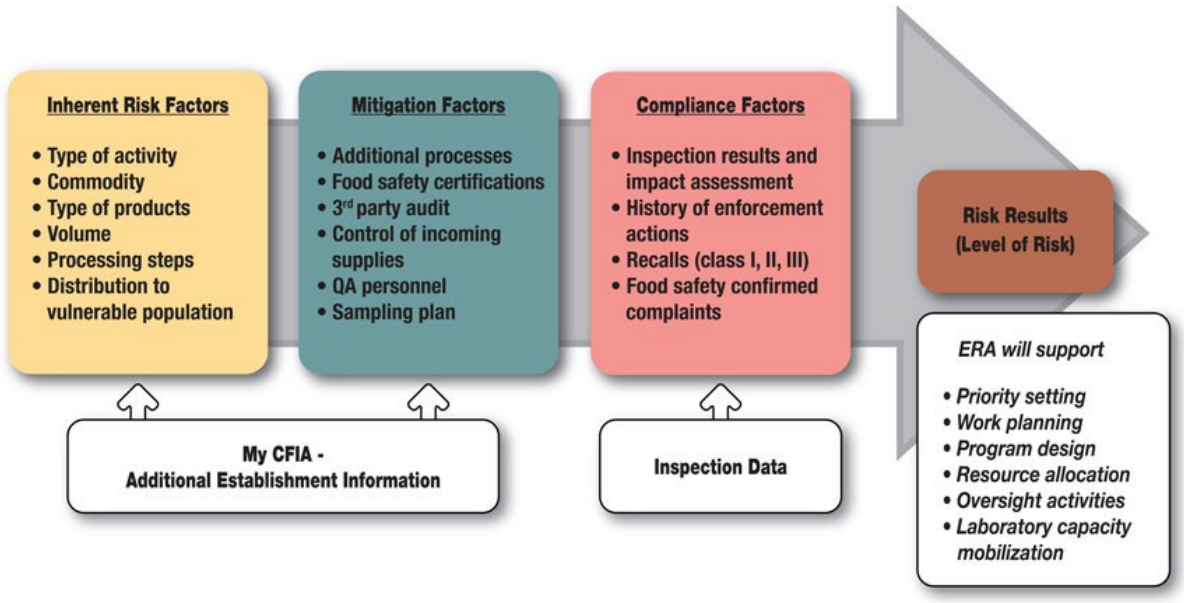

Figure 8: CFIA Establishment-based Risk Assessment model

For measuring culture risk or cultural entropy, Cultural Transformation Tools (CTT) have been used globally to map values and measure their distribution across all levels of needs that an organisation or group must master in order to achieve its potential and serve its stakeholders. The first three levels focus on the basic needs of business; the fourth level is focused on growth, change and adaptability and the focus of the upper levels is on the common good. The common good is characterised first by organisational cohesion, the ability to build mutually beneficial alliances and partnerships and to safeguard the well-being of society and the planet.[32] This mapping then forms the basis for a conscious programme of culture change towards a desired set of values and behaviours underpinning a healthy culture.

4.2.3 Technology and Data as Enablers

As regulators embark on risk-based approaches, they will need to make informed decisions based on a comprehensive knowledge of the types and nature of the regulated environment especially when dealing with emerging economies of the future such as the aforementioned technologies.

Risk Assessment is fundamentally reliant on the use of good-quality and relevant information. Within RDM, the examination of the practice of risk-based prioritization involves a careful

[32] Barrett, above, 68.

consideration of how regulatory agencies are gathering, accessing and analyzing data, information and intelligence in order to make informed assessments of regulatory risk at all levels.

The task of regulatory agencies is often expressed in terms of mitigating risk or ensuring compliance with regulation. It fundamentally involves designing and executing interventions based on *evidence and commensurate to the levels of risk*. Technologies can play a significant part in establishing the necessary evidence for estimating risk and informing regulators to help set priorities and make intervention choices. Digitizing regulatory delivery is therefore an essential evolution of the regulatory decision-making processes that needs to take place.

Digital technologies offer tremendous opportunities for regulators to more closely monitor compliance and have regulatory solutions better tailored to risks. This would enable more efficient and effective outcomes across the main regulatory activities[33]:

- Improving regulatory quality - The use of technologies such as AI, and the growing uptake of open data, as well as social media enable regulators to collect timely information, conduct analysis and engage with stakeholders when developing coherent policies. Digital technologies can also replace or complement traditional compliance enforcement methods and support policy evaluation.

- Communication and compliance education - Technology could improve the information available to individuals and businesses on their compliance obligations. Information may also be better tailored to individual circumstances or characteristics and disseminated in a more accessible and/or timely manner.

- Inspections - Increased connectivity combined with some of the emerging technologies like IoT, drones etc. could increase the use of real time remote monitoring.

- Enforcement - New technologies could also be used to facilitate enforcement strategies, such as automated warnings or the remote disabling of services

- Risk-based assessment - Increased data collection and analytics could allow more targeted inspections through better assessment of the risks posed by classes of businesses, as well as particular entities.

While the use of digital technologies for regulatory delivery has been extensively captured in other studies[34][35], some examples are provided below that demonstrate the role of technologies and the value of collaborative partnerships in harnessing data for risk-based and informed regulatory decision making. In addition, the concept of data trusts is also discussed who could play the role of intermediaries as stewards of data.

[33] OECD and Prism Institute, "Digitizing Regulatory Delivery using Emerging Technologies – A Review of Current Practices", 2020 (Forthcoming)

[34] The World Bank Group, "Internet of Things – The New Government to Business Platform", 2017.

[35] The World Bank Group and Prism Institute, "Use of New Technologies for Regulatory Delivery – Summary Note and Case Studies", Donor Committee for Enterprise Development (2019).

4.2.3.1 *Canadian Food Safety Information Network*

The Canadian Food Safety Information Network (CFSIN) is a federal initiative that will better anticipate, detect and respond to food safety events and emergencies, by connecting and coordinating federal, provincial and territorial (FPT) food safety and public health authorities.

CFSIN is led by the Canadian Food Inspection Agency (CFIA) and delivered in collaboration with

- The Public Health Agency of Canada
- Health Canada
- Provincial and territorial partners

The vision and objectives of CFSIN were formed following a 2008 outbreak of listeriosis that tragically claimed the lives of 22 Canadians. Following the outbreak, the Government of Canada appointed an independent investigator, who recommended the establishment of an integrated FPT (Federal, Provincial and territorial) network to better respond to future food safety emergencies. This network will create a shared food safety data repository, analytical tools to identify emerging issues, and provide a platform for partners to share information and resources securely and quickly during food safety incidents and emergencies. Greater sharing and analysis of data will improve the identification of food safety issues. When issues do arise, rapid alerts and early warnings will mean CFSIN partners can take quick and coordinated action to help reduce the impact of outbreaks. These tools will strengthen the ability of food safety authorities to work together for a better protected food supply across Canada.

4.2.3.2 *Safe Food Queensland*

In Australia currently, Safe Food Queensland (SFQ) is moving towards a more flexible system of monitoring, using data supplied directly by food businesses that voluntarily monitor a number of verification points across the supply chain. They have realized that reliance on auditing and other relatively prescriptive processes to monitor compliance is expected to occur less and less over time. As a result, SFQ supports the use, where possible, of electronic supply chain verification systems that are supported by industry and that give a better overview of the complete food safety story. Flexibility in monitoring food safety outcomes is provided under the *Food Production (Safety) Regulation 2014*. Safe Food may monitor compliance with food safety schemes by one or more methods that are considered appropriate to the nature of the business engaging in the production of primary produce and the risks associated with the business.

4.2.3.3 Fisheries Queensland

Fisheries Queensland manages the sustainability and allocation of fisheries and forestry resources for all Queenslanders[36]. This is vital to create the basis for profitable businesses and enjoyable recreational fishing experiences for locals and visitors. The organization ensures fisheries remain sustainable and productive by monitoring, determining and controlling access and development as needed; providing education and enforcing fishing regulations to promote equitable access to fisheries resources; maintaining supplies of state-owned forest products and quarry materials to industry.

Queensland's commercial fishers operate regional businesses across more than 7000 kilometres of coastline, providing employment and fresh seafood to their local communities and overseas. Effective monitoring of these commercial fisheries is vital to ensuring healthy fish stocks that will support thousands of Queensland jobs, but current approaches are costly, time consuming, and prone to inaccuracies. Fisheries Queensland, through the *Sustainable Fisheries Strategy 2017-2027*, is committed to improving monitoring and research for fisheries management. Currently, most of the agency's monitoring data comes from commercial fishers filling out paper logbooks and calling an automated voice recognition system to report on quota. These approaches are costly and time consuming for government, but also place considerable burden on the fishers.

