



ACT
Government

ACT Health

Regulatory Accountability Framework 2024-2030

Consultation Draft

February 2024



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Our Vision

A healthier Canberra through accountable regulatory services.

Our Mission

We protect and enable the health of our community through a principles-based approach to regulation.

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Scope

This Framework serves to support all regulatory functions across the ACT Health Directorate.

Regulation, as a practice, involves the administration of any law or rule which is put in place by government, with government authority (or support), where there is a reasonable expectation of compliance. Regulation seeks to influence or compel specific behaviour by a person or regulated entity...¹.

This Framework captures all regulatory practices pertaining to ACT legislation and subordinate instruments for which ACT Health Directorate is responsible².

The Framework captures the entire regulatory life cycle, including policy development through to administration, enforcement and evaluation. This recognises that regulation occurs within a continuous cycle of improvement and should be informed by evolving community needs.

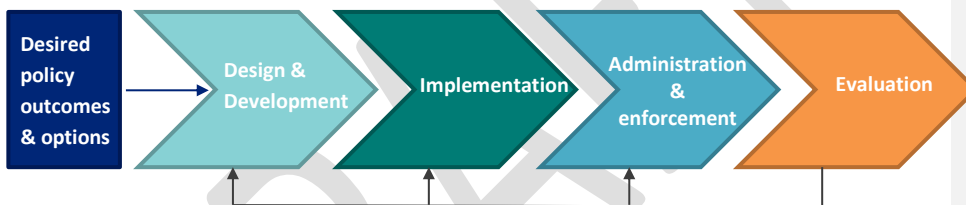


Figure 1. Stylised regulatory life cycle³

Administration functions are broad and may include public advice and guidance, licensing and approvals, secretariat support for statutory bodies or compliance monitoring. They may also include public health preparedness, surveillance and response functions performed in accordance with statutory responsibilities under the *Public Health Act 1997*.

Regulatory support functions are also captured by this Framework to the extent that they support regulatory activity. For example, administration of regulatory systems or data, forensic analysis of samples by approved analysts or provision of policy or expert advice.

This Framework captures all functions where the Directorate is acting as the *regulator* in accordance with ACT legislation for which it is responsible. It does not capture matters where the Directorate is acting as the regulated entity to comply with ACT or other legislation, for example:

- Directorate reporting to the national funding body in accordance with Commonwealth legislation, or

1 Pink, G. (2021). *Navigating Regulatory Language; An A to Z Guide*. Canberra: RECAP Consultants.

2 As defined by ACT Government Administrative Arrangements or other means.

3 Victorian Competition and Efficiency Commission (2011). *An Inquiry into Victoria's regulatory framework: Strengthening Foundations for the Next Decade*, Summary report. State of Victoria.

- Administration of a Territory database containing health records in accordance with the *Health Records (Privacy and Access) Act 1997*.

Principles

Risk-based

- We take a risk- based approach to regulating harms in our community.
- Our efforts are focused on minimising harms, not just enforcing compliance with laws.
- We work with regulated businesses and individuals to promote compliance, through positive education and engagement.
- We pick important problems and try to fix them, in collaboration with our partners.
- Our activities are informed by risk assessments informed by available evidence including data.

Data and evidence informed

- Our data informs our program delivery, resource allocation and policy development.
- We proactively monitor our data to identify community trends and potential harms.
- We use available datasets to investigate and resolve problems.
- We deliver evidence-based programs that prevent disease and improve health outcomes.
- We evaluate our programs and public health responses so that we can learn from the past and continuously improve.
- We invest in our systems, skills and expertise to manage, analyse and use our data.
- We are outcomes focused and will seek to measure public health outcomes using both qualitative and quantitative indicators.

Transparent

- We publish our core policies and procedures for regulating ACT businesses and health services.
- We are open about our regulatory performance, including areas for improvement.
- We publish helpful factsheets and guidance material to help regulated parties understand their obligations and assist them to comply.
- We welcome feedback about our service delivery and will use it to continually improve our service to businesses and the public.

