REGULATING HIGH-RISK TECHNOLOGIES: COMPARING REGULATORY APPROACHES TO ARTIFICIAL INTELLIGENCE AND GENE TECHNOLOGY

HARIS YUSOFF*

Artificial intelligence ('AI') systems are increasingly used in high-stakes contexts such as healthcare, where their application can directly influence patient outcomes, reinforce health inequalities, and erode public trust. In recognition of these stakes, the accompanying risks, and the promised gains of AI systems, the Australian Government has issued a set of policy documents revealing its intention to enact horizontal AI legislation in pursuit of its opaque 'Safe and Responsible' AI agenda. In doing so the Government takes express inspiration from the newly enacted European Artificial Intelligence Act, favouring a similar risk-based framework, embedding product safety principles, and proposing regulatory features compromised by a pro-industry objective. These are insufficient to protect against the unpredictable nature and complex risks posed by health-related AI systems. This article seeks to inform Australia's policy choices, not only by critiquing the European framework, but by arguing that inspiration should be drawn from another legislative scheme reflecting over two decades of national experience regulating a comparably high-risk and unpredictable technology: gene technology as regulated under the Gene Technology Act 2000 (Cth). Comparing the two legislative frameworks reveals that the Gene Technology Act takes a precautionary, high-touch, and granular approach to regulating risk and achieves this by centralising risk assessment through evidence-based decision-making with significant public participation and accountability. Australia still has the opportunity to overcome deficiencies in the Artificial Intelligence Act, and it can do so by learning from how the European regime understands AI technologies, while also introducing the rigorous structural protections of the Gene Technology Act to regulate AI systems in a responsible and safe manner.

* BA, JD, The University of Western Australia; LLM Candidate, University College London. I am grateful to my supervisor Julia Powles for her invaluable feedback and guidance, and to the anonymous reviewers for their helpful comments.

I INTRODUCTION

This article engages with two technologies, gene technology and artificial intelligence. Gene technology is a 'modern branch of biotechnology' that allows for changes to be made in the genes of organisms.[1] Australia regulates gene technology under the *Gene Technology Act 2000* (Cth) ('*GTA*').[2] At the centre of the *GTA*'s regulatory scheme is the Office of the Gene Technology Regulator ('the Regulator'), an independent statutory body tasked with identifying and managing risks posed by gene technology.[3]

Gene technology has applications in various medical contexts, such as vaccine production, as well as agricultural contexts, such as improving crop resistance and yield.[4] The *GTA*, in turn, protects against risks posed to (1) human health, such

[1] Australian Government Department of Health, Office of the Gene Technology Regulator ('OGTR'), *What is Gene Technology?* (Factsheet, June 2018) 1.
[2] *Gene Technology Act 2000* (Cth) ('*GTA*').
[3] Australian Government Department of Health and Aged Care, *Office of the Gene Technology Regulator* (Web Page, 22 April 2024) <https://ogtr.gov.au/>.
[4] Senate Standing Committee on Community Affairs, *A Cautionary Tale; Fish Don't Lay Tomatoes*: *A Report on The Gene Technology Bill 2000* (Report, November 2000) ('*Senate Report on Gene-Tech Bill 2000*') 15–17.

as through ingestion or bodily exposure to genetically modified organisms (the regulatory subject of the *GTA*);[5] and (2) environmental risks such as to non-target flora and fauna.[6]

The second technology discussed in this article is Artificial Intelligence ('AI'). AI systems are 'machine-based' systems that infer, from input (ie, data) they receive, 'how to generate outputs such as predictions, content, recommendations, or decisions'.[7] This article will focus on health-related AI applications, which vary significantly in their adaptiveness and autonomy, spanning tools that perform disease diagnosis or clinical decision-making assistance, to those predicting hospital readmission or health insurance pricing.

While definitions of health-related AI applications are often limited to clinical decision-making tools that constitute 'Medical Devices',[8] this article will consider the full spectrum of possibilities with a view to informing new governance frameworks for AI in health more generally, not only as they relate to existing legislative frameworks.