The cutting-edge solutions that Fisheries Queensland are exploring have the potential to almost completely eliminate this burden, while providing with accurate, real-time information needed to effectively manage Queensland's fisheries. Through the Advance Queensland Small Business Innovation Research (SBIR) program, the agency is working with two innovative start-ups to develop cutting-edge systems which can track fishing activity and location, as well as use cameras, sensors and machine learning to automatically recognise the types and quantities of fish caught and discarded.

4.2.3.4 UK Food Standards Agency

The UKs Food Standards Agency (FSA) seeks to utilise data, analytics (and their associated technology and capabilities) to enhance its 'situational awareness', and inform its strategy, policy, and the operational activity of various other regulatory actors at the national and local level. Working in collaboration with other parts of government (local and national), academia and industry the FSA has created a strategic surveillance capability, which identifies real-world issues and data sources, and then creates analytical models that generate new insights. These insights are validated, so that risk can be predicted, and the insights can enable data informed decisions for intervention. Where appropriate, products and services have been created. For example, a Risk Likelihood Dashboard[37], which flags potential and emerging food and feed safety risks in terms of commodity, country of origin and hazard, or the digital service for dairy hygiene inspectors, which improves the capture of inspection results.

[36] Prism Institute, "Risk Based Regulatory Delivery –Review and Toolkit of Modern Practices: Report to Transport Canada", 2017

[37] https://www.food.gov.uk/sites/default/files/media/document/fsa-20-01-05-annual-surveillance-report-_1.pdf

The FSA has sought to develop a risk model to determine the nature, frequency and intensity of official controls. It has explored whether advanced Artificial Intelligence (AI) deep learning techniques can be used to determine the risk profile of any food business establishment. To manage stakeholder concerns as to the appropriateness, fairness or transparency of the initiative, the FSA has aligned with the Data Ethics Framework published by the Alan Turing Institute[38] as a guide for the use of AI within the UK public sector.

The FSA is tackling Authenticity, by working with industry to explore whether blockchain technologies could be used to ensure a robust, digitally traceable farm to fork process. Two pilots in the meat sector have been successfully completed to date[39].

The FSA is addressing issues around data access and consumer trust with regard to the use of data-enabled decision making through the concept of 'Data Trusts'[40]. Data Trusts are relatively new, and how they are defined and operate is still developing. A common definition is that a data trust provides independent, fiduciary stewardship of data.

Working in partnership with others, the FSA is seeking to provide a 'digital collaboration framework' for food safety[41]. It is hoped that the establishment of such trusts will persuade all parties active within the food data ecosystem to share data, in recognition of the mutual benefit to all, be they consumer, regulator, or business. Encouragingly, established organisations such as NSF[42] are exploring how they can support the concept. NSF, for example, are leveraging recognition of their audit/assessment/compliance role as a trusted intermediary in being able to hold suppliers' confidential data without giving away commercially sensitive information to competitors.

In the Australian context, the following text box provides an illustrative scenario demonstrating the application of risk and data using the above-mentioned approaches.

Future scenario: An extreme weather event (e.g. drought, bush fires, typhoon) has put pressure on the production of certain agricultural commodities. This pressure may create the conditions for illegal activity, with implications for food authenticity and safety, e.g. undisclosed replacement of more scarce/expensive ingredients with cheaper, untested ingredients, without concern for consumers with specific food sensitivities.

The application of machine learning and other advanced data analytical practices, (all of which are published, and operated within a transparent governance framework) to multiple data sources (e.g. trade data, historic regulatory activity, health, data covering criminal activity (prosecution/police data)) by a regulator, academic body or commercial organisation identifies signals/anomalies. These are investigated by data scientists and regulatory experts to identify new risks and/or changes to profile of existing risks (such as adulteration of commodities by criminal gangs to maximise profit).

[38] https://www.turing.ac.uk/sites/default/files/2019-06/understanding_artificial_intelligence_ethics_and_safety.pdf

[39] https://www.ledgerinsights.com/food-watchdog-fsa-blockchain-pilot/; https://www.innovationnewsnetwork.com/using-blockchain-in-the-global-food-industry/4466/

[40] https://theodi.org/article/what-is-a-data-trust/

[41] https://www.foodchain.ac.uk

[42] https://www.nsf.org

This risk is assessed using an established and agreed risk framework. The framework is maintained under established governance arrangements and ensures the consistent identification, assessment and articulation of risk across all regulatory bodies. The risk framework maps the impact of the occurrence, identifying, for example, likely impacted products, particular ports and transportation patterns, manufacturing processes (and thereby specific operators), susceptible markets (in terms of geography, i.e. specific States or regions) and consumer groups with particular health concerns.

Once identified, the relevant stakeholders can be notified of this increased risk. Communications of key messages can be automated across some stakeholder communities using predetermined communication channels and protocols.

With the risk identified, categorised and communicated according to agreed, consistent criteria, the regulating community can focus on how this information informs its regulatory interventions. For example, a clear focus on engaging with key impacted parties, e.g. particular producers, manufacturers, consumer groups etc, to raise awareness, agree mitigation activity and monitoring. Crucially, this engagement, though occurring at local and national level, and across the sector, can be consistent, based as it is on consistent intelligence, risk management and communications. Moreover, this engagement is based on an agreed framework for Ethical Business Practice (EBP). The regulatory community, already trained in EBP methods, can follow agreed processes and templates to guide discussions.

This approach provides for:

	Benefit derived:	**Achieved through…**
√	**rapid/pre-emptive identification of risk to the food ecosystem, and/or rapid, consistent response to emerging issues.**	either in-house, outsourced or hybrid data science function to utilise machine learning/AI etc.
√	**predetermined and agreed use of data by all parties, including data sharing and processes flowing from insights from analysis.**	established data trusts/data cooperatives.
√	**consistent definition and articulation of risk for all parties across the food ecosystem, based on transparent methodology for identifying and assessing data, risk assessment criteria and processes.**	A defined, universal risk management framework, which is managed through governance body with representatives from regulators and industry. Common reference materials/templates, training etc.
√	**consistent, rapid and tailored communications across all parties.**	A defined communications process, with clear roles and responsibilities. Agreed communication protocols, channels, templates.
√	**consistent, but tailored intervention strategies for specific markets, producers, consumer groups.**	Regular stakeholder segmentation and analysis performed by governance working group. Analysis incorporates risk

		profiles, informed by engagement activity and assessment of compliance and ethical behaviour.
√	**consistent, automated processes for risk identification, evaluation and communication enable greater allocation of regulatory resources on how the food sector responds, and consistent engagement with stakeholders, and assessment of their performance through application of an agreed ethical business process framework.**	In addition to a defined, universal risk management framework, an agreed ethical business process framework, which is managed through governance body with representatives from regulators, industry, consumers. Common reference materials/templates, training etc.
√	**continuous improvement of effectiveness and efficiency of regime, assessed by governance with performance published on regular basis.**	Process of post-event reviews overseen by existing governance mechanism. This ensures lessons learned are fed back into the process, for example, revising risk criteria, improving communication protocols and channels, identifying additional data sources.

4.2.4 RDM - Intervention Choices

A traditional view would be that a regulator achieves compliance by imposing enforcement sanctions after breaches of the rules, on the assumption that that will deter future non-compliance. However, extensive evidence from behavioural science and empirical studies now forms the basis of a different approach.

The starting point is realisation that the task of a regulatory authority, in fulfilment of its Purposes, is fundamentally about *changing the behaviour* of regulated entities, and sometimes users. The question for a regulatory agency is therefore what will be most effective in ensuring the desired behaviour amongst those it regulates.

The scientific evidence-based approach establishes the following propositions:[43]

(a) There is little evidence to suggest that the theory of deterrence has much effect on behaviour – and certainly not the detailed effects that are desired. A repressive strategy of imposing more or higher fines on companies will *not* in fact produce greater compliance.
(b) Many humans do not make decisions or take actions based on rational thought but act automatically and subsequently justify their actions to themselves. It is advantageous to provide opportunities for time to reflect on actions before taking them and for challenge to thinking.

[43] C Hodges, *Law and Corporate Behaviour: Integrating Theories of Regulation, Enforcement, Culture and Ethics* (Hart Publishing, 2015). A theory that decisions will be made on the basis of an evaluation of benefits exceed costs presupposes that that is the mechanism by which humans reach decisions (whether all or some decisions), and that all actions are based on rational analysis of available evidence. Much behavioural science establishes that human mechanisms for acting are frequently neither rational nor involve cost-benefit analysis.