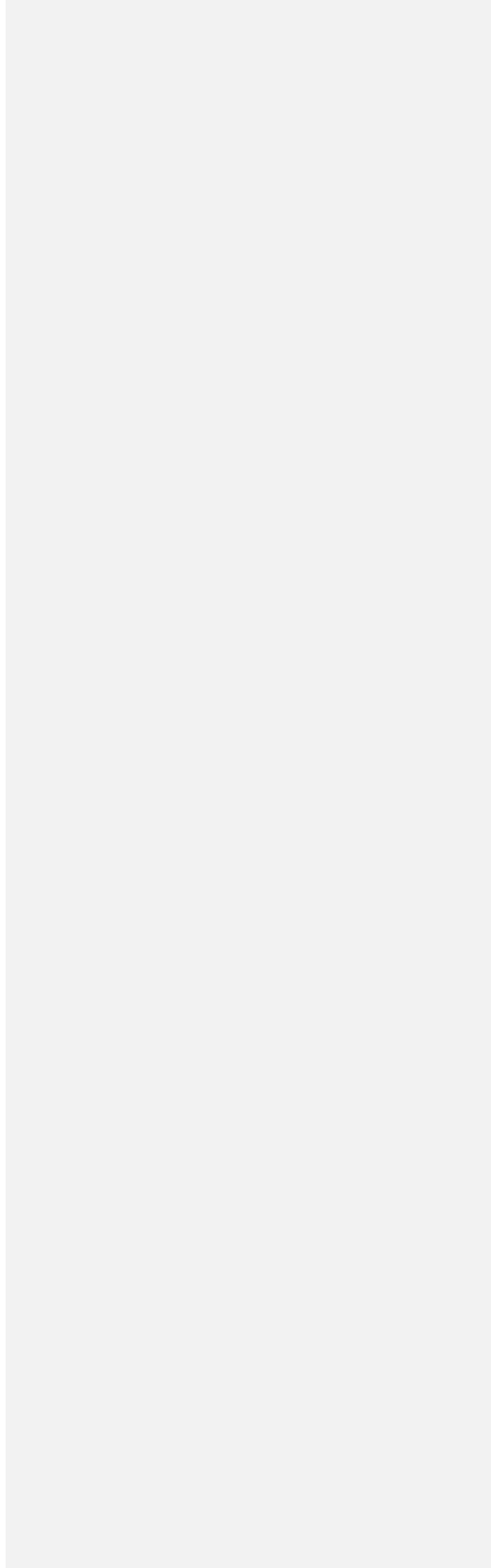
Proportionate

- Our enforcement decisions are proportionate to the seriousness of the offence or potential harm.
- We allocate our time, attention and resources according to level of public health risk.
- We look at problems systematically so that we can maximise the impact of our regulatory responses.
- We aim to ensure that any appreciable costs to the community are proportionate to the level of public health risk or harm when designing or reviewing regulatory schemes.

Text

Commented [LG1]: AVA support this point and highlight the benefit of providing clear guidance to the veterinary profession on the regulatory requirements in the Medicines, Poisons and Therapeutic Goods Act and Radiation Protection Act.

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Timely

- We are proactive in monitoring for potential harms in the community and mitigating risks.
- We are responsive to public health incidents or known harms.
- We are efficient and on-time in providing our regulatory services.

Consistent

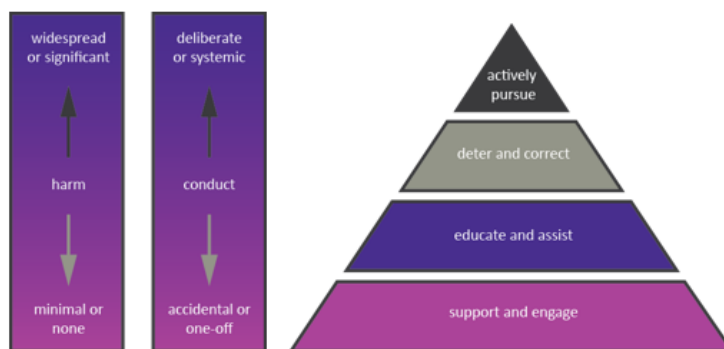
- We take a structured approach to decision making to ensure our decisions are consistent across decision makers and over time.
- We use standard operating procedures to maintain consistency and quality in our core regulatory services.
- We are predictable so our community knows what they can expect from us.
- We are reliable and, we will do what we say we are going to do and respond appropriately to risks or harms in the community.

Compliance pyramid

We primarily aim to reduce health harms through engagement and education. However, we will apply escalating enforcement actions where there are clear breaches of the law and depending on the level of harm these may cause in our community.

We will tailor our responses to public health risks or harms using a range of compliance and enforcement tools. As the level of risk or harm increases, so will the severity of the actions taken in response.