As happened previously with gene technology, governments have faced increasing pressure to regulate AI systems by virtue of increased awareness surrounding potential risks.[9] These risks are more expansively conceived than those associated with gene technology, and in addition to primary health and safety concerns, include discrimination based on biased outputs, reinforcement of health inequalities, inaccuracies in inputs, lack of accountability, and even existential risks.[10]

---

[5] Ibid 20–1; Gabrielle M O'Sullivan et al, '20 Years of Legislation: How Australia Has Responded to the Challenge of Regulating Genetically Modified Organisms in the Clinic' (2022) 9 *Frontiers in Medicine* 1, 9 ('20 Years of Legislation').

[6] *Senate Report on Gene-Tech Bill 2000* (n 4) 27–32; Michael Meissle, Steven E Naranjo and Jörg Romeis, 'Does the Growing of Bt Maize Change Abundance or Ecological Function of Non-Target Animals Compared to the Growing of Non-GM Maize? A Systematic Review' (2022) 11(1) *Environmental Evidence* 1, 2.

[7] This is a definition endorsed by the Organisation for Economic Cooperation and Development ('OECD') member countries, including Australia and the European Union. See OECD, *Explanatory Memorandum on the Updated OECD Definition of an AI System* (OECD Artificial Intelligence Papers No 8, 5 March 2024) 4.

[8] This is typical to align discussions with definitions found in medical device legislation. See, eg, *Therapeutic Goods Act 1989* (Cth) ('*TGA*').

[9] See generally Australian Human Rights Commission, *Human Rights and Technology* (Final Report, 1 March 2021) ('*AHRC Report on Human Rights and Technology*').

[10] Australian Government Department of Industry, Science and Resources, *Safe and Responsible AI in Australia Consultation: Australian Government's Interim Response* (Interim Report, 17 January 2024) 10–1 ('*Interim Discussion Paper*').

Australia, unlike other jurisdictions such as the European Union ('EU'), has not enacted AI-specific legislation to address these risks. However, inspired by other jurisdictions, in 2023–24 the Australian Government signalled an intent to begin drafting AI legislation through a discussion paper, *Safe and Responsible AI in Australia* ('*Interim Discussion Paper*'), and a *Proposals Paper for Introducing Mandatory Guardrails for AI in High-Risk Settings* ('*Proposals Paper*').[11] Alongside other policy documents, these comprise the Government's stated approach to achieving Safe and Responsible AI in Australia, which recognises AI in healthcare as a high-risk priority sector.[12] While horizontal legislation is anticipated (ie, legislation will apply to AI generally and will not be health or sector specific), this framework will be the main safeguard for health-related AI risks alongside less comprehensive privacy and medical device legislation.[13]

A distinct source of influence in the Government's proposed approach to AI regulation is the EU's newly enacted AI legislation, *Regulation 2024/1689 Laying Down Harmonised Rules on Artificial Intelligence*.[14] This Regulation is known as the *Artificial Intelligence Act* ('*AIA*'), and has inspired several of the Australian Government's proposed regulatory features, including categories that distinguish AI systems by risk level, with proportionate industry-friendly obligations overlaid across a highly decentralised model.

Australia is at a turning point in deciding the appropriate regulatory model for AI and should exercise significant caution in emulating a foreign, untested, and widely critiqued framework. Rather, this article argues that the Government should instead look domestically to find valuable and proven experience in regulating a similarly disruptive and high-risk technology — gene technology as regulated under the *GTA*. The *GTA* has a 22-year track record as an evidence-informed, technology-specific regulatory model, created in response to an emerging technology with far-reaching health consequences.