(c) Use of excessive force on people who think they are trying to obey the law has been shown to reduce general willingness to comply with any rules in future. People react badly to things they think are unfair.
(d) Adopting an evidence-based scientific approach to understanding and affecting human actions will be a more effective strategy than imposing sanctions after-the-event. Many individuals and (especially small) businesses may not be able to focus on detailed requirements or compliance issues, may misunderstand or not be aware of what they need to do, or not have the resources to comply. It is often the case that well-intentioned people lose sight of ethical issues when they are crowded out by other priorities (e.g. meeting targets or maintaining the success of their group).
(e) The *culture* of an organisation (especially whether it is ethical, open and transparent, listening and responsive) has a major impact on behaviour and decisions. Approaching behaviour through culture rather than through trying to ensure compliance is far more effective.

A fundamental question is to determine *why* rules are being broken, what particular types of non-compliance might be widely observed, and which particular individuals or organisations cause risk. The answers to those causation issues provides both the means of responding effectively to changing relevant behaviour and culture, and to reducing risk and achieving desired outcomes. This thinking leads to focusing on the *awareness, motivation and capacity* of those subject to regulation. That focus was highlighted in an OECD report that categorised three reasons for non-compliance:[44]

- The degree to which the target group *knows* of, and *comprehends* the rules;
- The degree to which the target group is *willing* to comply; and
- The degree to which the target group is *able* to comply with the rules.

A similar categorisation quoted in the RDM shows how accurate identification of the reason for non-compliance determines the selection or design of interventions that are appropriate to reducing future risk and changing behaviour in the circumstances.

[44] *Reducing the Risk of Policy Failure: Challenges for Regulatory Compliance* (OECD, 2000).

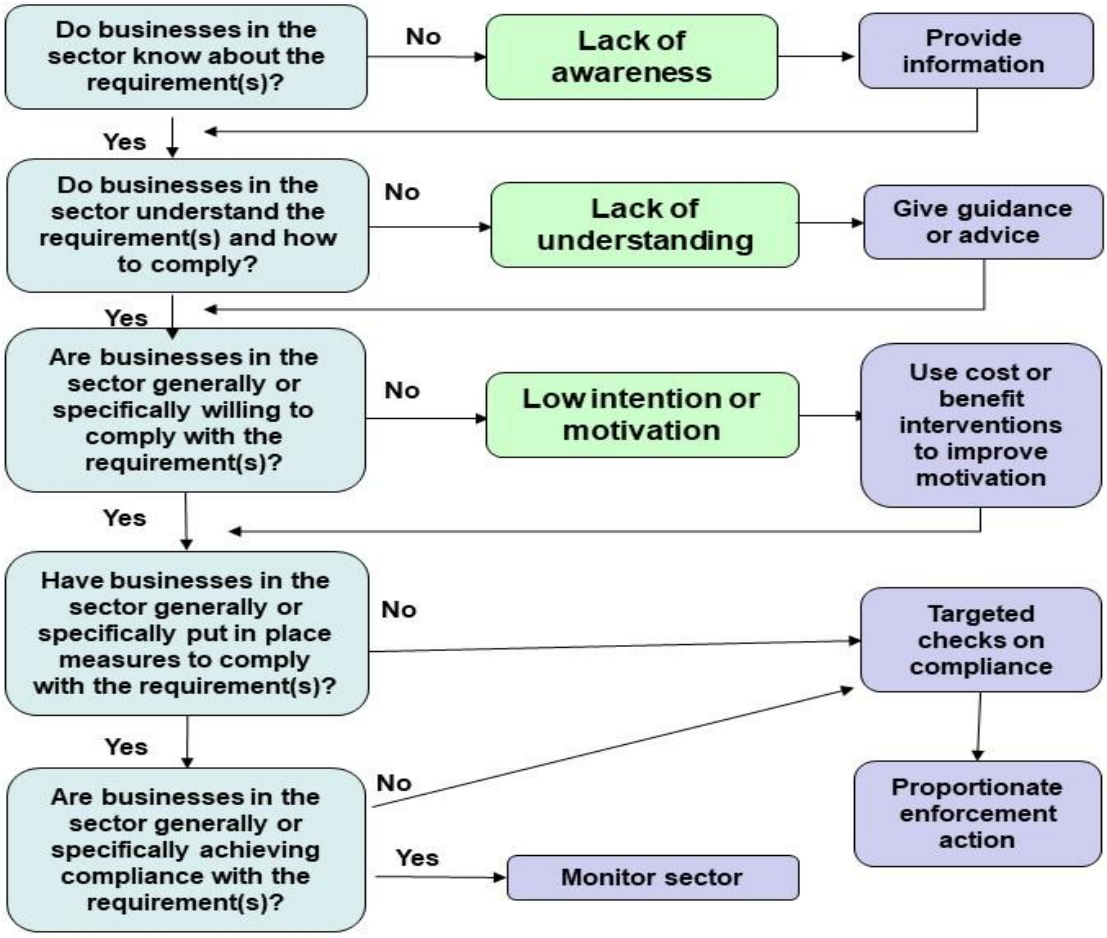

Figure 9: RDM Model for assessing non-compliance

Aiming to protect society and achieve the basic regulatory Purposes therefore focuses on changing human behaviour, basing the regulatory responses on the scientific evidence and insights into the reasons for non-compliance and how best to address the behaviour of individuals in regulated entities and the cultures of such entities. The effective regulator needs to be able to have a (significant) number of means of *intervening* in how things are done, selecting intelligently from a well-stocked toolbox of intervention tools so as to fit the circumstances. It is significant the RDM does not talk of 'enforcement' but of 'regulatory intervention' and regulators making *intervention choices*. Similarly, the concept of 'deterrence' is usually unhelpful. Used effectively, understanding of the awareness, capability and motivation of the regulated and of the beneficiaries enables a new breadth of potential resolutions which empower action and multiply impact.

An example of segmentation of non-compliance based on motivation of the offender and linked to differentiation of response is below:

Figure 10: Scottish Environment Protection Agency Enforcement Continuum

Interventions can occur before or after instances of breach are identified and should in fact be evaluated continuously. A wide range of interventions are available to most regulatory agencies that can be used in conjunction with or as alternatives to traditional licence, inspection or investigation-based approaches. These might include for example, initiatives to raise awareness and understanding of requirements amongst those they regulate; oversight of industry compliance initiatives; and initiatives to empower the beneficiaries of regulation, particularly those most at risk. Where a regulatory agency uses a narrow range of interventions, it is less likely to be effective. Comparisons and choices between interventions should be based on evidence of the effectiveness of different intervention strategies – whether these have been previously used by the regulatory agency itself or by other regulatory agencies.

4.2.4.1 Segmentation by Ethical Culture

A regulatee who practices EBP and relates to the regulatory agency through an EBR relationship, should be motivated to work spontaneously, and with the agency, to do the right thing, so that formal intervention steps may be unnecessary. The most efficient intervention by an authority is where a business volunteers, or agrees, to make changes to prevent occurrence of harm and to reduce future risk (in other words, to address all of the aspects in the circular problem-solving model outlined above). This spontaneous behaviour can be incentivised and encouraged by an agency adopting policies based on cooperation and ethical behaviour, such as making clear in a published enforcement policy that certain behaviour will be considered as mitigating factors (or conversely, aggravating factors) in considering interventions and sanctions. It can also be institutionalised in relationships and agreements, such as under the Primary Authority scheme discussed above.[45]

Businesses that adopt EBP and engage in EBR partnerships with regulators provide a basis for market segmentation between them and those businesses that do not demonstrate either an intention to, or a verified history of, 'doing the right thing'. That segmentation will have direct consequences where regulatory responses to non-compliance or harm occur. It will also enable culture-compliant businesses to be considered as low cultural risk, effectively partners in self-regulating through culture and the constant production of verifiable evidence of such culture, and hence to require less resource in inspections or other surveillance activities.

[45] See *Guidance on Primary Authority* at www.gov.uk/guidance/local-regulation-primary-authority

4.2.4.2 Using EBR to Affect Behaviour

Regulating through Culture, with EBR, provides a significantly enhanced means of changing behaviour and reducing risk. An EBP business should represent lower intrinsic risk than non-EBP businesses as a result of its consistent culture of commitment to 'doing the right thing'. In particular, an EBP business should be able to raise a problem at an early stage, cooperate in analysing the root cause of a problem and in risk-assessment, and in implementing corrective action to reduce future risk and to take restorative action to mend retrospective harm. The basic distinction is between acts that are intentionally and unintentionally ethical.

Intervention policies (traditionally known as enforcement policies) should distinguish between entities that demonstrate evidence that they can be trusted and take their responsibilities seriously, and those that do not. An intervention policy should then list the types of aggravating and mitigating factors that they will consider in deciding what level of enforcement response they should take to infringements and what seriousness of sanction might be appropriate. In some cases, a business that takes all of the above steps and, for example, voluntarily makes redress payments to customers, staff or suppliers, or to repair the environment, has been considered to deserve no extra financial sanction. Implementation will, of course, be monitored and breach at that stage can be regarded as serious.