Figure 2. Enforcement pyramid⁴.

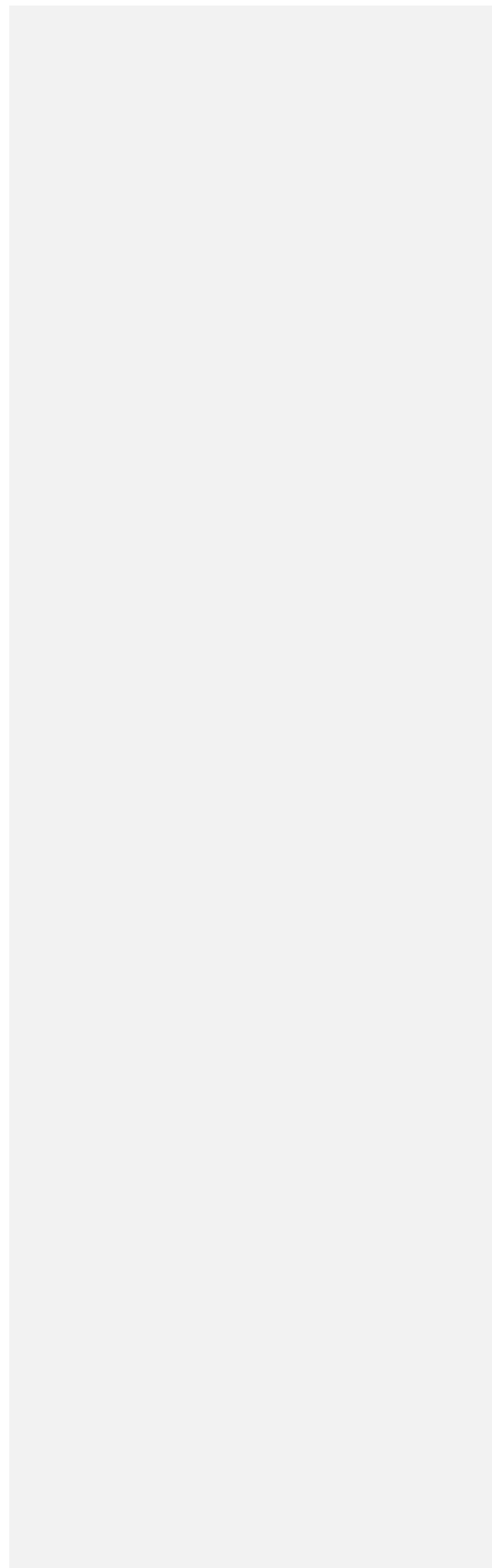


⁴ Adapted from Ayres and Braithwaite (1992). *Responsive Regulation: Transcending the Deregulation Debate*. Oxford University Press.

Data visualisation

Insert data visualisation depicting key public health statistics and regulatory activity performed by the Directorate.

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Directorate regulatory functions

As of December 2023, the ACT Health Directorate administers 24 sets of primary legislation, or Acts under the ACT Government Administrative Arrangements.

These Acts all serve different purposes and impose different levels of responsibility and functions across the Directorate.

Some Acts serve to protect the public from potential harms arising from environmental hazards or non-health related activities. Others serve to protect the public from potential harms arising through the delivery of health care. Some Acts serve to protect against a combination of these and public health risks more broadly.

The *Public Health Act 1997* serves to protect the public from a broad range of public health risks and heavily influences regulatory activity within the Directorate, including a strong focus on communicable disease threats and managing public health emergencies.

Example regulatory functions are depicted below. Often these functions require high levels of professional and technical expertise, including tertiary qualifications in health or related scientific disciplines.

	Example functions
Policy development	Development of new regulations and instruments Updates to existing regulations and instruments May also include a de-regulation focus
Administration	Licensing or registration Approvals Inspections Education and engagement Compliance monitoring Surveillance Public health incident or emergency responses Secretariat support to statutory bodies Administration of claims
Enforcement	Investigations Warnings and cautions Administrative or disciplinary actions Prosecution
Evaluation	Policy evaluations and reviews

	Program evaluations After Action Reviews
Support	Legal or expert advice Forensic analysis of samples Data or systems administration Planning and co-ordination Corporate support

The relationship between health care regulation and clinical systems governance

There is an intersecting relationship between health care regulation and clinical systems governance.