This article draws on more than two decades of direct national experience to directly illuminate a number of the policy choices that Australia faces in creating AI legislation. Lessons from the *GTA* will be drawn out by interposing the domain-specific example of European AI regulation under the *AIA*. While AI and

---

[11] Ibid; Australian Government, Department of Industry, Science and Resources, *Safe and Responsible AI in Australia: Proposals Paper for Introducing Mandatory Guardrails for AI in High-Risk Settings* (September 2024) ('*Proposals Paper*').
[12] *Proposals Paper* (n 11) 4, 56.
[13] *Privacy Act 1988* (Cth); *TGA* (n 8).
[14] *Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations* [2024] OJ L 2024/1689 ('*AIA*').

gene technology differ in many respects, there are comparable regulatory features, mechanisms, and objectives in the *GTA* and *AIA* that are also reflected in the Australian Government's stated objectives for future AI regulation. Two primary questions are addressed. First, how are risks presented by AI systems and gene technologies, particularly those posed to health, identified and addressed in these two discrete legislative instruments? Second, learning from this, what comparative lessons do these instruments present for the prospective regulation of health-related AI systems in Australia?

The article is divided into three parts. Part II will address how the *AIA* and *GTA* identify and address the risks of AI and gene technology. Given the novelty of the *AIA*, the absence of recent scholarship on the *GTA*, and the complexities of these frameworks, a large proportion of this part is necessarily descriptive. Part III will compare provisions of the *GTA* and *AIA*, responding to the emerging body of critical literature surrounding the *AIA* with demonstrations of how the *GTA* has functionally addressed many of the deficiencies raised with the *AIA*. Part IV will address what comparative lessons the *GTA* and *AIA* present for the prospective regulation of health-related AI systems in Australia. This will involve contextualising the stated priorities of the Australian Government in relation to AI and identifying distinct comparative features from Part III that inform policy choices available to Australia in pursuing AI regulation.

It is typical in law and technology to reference the 'pacing problem' — the notion that regulation persistently lags behind technological advancements,[15] particularly those with fast-moving risks.[16] Scholars have challenged this notion as being inconsistent with law in practice,[17] and the *GTA* serves as a practical example of new legal regimes that have been created in a timely manner in response to technological developments. Comparative analysis of the *AIA* is particularly pertinent in this context given the power of the European bloc and the influence of EU law internationally (often referred as the 'Brussels effect').[18]

---

[15] Steven Feldstein, 'Evaluating Europe's Push to Enact AI Regulations: How Will This Influence Global Norms?' (2023) 31(5) *Democratization* 1049, 1050.

[16] For AI, see *Interim Discussion Paper* (n 10) 4–6; *AHRC Report on Human Rights and Technology* (n 9). For gene technology, see *Senate Report on Gene-Tech Bill 2000* (n 4); James Collins, 'Gene Drives in Our Future: Challenges of and Opportunities for Using a Self-Sustaining Technology in Pest and Vector Management' (2018) 12(8) *BMC Proceedings* 9.

[17] See generally Joshua AT Fairfield, *Runaway Technology: Can Law Keep Up?* (Cambridge University Press, 2021).

[18] See especially Anu Bradford, *The Brussels Effect: How the European Union Rules the World* (Oxford University Press, 2020).

This article's findings demonstrate the utility of the comparative approach, both for current AI policymaking and the regulation of emerging health technologies more broadly. First, this article demonstrates that the *GTA* takes a precautionary, high-touch, and granular approach to regulating risk — necessary in a high-stakes health context — and achieves this by centralising risk assessment through evidence-based decision-making with significant public participation and accountability. By contrast, the *AIA* adopts a facilitative, pro-industry approach by only modestly regulating 'limited-risk' and 'minimal-risk' AI systems, externalising risk management of 'high-risk' AI systems to AI providers, internalising political agendas, and limiting public participation and accountability.

Further, the *GTA* demonstrates structural separation in its regulatory arrangements between political concerns, scientific expertise, and ethical and community considerations.[19] This affords flexibility to the Regulator in navigating evolving technological development, scientific understanding, and political and community expectations. This structural sophistication is not seen in the *AIA*'s approach, which has been critiqued as full of 'political compromises' and overly prescriptive in the face of complex AI-powered health tools.[20]

II UNDERSTANDING THE *GTA* AND THE *AIA*

This part addresses the question of how two legislative instruments, the *GTA* and the *AIA*, identify and address risks posed by gene technology and AI respectively.