If the motivation for the harm is intentional (i.e. the wrongdoing is criminal) then strong public sanctions will be entirely appropriate. That is clearly now a rare occurrence in aviation safety. In other situations, it is important for responses by regulatory authorities, employers, professional bodies, the public and the media accurately distinguish between ethical and unethical motivations in responding to harm, and do not seek to blame, or impose deterrent punishment on people who were trying to do the right thing.

The regulator has to possess an enforcement toolbox that contains a wide range of powers, and the discretion to select the tools that are appropriate and proportionate for the task. The powers can start with the ability to obtain information (investigation, review of data from and systems of businesses), require certain actions to be implemented (make improvements, make redress), and end with imposing fines, imprisonment or removal of licence to operate. The statement of what is in the toolbox is simple. What is far more important is to know which tools should be used in what circumstances. Here, there has been a change in understanding and practice. The classical binary model mandates a particular penalty as a response to a particular offence. It is a robotic system, leaving no discretion to the enforcer to respond to the situation, intent or history of the infringer.

To guard against arbitrariness, capture or corruption, this flexibility has to be governed by safeguards, such as a written enforcement policy that states the objectives of enforcement (achieving compliance or imposing punishment), fair processes, aggravating or mitigating factors that will be taken into account as (e.g. that evidence of ethical motivation and steps to minimise the risk, to make reparation and to prevent future risk) and public transparency and oversight. UK regulators typically possess a wide range of civil and criminal sanctions, hence with some being reserved for courts. In selecting the response to breaches, an example of a simple segmentation approach to individuals is that of the Scottish Environmental Protection Agency shown in the Figure 13. One would now expand that classification into considering the

historical evidence of ethical culture or its absence in an organisation, as outlined in this document.

4.2.4.3 *Examples of Progressive Intervention Approaches*

Dairy Food Safety Victoria has introduced Dairy RegTech which is a different way for DFSV to monitor food safety compliance, with a greater focus on people and behaviour to encourage improvement. Dairy RegTech supports DFSV's efforts to safeguard public health through a robust regulatory framework. This approach recognises that food safety systems depend on the people who implement them, and importantly the food safety culture of a business. While licensees who transition to Dairy RegTech will continue to undergo compliance audits, these audits will be targeted at areas that support better food safety practices and incorporate the other information gathered through Dairy RegTech. Transitioning to Dairy RegTech is voluntary for dairy manufacturers. It is not yet available for dairy farmers. Dairy RegTech allows a licensee's engagement with DFSV to be more constructive – licensees can celebrate the things about food safety they do well, and more easily identify risks and pathways for improvement.

Dairy RegTech uses two powerful resources – information about food safety performance combined with food safety culture – to drive performance, help prevent food safety incidents and provide a framework to guide continuous improvement for businesses. With a more proactive approach than the audit-only system, Dairy RegTech enables DFSV to identify potential issues earlier and support the licensee to address them. The food safety culture of a business is how everyone (owners, managers, employees) thinks and acts every day to make sure the food they produce is safe.

	Regular data to confirm food safety	Food safety culture
Overview	A more regular 'health check' of food safety systems. This allows DFSV to provide tailored support to dairy manufacturers to help them address potential issues before they disrupt production or create risks for consumers.	A focus on behaviours that strengthen food safety will generally prevent problems arising, but if they do occur, they will be dealt with faster and more effectively.
How it will operate in Dairy RegTech	○ Licensees regularly submit their food safety information via the **Dairy RegTech Portal.** ○ Licensees already collect the data they will submit to Dairy RegTech. It could include end product testing (microbiological testing), environmental monitoring, corrective action requests (timeliness of corrective action), and food safety training records. ○ DFSV will work with licensees to tailor what data they upload and how often to best fit with their existing business practices. ○ Through an individualised dashboard, licensees will be able to easily observe trends in the data and compare their	○ DFSV uses a 'food safety culture maturity model' that considers the activities, resources and traits which contribute to consistently high quality, safe food being produced. ○ It will identify strengths and areas for improvement in a business. ○ Licensees can see how their food safety score compares to the industry benchmark. ○ DFSV provides guidance and tools to help licensees improve their food safety culture. ○ Every 12 months, participants will have the opportunity to have their food safety culture re-evaluated.

	performance to industry benchmarks of food safety data and food safety culture scores. o This will make it easier for licensees and DFSV to monitor how production is responding to food safety challenges. o This will enable licensees to more easily identify areas for improvement. o DFSV will provide more regular feedback including about managing risk more effectively. o Auditors will look at this data including trends. This means audits will be more tailored and targeted, with less time spent manually checking records and more time discussing how to improve food safety culture and performance.	o · Improving everybody's understanding and appreciation of food safety, and their responsibility to maintain it, can help licensees make lasting improvements.

UK's Civil Aviation Authority which administers a performance-based regulation uses an approach called the State Safety Programme to ensure that industry can continually and safely develop innovative technologies while CAA aims to tackle the challenges of the future proactively. The overall management of the State Safety Programme (SSP) and the delivery of the UK aviation safety strategy is through the Safety Strategy Board (SSB). This is made up of senior representatives from the key aviation safety agencies. They are responsible for monitoring the safety performance of the UK aviation system and ensuring the state safety programme remains effective.

A key aspect of the SSP involves performance-based oversight (PBO). The PBO process allows Sector Managers from each capability area to use the information gleaned from oversight and other safety intelligence sources to build a single cross-capability risk picture, covering all operational aspects of each regulated entity. The outcomes of this approach include:

- Consistent gathering and analysis of safety risk information about all parts of an organisation's operations, captured in one place. PBR provides collated risks associated with each part of the organisation to enable them to be analysed together as a single regulated entity
- Effective safety oversight coupled with industry risk management provides confidence that safety risk controls are in place and effective
- Key aviation safety professionals and organisations reliably deliver what is expected of them
- Contribution to Better Regulation outcomes, for example through PBO, will help deliver proportionality of the oversight regime
- CAA achieves the best safety outcomes both current and future for the consumer with the resources available
- Robust and auditable safety decision-making to inform resource allocation
- Future oversight plans are tailored based on the latest assessment of an entity's safety risks and performance to help plans be proportionate and targeted.

The actions that result include:

- Support the CAA oversight teams to deliver, further refine and standardise the PBO process across the aviation entities it is applied to
- Design and deploy the mechanisms for incorporating risk information from simple, single privilege organisations into the PBO process
- Provide a central PBO planning function to create and maintain the sequence of cross-capability internal review meetings and ensure the right attendees and inputs are in place
- Lead on the continued development of the Entity Performance Tool that supports the PBO process
- As part of the PBR Total System, development of sector risk pictures and their integration into the RSMS with the aim of populating the 'Aviation Total Safety Risk' pictures.

The CAA is committed to engaging with the UK aviation industry to gather feedback on the introduction of performance-based regulation and the additional work needed to achieve the desired safety benefits. One of their innovative approaches involves their Inspectors being embedded in Airlines' Safety Management Committees. Inspectors therefore have high knowledge and confidence about the performance of those companies. This approach came out of a culture change programme, involving 18 secondees for 2 years.

The Canadian Food Inspection Agency's approach to accountability is based on the concept of a continuum. The compliance continuum is a relationship framework between the regulator (CFIA) and the regulated party(ies) in the context of regulatory compliance within the CFIA mandate. The purpose of the compliance continuum is to support the regulated party to comply with applicable legislation and when not in compliance, to guide them back into compliance. The compliance continuum is a circular model consisting of the following components: permission, compliance promotion, compliance verification (through standard inspection procedures), response to non-compliance, and recourse.

Figure 11: CFIA Compliance Continuum

Moving forward, the CFIA proposes to test the concept of Ethical Business Regulation with "champion" establishments/partners to explore a modified, shared risk relationship that encourages compliance and enhances information sharing. This initiative would provide

champion establishments with the opportunity to promote themselves as leaders in the industry, earning greater trust and credibility with the regulator, and consumers who place value on honest business practices. In addition, working collaboratively with regulators to provide insights and intelligence such as changes in innovation and technology in the sector could position the company as a leader and influencer in the industry-regulator relationship. As a result, both the regulator and regulated party would stand to benefit from this new relationship. Within two years, the CFIA will complete a pilot, as well as the analysis of results from it, which will help it to determine next steps.

The survey responses from Australian regulators suggests that their regulations provide them with the necessary intervention choices to affect the intended outcomes. Among the interventions include proportionate response to compliance and enforcement and the use of risk-based decision-making. However, they have also expressed a lack of awareness some of the modern and emerging tools like EBR and are very open to exploring new approaches to intervention and regulatory responses.