Health care regulation enables or mandates clinical governance, through the setting of minimum safety standards in legislation to protect consumers and public health. Clinical governance is broader in concept; for the purpose of ensuring patients and consumers receive both safe and quality health care within a cycle of continuous improvement. Clinical governance systems can be organisation specific (ie. within a single health care organisation) or system wide (ie. Territory wide or across multiple organisations).

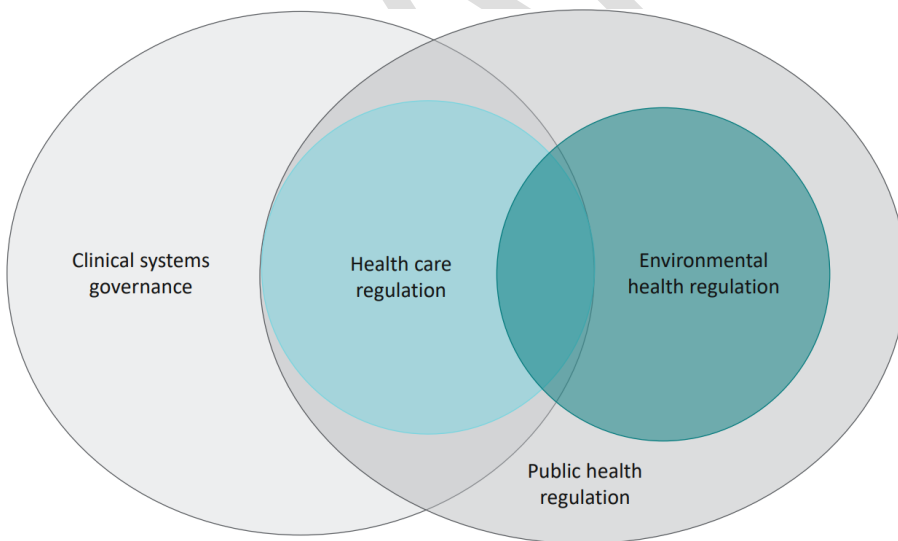


Figure 3. Relationship between health care regulation and clinical systems governance

Commented [LG2]: A third core area of health care Regulation needs to be added – Animal health. The one Health principal recognises the intersecting and mutually dependent spheres of human health, animal health, and environmental health.

Case study 1

TBC

Commented [LG3]: Suggest also including an animal welfare related case study.

Case study 2 – Mental Health Act delegations

Under the *Mental Health Act 2015*, the Minister must appoint a Chief Psychiatrist. The main function of the Chief Psychiatrist is to provide treatment, care or support, rehabilitation and protection for persons who have a mental illness. Other functions are to make reports and recommendations to the Minister with respect to matters affecting the provision of treatment, care or support, control, accommodation, maintenance and protection for persons who have a mental illness and to prepare guidelines for mental health facilities. The Chief Psychiatrist may delegate all their functions to a psychiatrist who is a public employee or is engaged by the Territory, except for granting of leave in emergency or special circumstances and making guidelines.

The Office of the Chief Psychiatrist holds a register of delegates appointed by the Chief Psychiatrist. Each application for delegation is accompanied by a Medical and Dental Appointments Advisory Committee recommendation letter, outlining their scope of practice. The applicant must complete online training and provide their completion certificate. Once satisfied, the Chief Psychiatrist may then appoint the person as their delegate. The appointments need to be made in a timely manner, to ensure seamless patient care.

Accurate and consistent administration of delegations under the MHA ensures that patients receive mental health care that is consistent with best practice and is provided by appropriately skilled and qualified health professionals.

Strategic context

Emerging public health threats

The health impacts of climate change have been identified by the World Health Organization as a significant global health threat, which is closely linked to an increased global risk of infectious diseases. Recent outbreaks of COVID-19, Japanese encephalitis and Mpox highlight this trend.

Preparing for and responding to future crises requires robust regulatory systems and structures and strong relationships with key partners including the new Australian Centre for Disease Control planned to commence from 2024.

Emerging technologies and data

Advances in technology and data present both opportunities and challenges for regulation. There are opportunities to leverage data and technology to improve regulatory service delivery, in an era of Artificial Intelligence and Big Data. Digital health is also a reality in the ACT, with the introduction of the Digital Health Record across ACT public health services in 2022.

It is important ACT Health Directorate invests in its systems for collecting and analysing data so that it can better monitor and respond to public health risks or trends. It is also important the Directorate has adequate data analytics capability to keep up with industry and remain relevant.