A *Gene Technology Act*

First proposed by the Federal Government in June 2000, the *GTA* entered into force on 21 June 2001.[21] The *GTA* functions within a broader regulatory scheme, comprising the *GTA*, the *Gene Technology Regulations 2001* (Cth) ('*GT Regulations*'),[22] the intergovernmental *Gene Technology Agreement 2001*

[19] David Tribe, 'Gene Technology Regulation in Australia: A Decade of a Federal Implementation of a Statutory Legal Code in a Context of Constituent States Taking Divergent Positions' (2012) 3(1) *GM Crops & Food* 21, 21.
[20] Lillian Edwards, *Expert Opinion: Regulating AI in Europe: Four Problems and Four Solutions* (Ada Lovelace Institute, 31 March 2022) 25; Health Action International, *Interpreting the EU Artificial Intelligence Act for the Health Sector* (Report, February 2022) 14, 19.
[21] Australian Government Department of Health, OGTR, *Retrospective Report 1: Overview of the Scheme* (Report, 21 June 2021) 3–4.
[22] *Gene Technology Regulations 2001* (Cth) ('*GT Regulations*').

('*GT Agreement*'),[23] and corresponding state and territory legislation.[24] The *GTA* establishes the various bodies and stages of regulation that identify and manage risks posed by gene technologies, while the *GT Regulations* manage scope by clarifying technical definitions, setting decision-making timelines for subsidiary bodies, and serving other practical functions. The *GT Agreement* facilitates a consistent national scheme by outlining various understandings and cooperative measures between federal, state, and territory jurisdictions.

Within the *GTA*, two key terms are defined — 'gene technology' and 'genetically modified organism' ('GMO'). Gene technology is defined expansively to mean 'any technique for the modification of genes or other genetic material'.[25] GMOs include organisms modified by gene technology, as well as organisms with inherited traits because of a previous organism's genetic modification.[26] The *GT Regulations* provide clear examples of when an organism may be automatically excluded as a GMO (eg, a previously modified organism no longer demonstrating traits of modification).[27] As outlined in the explanatory statement to the *GT Regulations*, these definitions are intentionally broad to ensure they do not 'become outdated and ineffectual in response to rapidly changing technology'.[28]

1 *Regulatory Objective and Trigger*

The *GTA*'s stated objective is 'to protect the health and safety of people, and to protect the environment by identifying risks posed by or as a result of gene technology'.[29] To achieve this protective objective, the *GTA* functions under what the policy documents term a pre-market 'process trigger'.[30] This means that, rather than the *GTA* prescribing a list of final *characteristics* of a GMO that may trigger regulatory intervention (namely a 'product trigger'), it is instead the

[23] *Gene Technology Agreement 2001* ('*GT Agreement*').
[24] *Gene Technology Act 2003* (ACT); *Gene Technology Act 2003* (NSW); *Gene Technology Act 2004* (NT); *Gene Technology Act 2016* (Qld); *Gene Technology Act 2001* (SA); *Gene Technology Act 2012* (Tas); *Gene Technology Act 2001* (Vic).
[25] *GTA* (n 2) s 10.
[26] Ibid.
[27] *GT Regulations* (n 22) schs 1A–1B.
[28] Explanatory Statement, 'Gene Technology Regulations 2001 No 106)' (Cth) 3.
[29] *GTA* (n 2) s 3.
[30] Australian Government, Department of Health, Disability and Ageing, *Third Review of The National Gene Technology Scheme* (Final Report, October 2018) ('*Gene Technology Scheme Third Review Report*') 36.

process of interacting with an organism through gene technology that triggers regulation.[31]