The future scenario provided in Section 3.3.1 involving the Primary Authority Model illustrates the means by which some of the discussed intervention choices may be implemented. The major shift that needs to happen when considering the proposed approach to selecting and executing intervention choices is moving from traditional compliance and enforcement approaches and focusing on measuring and improving the culture of regulated businesses. In considering this shift regulators should ensure that they:

- have a regulatory toolkit that is broad and encompasses mandatory and voluntary methods of intervention (including non-intervention)
- have the powers (mandatory and discretionary) to apply these tools commensurate with the overall risk (including culture risk) posed by businesses
- have the necessary 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 (e.g., look at alternate means of achieving compliance if inspections over time have not yielded the outcomes)
- select intervention choices based on a good understanding of the sector (avoid a one size fits all approach)
- are able to invest in and drive a culture of change within their departments including reskilling, capacity building and training operations personnel
- are open and willing to partner and collaborate with other regulators and the sector in collectively driving a culture of transparency and openness in achieving regulatory outcomes

4.3 Summary

Regulations must be delivered effectively for them to be attributed as being successful. Effective delivery will only lead to achieving the desired outcomes or identified regulatory objectives. As discussed in this section, a successful regulatory delivery model consists of three pre-requisites (governance, accountability and culture) and three practices (outcome measurement, risk-based prioritization and intervention choices).

Key recommendations to be considered in the context of Australia's modernization efforts include:

- ***The regulatory delivery governance framework should clearly identify the roles and responsibilities of each regulator associated with the regulatory system, their interactions with other regulators and industry***
- ***Ensure the consistent implementation of standards and food safety requirements by creating formal accountability structures (e.g., codes of practices); the regulatory delivery accountability framework should set measurable performance objectives for regulators, and provide direction to demonstrate consistency and transparency in their roles***
- ***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***
- ***In addition to leveraging technology for data collection, partnerships with industry and amongst regulators (e.g., data sharing agreements, joint inspections etc.) will help reduce uncertainty in risk assessments and increase consistency in risk-based decision making***
- ***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***
- ***Intervention choices should be designed to build and maintain trust with industry, consumers, governments and the public.***

5 Section IV - Conclusions

This paper prepared by Prism Institute experts lays out options for Australia to consider in its endeavour to achieve the following objectives, on the basis of the contemporary practices advocated by leading academics in the regulatory space and adopted by OECD and other countries globally.

- Creating greater consistency in the implementation of policies and standards at national and bi-national settings and with imported food
- Shifting from a highly prescriptive to an outcome-focused Model Food Provisions (MFPS)
- 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 innovations to respond to emerging trends and remaining at the forefront of best-practice regulation.

The paper specifically analyzes practices in regulatory design and delivery across various jurisdictions, especially the UK, Canada, New Zealand, Australia and elsewhere, and arrives at seven broad recommendations for Australia to consider in its modernization efforts.

Based on the vision and concepts set out in this paper, it will be necessary to engage in an **implementation programme** involving sequences of actions:

- Explanation, familiarisation, and acceptance of different constituencies with the concepts, proposed vision, stages of maturity and milestones etc. to officials at all levels, industry likewise, using different techniques of outreach
- Strategic planning, agreement on specific actions under each of the recommendations,
    - Reforming the current basic governance and accountability structure which supports a separation between political and policy governance, and implementation and addresses the key aspects of the RDM prerequisites
    - Developing a regulator's code of practice that lays out regulatory delivery principles applicable to all regulators and provides guidance for consistent implementation
    - Establishing principles for regulatory experiments such as sandbox environments to test different concepts such as Primary Authority Models, technology enabled regulatory oversight, new and advanced risk-based decision-making tools
- Using sandbox environments to also design and test EBP/EBR based intervention methods EBP:
    - cascading change by industry and by public bodies of their approach to culture and engaging with the evidence that will build why they should be trusted. This involves introspection but also open discussion with all stakeholders.
    - EBR: actual engagement on the basis of trust, and agreement on how this is done so as to be sustainable

The immediate next steps that are recommended for the AFSR to consider include:

- Evaluate the proposed recommendations to determine their relevance and priority
- Develop an action plan to outline the scope and implications of the prioritized recommendations

- Develop a strategy to implement the prioritized recommendations
- Establish an external expert committee/panel to provide ongoing advice on the design, implementation and monitoring the progress of the recommendations

Appendix 1. Australia New Zealand Food Regulatory System

Food Legislation, Treaties and Agreements

A number of important treaties, agreements and legislation form integral parts of the joint food regulation system in Australia and New Zealand. They include the Joint Food Standards Treaty between Australia and New Zealand, the Food Regulation Agreement (Australia) and the *Food Standards Australia New Zealand Act 1991 (FSANZ Act)*. Each of these initiatives articulates a set of common objectives and principles for food regulation, some of which are discussed in the following section.

In Australia and New Zealand, the regulation of food for domestic sale is covered by a range of laws and policies. Each Australian State and Territory has a Food Act based on the Model Food Provisions and most have one or more Acts which regulate aspects of Primary Food Production. Food Standards Australia New Zealand is a statutory authority operating under the Food Standards Australia New Zealand Act 1991. The Act sets out the functions of FSANZ, including the development of food standards.

Under the National Food Standards Agreement (1991) between the Commonwealth and states and territories, the states and territories adopt, without variation, food standards once they have been developed by FSANZ and approved by the Forum. Under the Forum Process, and the FSANZ Act, Ministers can ask FSANZ to review its decisions.

The Australian Government regulates imported food through the Imported Food Control Act, the Biosecurity Act, 2015 and the Food Standards Code. All imported food must meet Australia's biosecurity requirements (under the *Biosecurity Act 2015*) and food safety requirements of the *Imported Food Control Act 1992*. Labelling on imported food is assessed for compliance with the requirements under the Imported Food Inspection Scheme.

New Zealand also has a Food Act, Animal Products Act, Wine Act and Agricultural Compounds and Veterinary Medicines Act, all of which regulate aspects of food production. A list of relevant food legislation is included in Appendix 1.

The Food Regulation Agreement (FRA), signed by the Council of Australian Governments (COAG) in November 2000 resulted in a new food regulatory system. The Commonwealth of Australia and all the Australian states and territories are signatories to the Agreement.

The 1995 Agreement between the Government of Australia and the Government of New Zealand concerning a Joint Food Standards System opened the door for New Zealand's participation in the system and also specifies the role of FSANZ in relation to New Zealand.

In July 1996, an agreement to establish a joint food setting system between Australia and New Zealand came into force. The joint arrangement aims to harmonize food standards between the two countries; reduce compliance costs for industry and help remove regulatory barriers to trade in food. The agreement contains provisions which allow New Zealand to opt out of a joint standard for exceptional reasons relating to health, safety, environmental concerns or cultural issues.

The different pieces of legislation include:

Australian legislation

- Food Standards Australia New Zealand Act 1991
- Food Standards Australia New Zealand Regulations 1994
- Imported Food Control Act 1992

New Zealand legislation

- Food Act 2014
- Animal Products Act 1999
- Wine Act 2003

State and Territory Legislation

- Australian Capital Territory (ACT)
  - Food Act 2001 and Food Regulations 2002
  - Public Health Act 1997, Fair Trading (Australian Consumer Law) Act 1992
- New South Wales (NSW)
  - Food Act 2003 and Food Regulation 2015
- Northern Territory (NT)
  - Food Act 2004 and Food Regulations 2014
  - Meat Industries Act, Fisheries Act
- Queensland (QLD)
  - Food Act 2006 and Food Regulation 2016
  - Food Production (Safety) Act 2000
  - Food Production (Safety) Regulation 2014
- South Australia (SA)
  - Food Act 2001 and Food Regulations 2017
  - Primary Production (Food Safety Schemes) Act 2004 and associated Regulations
- Tasmania (TAS)
  - Food Act 2003 and Food Regulations 2012
  - Primary Produce Safety Act 2011
  - Dairy Industry Act 1994
- Victoria (VIC)
  - Food Act 1984
  - Meat Industry Act 1993, Dairy Act 2000, Seafood Safety Act 2003
  - Public Health and Wellbeing Act (2008)
- Western Australia (WA)
  - Food Act 2008 and Food Regulations 2009
  - Biosecurity and Agriculture Act 2007; Industrial Hemp Act 2004; Gene Technology Act 2006; Emergency Management Act 2005; Public Health Act 2016
- Commonwealth
  - Export Control Act 1982
  - Biosecurity Act 2015
  - Imported Food Control Act 1992

Figure 1 provides an illustration of the current Australia-New Zealand food regulatory system. It includes the various agencies set up to administer elements of the system and their roles and responsibilities.