The emergence of health technologies like precision medicine and gene technology also necessitates flexible and responsive regulations that enable innovation whilst ensuring adequate safeguards.

The move towards Better Regulation

Regulatory regimes can be shaped by global trends in regulatory best practice. In recent years, ACT Health Directorate has sought to adopt a risk-based regulation approach, by aiming to focus on controlling practices that present the greatest risk of public health harm in our community.

Better Regulation expands on risk based regulation as a concept, with a focus on reducing regulatory burdens. The ACT Government established its Better Regulation Taskforce in 2020 in response to the impacts of the COVID-19 pandemic on local business. ACT Health Directorate will seek to align with the Government's Better Regulation reform agenda to ensure consistent and reliable regulatory service delivery to local businesses and health services.

Emerging regulatory functions

Several new regulatory schemes are planned or being proposed for introduction from 2024, which will impose new functions and responsibility within ACT Health Directorate. Examples include voluntary assisted dying, cross jurisdictional tobacco and vaping reforms, assisted reproductive technologies and variations in sex characteristics (restricted medical treatment).

All these proposed or planned schemes intersect with the health system and clinical practices within complex and sensitive environments, so it is important to have the skills and capability at an organisational level to implement these effectively.

Commented [LG4]: Globally the majority of emerging infectious diseases in humans have crossed from animals (zoonoses) including (as noted) COVID 19, Monkey Pox and Japanese Encephalitis. Monitoring of animal health in food and fibre production animals, performance and display animals, laboratory animals and companion animals, and the regulation of all matters pertaining to their health, is important for all Australians.

Commented [LG5]: Suggest amending to 'human and animal health services'.

Alignment with other frameworks

- OECD Best Practice Principles for Regulatory Policy
- ACT Government Better Regulation Agenda
- ACT Health Directorate *Accessible, Accountable, Sustainable: A Framework for the ACT Public Health System 2020–2030*
- ACT Health Directorate *Strategic Plan 2020-25*

Key concepts

Regulatory practice is both a craft and a science, that uses a number of concepts to inform program delivery and drive improvement and innovation.

Risk based regulation

Risk based regulation focuses on controlling risks and harms in the community, not just ensuring compliance with laws and rules.

It involves a regulator targeting or directing resources and activities towards the most serious risks. It uses risk management methodology to direct efforts towards the most unacceptable risks⁵.

The OECD defines the concept of risk-based regulation as a “*systematised decision-making framework and procedures that prioritise regulatory activities and deploy supervisory resources, in particular those of inspection and enforcement, based on an assessment of the risks that activities pose to a regulator’s objectives*”⁶.

Smart regulation

The ‘smart regulation’ model involves business and private actors in the regulatory process where appropriate to enforce regulations. It may involve self-regulatory or co-regulatory initiatives or third parties to act as ‘surrogate regulators’⁷.

Smart regulation reflects a wholistic and integrated approach to regulation which is based upon the theory that multiple regulatory interventions and/or strategies used in combination are more effective than standalone. The aim of smart regulation is to achieve public policy objectives and deliver regulatory outcomes in the most effective way, with maximum buy-in and societal support⁵.

Smart regulation terminology has since been superseded by better regulation terminology⁷.

Commented [LG6]: Suggest providing greater clarity of the intention and interaction between this section and the section ‘Independent Regulator’ it includes the following:
“It is important that regulators act independently from government and the industry they regulate. This ensures regulatory decision making occurs without undue external influence.”

⁵ Pink, G. (2021). *Navigating Regulatory Language; An A to Z Guide*. Canberra: RECAP Consultants.

⁶ OECD (2010). *OECD Reviews of Regulatory Reform: Risk and Regulatory Policy - Improving Governance of Risk*.

Better regulation

Better regulation extends on risk based and smart regulation as concepts, to include principles of proportionality, accountability, consistency, transparency and targeting. Better regulation seeks to increase competitiveness and reduce regulatory burdens, as well as increase the legitimacy of regulation by requiring transparency of the process of developing and implementing regulations. It may also capture concepts of reviews, evaluations and evidence informed policy making⁷.

Commented [LG7]: Better Regulation -additional concepts include clarity and lack of ambiguity, and the use of plain English.

Regulatory posture

Regulatory posture is the approach or stance that a regulator adopts towards those it regulates. It involves the regulator balancing a range of tensions to achieve desired outcomes; including for example, the nature of the legislation administered, risks and harms to address, stakeholder relationships and the authorising environment⁵.