Importantly, this process trigger is recognised — both by scholars and policymakers — as a preventative and predictable approach to a fast-moving technology presenting indeterminate risks.[32] The existence of indeterminate risk was a prevalent topic in the *GTA*'s legislative history, frequently referenced alongside the 'precautionary principle'.[33] This is an established legal principle often present in health legislation, prioritising scientific certainty and, in the absence of such, requiring significant caution in proceeding with an action.[34]

While the *GTA*'s text does not explicitly refer to the precautionary principle, its discussion in both drafting phases and the risk analysis framework accompanying the *GTA* means that the principle is implicit in the final design of the Act.[35] The precautionary approach is also functionally integrated into the *GTA*, as at *no stage* of risk analysis is the potential utility or economic benefit of a gene technology considered.[36] As discussed in Part III, this precautionary approach contrasts sharply with the *AIA*.

2 *Categories of Regulation*

The *GTA* regulates 'dealings' with GMOs, which includes, for example, making, breeding, supplying, or possessing GMOs.[37] Dealings are prohibited unless they fall within one of four streams: a licenced dealing, an exempt dealing, a notifiable low-risk dealing, or an emergency dealing. For all dealings, approval must be sought from the Regulator. This approval process involves (1) an application to the Regulator — involving a risk assessment and risk management process;

---

[31] Peter Thygesen, 'Clarifying the Regulation of Genome Editing in Australia: Situation for Genetically Modified Organisms' (2019) 28(S2) *Transgenic Research* 151, 151; Joe Smith and Heidi Mitchell, 'Challenges Researchers Need to Consider When Dealing with Regulators' (2014) 9(S1) *Journal für Verbraucherschutz und Lebensmittelsicherheit* 65, 68.

[32] Thygesen (n 31) 152–3; O'Sullivan et al, '20 Years of Legislation' (n 5) 2; *Gene Technology Scheme Third Review Report* (n 30) 36–7.

[33] *Senate Report on Gene-Tech Bill 2000* (n 4) 23, 32; Sumit Salaria, 'Governing Genes for Climate Change: Analysing Values and Ideologies in Australia's Gene Technology Regulation' (Masters Thesis, Macquarie University, 2015) 94.

[34] Zada Lipman, 'Gene Technology Regulation and the Precautionary Principle: How Australia Measures Up' (2005) 8(1) *Journal of International Wildlife Law & Policy* 63, 66–8.

[35] *Senate Report on Gene-Tech Bill 2000* (n 4) 32–45; Australian Government, Department of Health, Disability and Ageing, OGTR, *Risk Analysis Framework 2013* (Policy Publication, May 2013) ('*Risk Analysis Guidance Framework*') 9.

[36] *Risk Analysis Guidance Framework* (n 35) 13–14; O'Sullivan et al, '20 Years of Legislation' (n 5) 4.

[36] *GTA* (n 2) s 10.

[37] Ibid.

(2) for successful cases, an approval with conditions (eg, licence conditions or facility accreditation requirements); and (3) ongoing regulatory compliance by the person dealing with the GMO.[38] Stage (3) will be revisited in discussions of accountability below.

(a) Licenced dealings

The most common type of approval at stage (2) is the provision of a licence, with the majority now involving human therapeutics.[39] Three specific situations under the *GTA* are envisaged as giving rise to a licence. First, an 'inadvertent dealings' licence may be available to a person who has unintentionally come into possession of a GMO, for example through unauthorised importation of a genetically modified plant.[40] This functions as a 12-month (maximum) licence permitting further dealings with, including the destruction of, a GMO.[41]

A licence is also required in two other scenarios: 'intentional release' of a GMO into the external environment,[42] or 'intentional release' within a containment facility.[43] The focus of the *GTA* is on these two streams, which typically involve higher risk applications such as in vivo human gene therapy.[44] Licences will be issued if, following risk analysis, the Regulator is satisfied that risks posed by the dealings are able to be managed in a way that protects the health and safety of people, and the environment.[45] Risk analysis is complex and central to the scheme, with licence conditions and reasons for approval made publicly accessible on the Regulator's website.[46]