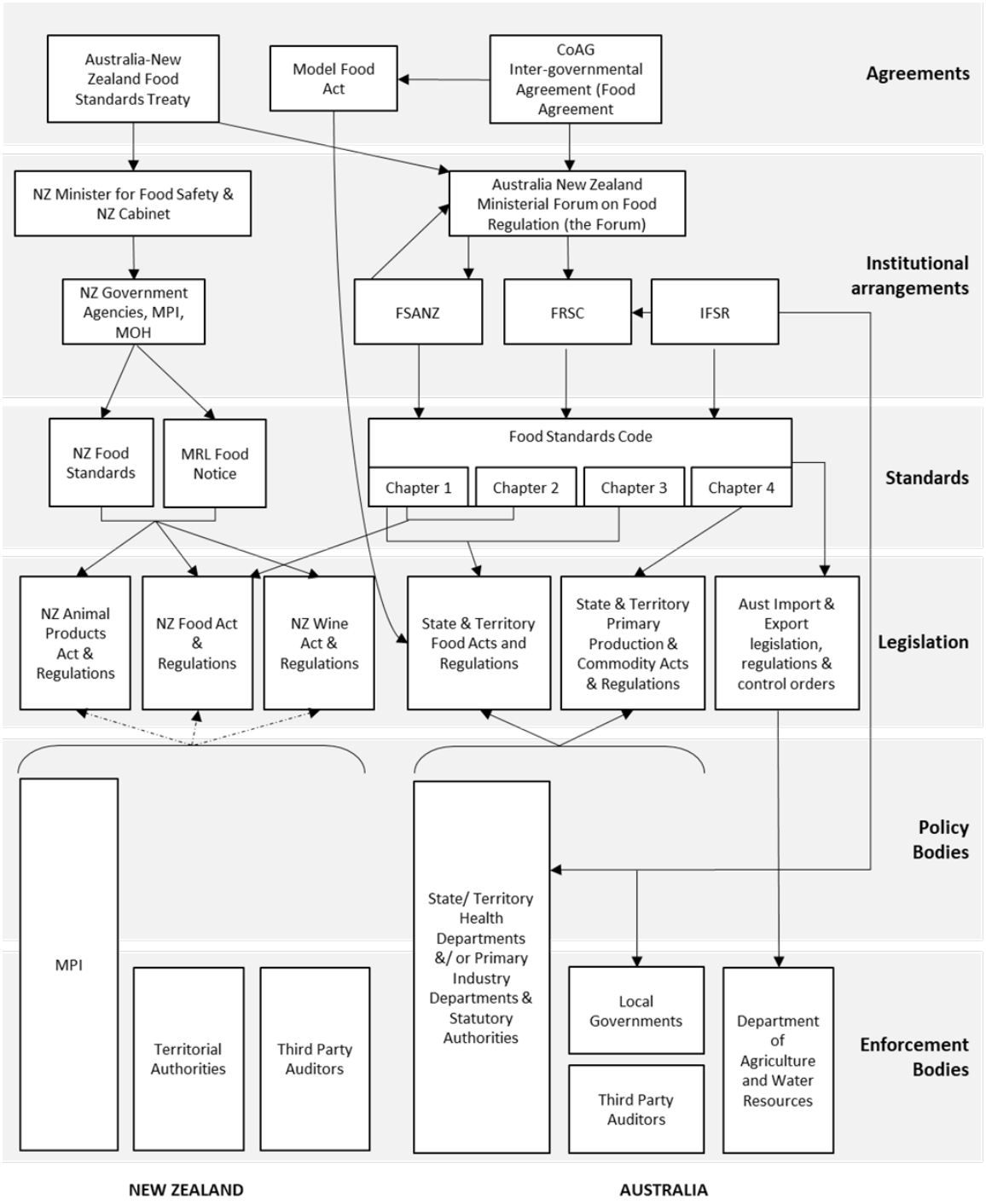

Figure A1: Australia-New Zealand Food Safety Regulatory System

The Food Regulation Policy Framework in Appendix 2 is currently being trialled and illustrates the steps followed by the Food Regulation Standing Committee (FRSC) working groups to identify and assess potential food issues. These steps help ensure the most appropriate policy response is applied. The Framework takes account of the nature and extent of the issue or risk posed, and considers different options for response, which may include non-intervention, self-regulation, co-regulation or regulation.

Each of the steps outlined in the policy framework are integral to delivering the best possible policy outcome. The policy making process can be paused at any stage as more evidence is gathered and stakeholder consultation takes place. Detailed information about each step of the policy framework can be found here.

The FSANZ Act sets out the process for developing and amending food standards in Australia and New Zealand. The steps undertaken are set out in Appendix 2 and involve a risk analysis by Food Standards Australia New Zealand (FSANZ), stakeholder consultation, and oversight by the Forum. Food standards are developed under the Australia New Zealand Food Standards Code, which is administered by FSANZ and enforced by state and territory governments.

The Forum reviews all draft standards or variations developed by FSANZ prior to approval and gazettement. FSANZ may also review an existing food standard at the request of an outside party or the Forum.

Food Standards Compliance, Monitoring and Enforcement

The Australian State and Territory and New Zealand government agencies are responsible for implementing, monitoring and enforcing food standards through their own jurisdictional food legislation. The responsible agencies vary in each jurisdiction, but generally include the following:

- New Zealand government departments (imported, exported and domestically produced food);
- State and Territory government departments and authorities; and
- Local government – There are more than 530 local councils in Australia, and 67 territorial authorities in New Zealand, involved in monitoring and enforcement activities.

DAWE enforces the Food Standards Code at the border in relation to imported food.

Food regulators work together to ensure regulations are implemented and enforced consistently. They conduct their activities within the scope of the following areas:

- Generating compliance
  - **Key Activities**
    - Education
    - Information and advice
    - Use of integrated model in standards development
    - Mediation
    - Public disclosure e.g. register of prosecutions

- Monitoring and assessing compliance
  - **Key Activities**
    - Audits and inspections
    - Sampling and surveys
    - Trends analysis of data, including complaints and compliance data
- Responding to non-compliance
  - **Key Activities**
    - Warning/corrective action order
    - Notice/order
    - Conditions on/cancellation of registration
    - Seizure or mandated recalls
    - Enforceable undertakings
    - Expiation/penalty infringement notice or on the spot fine
    - Prosecution

Through ISFR, food regulators work together to ensure regulations are interpreted, implemented and enforced consistently. ISFR is not a policy body, standards setting body or regulator with enforcement authority. It is a subcommittee where Australian and New Zealand food regulators meet to discuss and determine common approaches to implementing food standards which are then agreed and produced as guidelines. ISFR's key roles include the following:

- to determine common approaches to implementation of food standards
- to produce guidelines for these common approaches
- to monitor the safety of the food supply
- to develop protocols and tools to support national food incident responses
- to develop a surveillance plan that identifies and prioritises survey activities

The results of this monitoring are made publicly available as food survey reports on the FSANZ website. ISFR's role applies equally to imported, exported and domestically produced food.

While all jurisdictions involved in food regulation work together on implementing and enforcing food regulation, there are sometimes differences in the way jurisdictions administer food law. ISFR consults with the various jurisdictions with the aim of minimising these differences across jurisdictions as much as possible. To assist with consistent enforcement ISFR has developed a Strategy for Consistent Implementation and Enforcement of Food Regulation in Australia, In addition, ISFR has developed a number of Guidelines to help industry comply with legislative obligations.

5.1.1 Incident Response

The Australian state and territory and New Zealand government agencies are the first point of contact for managing food recalls and incidents including foodborne illness outbreaks. The process for responding to foodborne illness outbreaks includes outbreak identification, outbreak investigation and action. It involves public health agencies, food safety agencies, laboratories and local governments working together. The agency or agencies that participate in an investigation depends on the size and scope of the outbreak.

1. **Identifying an outbreak**

Foodborne illness outbreaks can be identified by health and/or food safety agencies and/or local government through a range of mechanisms, including reports from the public, general practitioners, food businesses and via the analysis of surveillance data.

2. Outbreak Investigation

Investigations into outbreaks of foodborne illness are coordinated by public health and food regulatory agencies in each jurisdiction. The purpose of an outbreak investigation is to work out what is making people sick, stop it continuing and prevent the likelihood of future outbreaks. Each agency determines what needs to be done in their jurisdiction and responds according to their food law, response plans and protocols.

A successful outbreak investigation involves three main components – the laboratory, epidemiological and environmental investigations. These may occur in sequence or simultaneously throughout the outbreak investigation.

3. Action

Based on findings of an outbreak investigation, action is taken to help stop the outbreak and avoid a similar one in the future. Outbreak control measures may include:

- Removing unsafe food from sale. This may require a food recall or stopping a business from producing and selling food until factors that caused the outbreak are remedied.
- Enhance food safety management practices by changing processes or equipment, cleaning and disinfecting facilities and equipment, training or retraining employees.
- Changing industry-wide practices.