Regulatory posture may also be referred to as regulatory philosophy, which may be communicated by regulators in a variety of ways to provide transparency to those they regulate and the public. For example, compliance pyramids (see Figure 2), principles or statements (eg. 'firm but fair' or 'educate, engage, enforce') can all be used to convey and organisation's regulatory posture.

Regulatory capture

Regulatory capture is a form of misconduct which can occur when regulators either over-identify with the industry they regulate, over-sympathise with the problems and issues faced by the industry or there is an absence of toughness by the regulator.

Regulatory capture is insidious and often arises when regulators focus too much on engagement and education, at the expense of enforcement. It may also occur where there is an over focus on advice, guidance, licensing or approvals work over compliance monitoring and enforcement activities⁵.

Regulator independence

It is important that regulators act independently from government and the industry they regulate. This ensures regulatory decision making occurs without undue external influence.

Commented [LG8]: As above in Smart Regulation section.

There are several areas where regulators are susceptible to undue influence, including:

- Perceptions about the regulator's role and functions by the executive government,
- Relationships between the regulator and its regulated entities or stakeholders,
- Employment of regulatory staff, and
- Regulator funding sources⁵.

⁷ van der Heijden, J., Hodge, G. (2020). *Ten Global Trends in Regulation: A Future Outlook*. In: Sullivan, H., Dickinson, H., Henderson, H. (eds) *The Palgrave Handbook of the Public Servant*. Palgrave Macmillan, Cham.

Case study 3

TBC

Case study 4

The annual National Multicultural Festival is a high-risk food safety event with approximately 100 temporary food stalls operated by community organisations with limited food safety knowledge and experience. The event is held in summer over a three-day period with daily temperature range between 30-40 degrees.

The Environmental Health team has a very active presence around the time of the festival proportionate to the food safety risk. This includes an intense regulatory response throughout the festival, engagement with stall holders at information sessions and close working relationships with event organisers, Access Canberra liquor licensing and other event personnel. The face to face and online information sessions, factsheets and stall holder checklists provide transparency to the food safety requirements such as stall set up, processing and cooking of food and onsite food safety inspections.

During the festival, there is a high level of compliance as Environmental Health Officers work with stall holders to rectify any issues. Where critical breaches are identified, food is seized and disposed of to protect public health.

This proactive regulatory approach helps to ensure the safe supply of food at the festival under high risk conditions, so that all who visit can enjoy sampling the international cuisine and leave with a positive experience.

Strategic domains

The following domains will guide future improvements to the way ACT Health Directorate regulates and delivers public health outcomes. Each of these domains will be underpinned by a series of actions to help improve our regulatory programs and ensure we can effectively deliver our Vision of a healthier Canberra through accountable regulatory services.

Domains	Description
People, roles and relationships	<p>This domain focuses on our people to ensure we have the right skill mix, technical expertise, capacity and culture to deliver effective regulatory services in accordance with this Framework.</p> <p>It also focuses on clarifying regulatory roles across the Directorate and shared roles with other Directorates to ensure we can deliver efficient regulatory services in an environment of increasing regulatory demand and complexity.</p>
Data and technology	<p>This domain focuses on effective use of data to drive evidence-informed decision making and program delivery and optimising our technology systems to support delivery of regulatory services.</p>
Processes and practice	<p>This domain focuses on our regulatory maturity and ensuring we have the right processes, tools and procedures in place to deliver effective and accountable regulatory services.</p>
Regulations and reform	<p>This domain focuses on reviewing our stock of existing regulations and evaluating our regulatory programs to ensure they are fit for purpose and align with principles of this Framework.</p>
Accountability mechanisms	<p>This domain focuses on measuring and monitoring our regulatory performance so we can demonstrate our accountability to Ministers and the public and help drive improvements in public health outcomes over time.</p>