(b) Exempt dealings and notifiable low-risk dealings

For both exempt and notifiable low-risk dealings, applications will be approved if particular risk management conditions are met in a certified containment facility. For notifiable low-risk dealings, the Regulator must consider the risks posed to

---

[38] 'Approval Process Overview', *OGTR* (Web Page, 30 January 2024) <https://www.ogtr.gov.au/about-approval-process/process-overview>.
[39] 'Types of GMO Dealings', *OGTR* (Web Page, 29 January 2024) < https://www.ogtr.gov.au/about-approval-process/types-gmo-dealings>.
[40] 'Licence Application ID-01', *OGTR* (Web Page, 1 June 2017) <https://www.ogtr.gov.au/what-weve-approved/inadvertent-dealings-id>.
[41] *GTA* (n 2) s 60(3).
[42] Ibid pt 5 div 4.
[43] Ibid pt 5 div 3; OGTR, 'What Do We Mean by Intentional Release?' (Media Release, 22 April 2024) <https://ogtr.gov.au/news/announcement/what-do-we-mean-intentional-release>.
[44] O'Sullivan et al, '20 Years of Legislation' (n 5) 4.
[45] *GTA* (n 2) div 5.
[46] *GTA* (n 2) s 40A(1); 'What We've Approved?', *OGTR* (Web Page, 3 March 2025) <https://www.ogtr.gov.au/what-weve-approved>.

human health, safety, and the environment before the dealing is listed as low-risk in the *GT Regulations*.[47] For exempt dealings, the Regulator has less of a decision-making role for individual approvals as these typically 'correspond to basic molecular biology methods', such as those used in university research laboratories.[48] Despite this, the Regulator may at any time review — meaning revise, de-list, or add a dealing to — the current list of these dealings provided in the *GT Regulations*.[49] If either dealing is intentionally released, it no longer falls within its approval and requires a new licence.[50]

(c) Emergency dealings

In exceptional circumstances of an 'actual or imminent threat' to either human health and safety or to the environment (eg, disease breakout or pests), the *GTA* provides for an emergency dealing determination. This determination allows for the Minister responsible for gene technology[51] to expedite an approval process for a dealing to either temporarily declare something a GMO or to permit the removal of licencing conditions.[52] Emergency dealing determinations are subject to advice from the Regulator,[53] and carry specific case-by-case conditions.[54]

In summary, the *GTA* functions under a process trigger creating different regulatory streams for GMO dealings, tiered to both context of use and risk. There are two important consistencies across these different streams that will inform the comparison in Part III. First, risk is framed from a *consistent* and legislated perspective — that is, risks posed to human health and safety and the environment. Second, the Regulator maintains a key decision-making role across each of the four streams of regulated dealings. The next section provides a detailed example of this decision-making process for the *GTA's* two main sub-streams of licensed dealings: intentional environment releases and intentional contained releases.

3 *Decision-Making Process and Risk Management Structure*

Prior to approving licences for GMO releases that are either intentional releases into the external environment, or intentional releases in a containment facility,

---

[47] *GT Regulations* (n 22). For notifiable low-risk dealings see s 74; for exempt dealings see div 7.
[48] Tribe (n 19) 26.
[49] *GTA* (n 2) div 7.
[50] *GT Regulations* (n 22) s 6(1)(d).
[51] This is the Minister for Health and Aged Care.
[52] *GTA* (n 2) pt 5A div 3.
[53] Ibid s 72B(2)(c).
[54] OGTR, *Guidelines for Emergency Response Under the Gene Technology Act 2000 and the Gene Technology Agreement* (Guidance Document, July 2009) 11.

the Regulator must prepare Risk Assessment and Risk Management Plans ('RARMPs').[55] Structured from guidance documents prepared by the Regulator, RARMPs are detailed documents of 40–80 pages in length that individually assess potential sources of risk, specify methods for management, and impose necessary licence conditions. For GMOs used in medical applications, RARMPs typically consider factors including pathogenicity and transmissibility.[56] During the drafting stages of RARMPs, the Regulator typically invites and considers public submissions during designated consultation periods.[57]