Appendix 2. Recommendations: Benefits and Challenges

Stage	Recommendation	Example Practice(s)	Benefit	Challenges
Regulatory System Design	***1. Need to ensure that the regulatory purpose/objectives address the increasing interconnectedness of supply chains and, balance between social and economic outcomes***	1. UK Growth Duty Directive 2. New Zealand Government Expectations for Good Regulatory Practice 3. Canada's Policy on Regulatory Development	○ 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	○ 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.
	2. Explore the possible application of alternate system governance (e.g. primary authority model) that account for	4. Ethical Business Practices and Regulations 5. UK's Primary Authority Model	○ Enables a holistic approach to all activities. [Potentially very powerful.]	○ May require new legislation or amendments to existing legislation

Stage	Recommendation	Example Practice(s)	Benefit	Challenges
	human/organizational behaviours and enable trust-based relationships between the various actors in the system	6. Third-Party Assurance (Canada's Delegated Authority Model)	○ 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) ○ Provides flexibility to regulators to test a range of regulatory tools to achieve outcomes without the	○ 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 and upskilling and training of personnel. ○ Differing levels of commitment or achievement may

Stage	Recommendation	Example Practice(s)	Benefit	Challenges
			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	confuse and undermine confidence.
	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	7. Outcome-based regulations (Canada's Safe Food for Canadians Regulations) 8. Co-Regulations (Ontario, Canada Alternate Rules and Code Adoption Regulations) 9. Health Canada's Regulatory Sandbox for regulated Advanced Therapeutic Products	○ 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	○ 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

Stage	Recommendation	Example Practice(s)	Benefit	Challenges
				experimentation in the event of failures
Regulatory Delivery Model - Prerequisites	***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 regulators and industry to ensure consistency in decision making.***	10. UK Regulator's Code 11. Canada's Integrated Agency Inspection Model 12. New Zealand Regulatory Stewardship 13. OECD Guidelines on Regulatory Inspections and Enforcement	○ 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 indicators to achieve regulatory outcomes ○ Drives regulators to better understand business environments and establish relationships of trust	○ 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
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***	14. UL 2984 Standard on Risk Management 15. Canadian Food Inspection Agency's Establishment Based Risk Model	○ Provides guidance and confidence to regulators in defending risk-based decisions ○ Influences stakeholders of the	○ Events such as major incidents may put risk-based approaches under greater scrutiny ○ May create perception of "bowing

Stage	Recommendation	Example Practice(s)	Benefit	Challenges
	objective understanding of the overall safety system but help better allocate regulatory resources		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	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	16. UK FSA 17. Data Trusts 18. Canadian Food Safety Information Network 19. Safe Food Queensland	○ 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	○ Time-consuming process involving exhaustive stakeholder consultations ○ Change management to obtain buy-in from regulators ○ May require reassessment of the roles and

Stage	Recommendation	Example Practice(s)	Benefit	Challenges
			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 indicators to achieve regulatory outcomes ○ 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	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 ○ Requires investment in skills and technology by regulator and business

Stage	Recommendation	Example Practice(s)	Benefit	Challenges
			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	
	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.***	20. UK Civil Aviation Authority 21. Canadian Food Inspection Agency Integrated Risk Management Framework 22. Dairy Food Safety Victoria (Dairy RegTech)	○ 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	○ 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.

Appendix 3: Regulators' Survey Analysis

SURVEY FINDINGS

Approach

- A standard questionnaire was distributed to jurisdictional regulators involved in food regulation in Australia and New Zealand.
- The objectives of the survey were primarily to:
    - Develop a common understanding of the current regulatory framework and environment that applies to the food supply chain in Australia.
    - Identify key benefits of, challenges and barriers in the current regulatory delivery system to ensure a safe, productive and efficient supply chain.
    - Identify regulators' views on emerging modern practices in regulatory delivery.
- The questionnaire structure is designed to collect information on the following three themes:
    - Policy and Regulatory Governance
    - Regulatory Delivery - Prerequisites (Governance, Accountability and Culture)
    - Regulatory Delivery - Practices (Outcome Measurement, Risk Based Prioritization, Intervention Choices)
- Twelve (12) jurisdictional regulators and one (1) government department responded to the survey. They include Agriculture Victoria (AgVic), Australian Capital Territory (ACT), Dairy Food Safety Victoria (DFSV), PrimeSafe Victoria, Department of Health and Human Services Food Safety Unit (DHHS)[46], Department of Health Tasmania, Department of Health WA, Department of Health NT, New South Wales, Queensland, South Australia and the Preventive Health Policy Branch of the Australian Department of Health .

KEY SURVEY FINDINGS

POLICY AND REGULATORY GOVERNANCE

Does the Food Regulation System serve the purpose of developing policies and promoting the consistent implementation of standards and food safety requirements?

- All the respondent regulators believe the Food Regulation System adequately serves the purpose of developing policies and promoting a consistent implementation of standards and food safety requirements. Most respondent regulators regard this as a high priority area but believe there is room for improvement since implementation is not consistent across jurisdictions.

Does the System's governance structure and approach to policy development and arbitration allow for adequate consultation to ensure balancing interests of all the affected stakeholders?

[46] DHHS is not the regulator per se. Its responsibility resides with each of the 79 local government authorities in Victoria

- All the respondent regulators believe the Food Regulation System's governance structure and approach to policy development and arbitration allows for adequate consultation. Majority of respondent regulators consider this a high priority area but believe the complexity of the system makes it challenging for stakeholder engagement, particularly when it comes to balancing industry objectives and trade objectives and incorporating the views of small businesses.

Does the Food Regulation Policy Framework meet the needs and demands of current industry practices and supply chains?

- Majority of respondent regulators believe the Food Regulation Policy Framework does not meet the needs and demands of current industry practices and supply chains due to its inability to respond to industry innovation. For example, where duplicated processes are identified, it is often a lengthy and protracted process to address these duplicated processes and it can take excessively long time to develop and/or amend policy and see it through to implementation. Majority of respondent regulators believe this is a high priority area.

Does the Food Regulation Standing Committee (FRSC) have the right structure and authority to provide guidance and oversight to the development of policies to be implemented consistently across jurisdictions?

- Majority of respondent regulators believe FRSC has the right structure and authority, however, it does not always consider consistency in policy implementation across jurisdictions. An integrated approach that includes linking in with ISFR is recommended. The system also relies on very busy people who volunteer for important policy work. Consider allocating dedicated professional resources. Majority of respondent regulators believe this is a medium to high priority area.

Is the process for the development/amendments to the Australia New Zealand Food Standards Code adequately aligned with policy directions and promote the consistent application of standards?

- Majority of respondent regulators believe the process for the development/amendments to the Food Standards Code is not adequately aligned with policy directions and does not promote the consistent application of standards. Sometimes amendments to the Food Standards Code are made without a clear policy direction and the input of jurisdictions is not always considered. The standards development/amendments process is not adequately equipped to deal with the conflict between industry priorities and broader policy initiatives/goals. The speed at which change to the Food Standards Code occurs is limited by skills availability and resourcing. Majority of respondent regulators believe this is a high priority area.

Are the Standards developed by Food Standards Australia and New Zealand nimble, flexible, relevant, and outcome based?

- Majority of responding regulators do not believe the standards developed by FANZ are nimble, flexible, relevant, and outcome based. In general, some aspects of the standards (particularly the newer ones) are flexible and outcome-based while others (the older ones) are prescriptive. Some parts of the Code are no longer relevant/adequate given

changing market demands. However, to address food safety needs, a combination of both outcome-based and prescriptive standards is desirable. Majority of respondent regulators also believe this is a high priority area and recommend adjusting the Standard setting process, which is currently considered lengthy and unresponsive to changes in industry.

Are your State's/Territory's food safety and related regulations nimble, flexible, relevant and outcome based?

- Majority of responding regulators are split 50:50 on the question whether their State's/Territory's food safety and related regulations are nimble, flexible, relevant and outcome based. The regulators also see this as a medium priority area. Those who believe that their State's/Territory's food safety and related regulations are not nimble, flexible, relevant and outcome-based state that these legislations are outdated, prescriptive and require review to make them outcome based.

Do the State/Territorial food safety and related regulations create barriers for trade?

- Though some states say barriers to trade exist, majority believe State/Territorial food safety and related regulations do not create barriers for trade. States consider this a high priority area and say trade barriers exist due to differences between domestic food safety requirements and international requirements. An example of a trade barrier is unpasteurised milk whose production and sale is in accordance with the Food Standards Code, but the milk is not allowed to be sold in certain jurisdictions. Recommend harmonizing these requirements where possible.

Does the State/Territory's current regulatory governance structure cause burden to industry?