Early actions

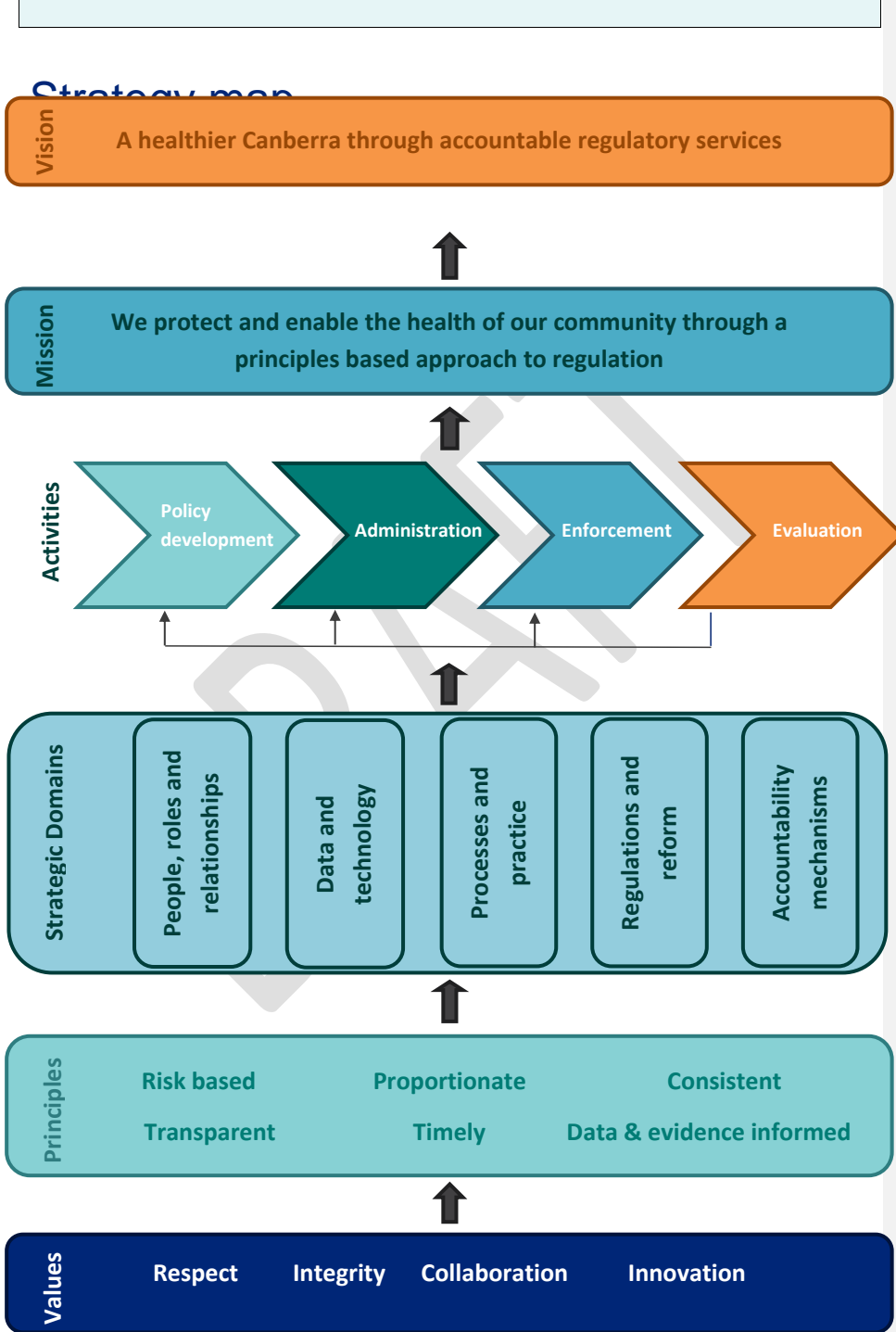
Some early actions arising through this Framework are summarised below. Each of these initiatives aim to strengthen regulatory policy development, programs and services across ACT Health Directorate. This will ensure the Directorate is best able to deliver its Vision of a *healthier Canberra through accountable regulatory services*.

A detailed Action Plan will be developed to support successful implementation of this Framework.

Strategic Domain	Action	Description	Expected Impact
People, roles and relationships	1.	<i>TBC subject to consultation with Divisions on the First Action Plan. Not all proposed actions will be published here—only a selection appropriate for a public audience.</i>	
Data and technology	2.		
	3.		
Processes and practice	4.		
Regulations and reform	5.		
	6.		
Accountability mechanisms	7.		

Case study 5

TBC



ACKNOWLEDGMENT OF COUNTRY

ACT Health acknowledges the Traditional Custodians of the land, the Ngunnawal people. ACT Health respects their continuing culture and connections to the land and the unique contributions they make to the life of this area. ACT Health also acknowledges and welcomes Aboriginal and Torres Strait Islander peoples who are part of the community we serve.

ACCESSIBILITY

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