- Majority of responding regulators believe the State/Territory's regulatory governance structure does not cause burden to industry. It is difficult for regulators to comment on this considering it’s some form of self-criticism which most may not be amenable to. However, some point out that inconsistencies in the application of standards is a burden, while other such as DFSV point out that they are always on the lookout for opportunities to reduce the regulatory burden on businesses. Respondent states consider this a medium priority area.

Are alternate regulatory governance models (e.g., third party, primary authority etc.) considered?

- All respondent regulators consider alternate regulatory governance models and view this a medium priority area. The most common alternate models used are third-party audits.

Are there any other factors/issues you would like to raise with respect to the current regulatory governance and policy development framework, particularly as it relates to consistent implementation?

- The system is understandably complex as it involves a diversity of jurisdictions and sectors.
- Reforms should target clear lines of accountability and transparent process that would have a knock-on effect on consistency in implementation.

- Consistent implementation of the Code is a function of the FRSC Implementation Sub-committee.
- Adopt a coordinated and harmonized approach in the way jurisdictions review their legislation. Many jurisdictions have undertaken significant amendments to their legislation, resulting in inconsistencies impact the way the Food Standards Code is implemented.

REGULATORY DELIVERY - PREREQUISITES (GOVERNANCE, ACCOUNTABILITY AND CULTURE)

Does the IFSR have the appropriate authority and structure to ensure consistency, flexibility and nimbleness in guiding the implementation of standards?

- Majority of responding regulators believe IFSR does not have the appropriate authority and structure to ensure consistency, flexibility and nimbleness in guiding the implementation of standards. Majority also consider this a high priority area. Specifically, the highlight the following issues/observations:
    - An improved mechanism for referring to FRSC, policy issues emerging from ISFR implementation of standards. Currently, due to a crowded FRSC agenda, the time taken to resolve policy issues is significantly long.
    - ISFR is a 'volunteer' group that has many issues to deal with and cumbersome processes.
    - ISFR does not have the authority to dictate how a jurisdiction will choose to implement a Standard or Regulation.
    - ISFR does not have enforcement powers, decisions are ultimately made by the relevant regulator.
    - ISFR is not autonomous and relies on FRSC for decision making for policy guidance in implementation of standards.

Does the IFSR provide adequate support and guidance for the delivery of food safety requirements in a consistent manner and balancing the interests of the affected stakeholders?

- Majority of respondent regulators believe IFSR provides adequate support and guidance for the delivery of food safety requirements in a consistent manner while balancing stakeholder interests. ISFR has developed a number of useful guidance documents to support consistent implementation of food standards including the overarching approach to compliance Majority of responding regulators consider this a high priority area. However, IFRS does not have direct access to stakeholders and must rely on a partnership with FSANZ to achieve this.

Should the IFSR provide guidance and direction for determining the purposes, structures, powers and responsibilities of the regulators to ensure consistency, reduce overlap, and promote collaboration with other regulators?

- Most respondent regulators view this as a medium priority area and believe IFSR should not provide guidance and direction for determining the purposes, structures, powers and responsibilities of the regulators to ensure consistency. Some respondent regulators

believe IFSR could play a greater role but is challenged by individual jurisdictional regulations. Others say this should be the role of individual jurisdictions.

Is there consistency, reduced overlap, and sustainable collaboration between regulators on imported food?

- Respondent regulators are split 50:50 on the question of whether there is consistency and sustainable collaboration between regulators on imported food? Majority view this as a medium priority area. Some state that the commonwealth government is often reactive due to less collaboration among jurisdictional regulators. Sometimes, imported food inspection schedules allow for food that does not meet Australian and New Zealand food standards to enter the supply chain.

Is there consistency, reduced overlap, and sustainable collaboration between regulators on domestic food?

- Majority of respondent regulators believe there is consistency and collaboration between regulators when it comes to domestic foods. Majority also view this as a high priority area. One area where collaboration is witnessed most is food recalls. However, there is room for improvements when it comes to incident response e.g. handling foodborne illnesses.

Does your agency/department have adequate mechanisms and structures in place that demonstrate transparency in its decision making?

- Majority of respondents believe their regulatory agency has in place adequate mechanisms and structures to demonstrate transparency in decision-making. This includes regular consultations and compliance to the Freedom of Information Act. Most regulators consider this a medium priority area.

Are your agency/department's objectives aligned with the expected regulatory outcomes and are the outcomes well defined?

- Majority of respondents believe their regulatory agency objectives are aligned with the expected regulatory outcomes and that the outcomes are well defined and consistent with broader health outcomes as defined in the Food Act. Majority also view this as a high priority area.

Does your agency/department engage in a culture of practices that are focused on the outcomes?

- Majority of respondents believe their regulatory agency engages in a culture of practices that are focused on the outcomes. They also view this as a high priority area.

Does your agency/department have the appropriate leadership, values and competencies that support the culture of outcome-focused decision making?

- Majority of respondents believe their regulatory agency has the appropriate leadership, values and competencies that support the culture of outcome-focused decision making. Majority also view this as a high priority area.

REGULATORY DELIVERY - PRACTICES (OUTCOME MEASUREMENT, RISK BASED PRIORITIZATION, INTERVENTION CHOICES)

Does your agency/department periodically measure the outcomes and are the measures appropriate?

- Most respondent agencies periodically measure outcomes and view this as a medium to high priority area. Most agencies report their outcomes through the Annual Food Act Report.

Does your agency/department measure the impacts of its and other players in the system towards the achieved outcomes?

- Though most respondent agencies view this as a medium priority area, majority indicate that they do not measure the impact of their regulatory interventions.

Does your agency/department engage in third-party reviews (peer reviews) of its measurement methods and performance assessments?

- Most responding agencies engage in third-party reviews though most view this as a priority area. Some, such as Agriculture Victoria do conduct third-party departmental reviews to identify opportunities for improvement.

Does your agency/department explore all possible avenues for obtaining data and evidence that describe the performance of the entire food safety system?

- Respondent agencies are split 50:50 on the question whether they explore all possible avenues for obtaining data and evidence on the performance of the food regulatory system. Some agencies view this as a function of the commonwealth government. Others, such as DFSV are in the process of initiating this function while others collect data and evidence only where there are foodborne illness incidents and from third-party reports. Most agencies view this as a medium priority area.

Does your agency/department encourage industry to voluntarily provide data and evidence describing the achieved outcomes?

- Most respondent regulators view this as a medium priority area citing lack of data availability in industry while also seeing this as a function of the commonwealth government. Majority do not encourage industry to voluntarily provide data and evidence. However, some industries such as the dairy sector are spearheading leadership in voluntary provision of data. In addition, some States (e.g. Queensland) are using both quantitative and qualitative data to inform performance and culture within the sector.

Does your agency/department use best practice approaches to risk assessment for determining its priorities and allocation of resources?

- Most respondent regulators have adopted best practice approaches in risk assessment for determining its priorities and allocation of resources. They view this as a medium to high priority area. Those who have not adopted cite lack of an appropriate framework that can support this in the Food Act.

Does the risk assessment consider the broader aspects of industry performance including their existing culture and values?

- Most respondents consider broader aspects of industry performance in risk assessments and view this as a medium priority area.

Is your agency/department familiar with and/or use available technologies that improve the quality of data/evidence and reduce the uncertainty in risk assessments?

- Some agencies such as FSV use analytical tools that enhance risk assessment including established business intelligence software. FSU has adopted an online registration process (Streatrader) for mobile and temporary food businesses to collect and monitor data on local government food safety activities. The Department of Health-WA is currently investigating database options across its regulatory activities. Queensland's Food Production System uses real-time data across a range of producers.

Does your agency/department have a range of tools in its regulatory toolkit that allow for appropriate interventions? (non-intervention, incentives, behaviour changes, deterrence and enforcement)

- Most respondent agencies agree that they have a range of regulatory tools that allow for appropriate interventions. These tools are contained in their Food Acts and can be tailored depending on the situation. They also view this as a high priority area.

Does your agency/department have the flexibility and the culture of selecting their intervention choices that are most effective for achieving outcomes?

- Most agencies have the flexibility and the culture of selecting intervention choices that are most effective for achieving outcomes. Among the interventions include proportionate response to compliance and enforcement and the use of risk-based decision-making. They also view this as a high priority area.

Does your agency/department use inspections and enforcement as its most frequent intervention tool?

- Inspections and enforcement remain the primary intervention tools for most agencies with verification audits occasionally used as well. They also view this as a high priority area.

Is your agency/department familiar with and/or use alternate intervention choices (e.g., ombudsperson, Ethical business regulations, public rating schemes etc.)

- Some agencies are not familiar with alternate intervention measures while others such as DFSV use verification audits as its primary compliance tool and not inspections or enforcement.