(a) Centralised RARMP support: technical and ethics expertise

Various expert bodies support the preparation of RARMPs. The Gene Technology Technical Advisory Committee ('Technical Committee') must be consulted for every approved dealing,[58] and in turn provides expert advice on *technical* and *scientific* aspects of gene technology.[59]

Since the *GTA* was enacted, the Technical Committee has held over 80 meetings to address licence applications, with public communiques issued after each meeting.[60] These communiques advise the Regulator on specific matters to consider in preparing RARMPs, such as the potential for accidental exposure of a GMO to humans, or to seek further information from an applicant regarding, for example, specific contents of a vaccine.[61] The Technical Committee is comprised of members with domain-specific scientific backgrounds, including immunologists, molecular biologists, crop scientists, and biosafety experts.[62] It is mandated under the *GTA* that this body contains a 'broad range of skills', including the appointment of a layperson and a member from the ethics body discussed

---

[55] *GTA* (n 2) ss 47, 50.
[56] See, eg, OGTR, *Risk Assessment and Risk Management Plan (consultation version) for DIR 198: Clinical trial of a genetically modified alphavirus (Getah virus) for cancer treatment* (Risk Management Plan, 22 August 2023).
[57] This is permitted under *GTA* s 51(3). See, eg, OGTR, *Risk Assessment and Risk Management Plan for DIR 184: Clinical Trial with a Genetically Modified Human Adenovirus COVID-19 Vaccine* (Risk Management Plan, 25 June 2021); OGTR, *Risk Assessment and Risk Management Plan for DIR 185: Clinical Trial with Genetically Modified Bordetella Pertussis (BPZE1) for the Prevention of Whooping Cough* (Risk Management Plan, 8 December 2021).
[58] Note the statutory use of 'must' in *GTA* (n 2) s 50(3).
[59] Ibid s 101.
[60] 'Gene Technology Technical Advisory Committee', *OGTR* (Web Page, 3 July 2024) <https://www.ogtr.gov.au/committee/gttac>.
[61] See, eg, Gene Technology Technical Advisory Committee, '18 December 2023' (Communiqué, 18 December 2023) 2.
[62] See OGTR, *Gene Technology Technical Advisory Committee (GTTAC)* (Report, 4 July 2025).

directly below — both without the need for specific expertise in gene technology.[63]

In some but not all cases, the Regulator also consults the Gene Technology Ethics and Community Consultative Committee ('Ethics Committee').[64] Since the formation of the Ethics Committee in 2008, 18 meetings have been held. These meetings typically address general ethical issues as prompted by the Regulator, rather than specific matters within individual licence applications.[65] For example, the Ethics Committee has considered how concepts such as 'safety by design' may be incorporated into RARMPs, ethical considerations of consent and privacy when considering humans as GMOs,[66] and implications of public attitude surveys towards gene technology.[67]

As mandated under statute, the Ethics Committee is comprised of members with expertise in risk, bioethics, law, community engagement, and the environment.[68] While both committees can operate with significant flexibility, the *GT Regulations* outline their reporting and decision-making requirements, as well as disclosure of interest protocols.[69]

(b) Decentralised RARMP support: IBCs

The *GTA* also provides for the establishment of Institutional Biosafety Committees ('IBCs') which are formed upon accreditation by the Regulator.[70] These bodies facilitate decentralised risk management as they are embedded in regulated institutions,[71] similar to food safety,[72] pharmacovigilance,[73] or research ethics committees in other contexts.[74] The role of these IBCs includes evaluating low-risk dealings that do not require individual Regulator assessment, as well as

---

[63] *GTA* (n 2) s 100(5)–(8).
[64] Note the statutory use of 'may' in *GTA* (n 2) s 47(4).
[65] Ibid s 107.
[66] See generally Gene Technology Ethics and Community Consultative Committee, 'Meeting of 22 November 2022' (Communiqué, 22 November 2022).
[67] 'Gene Technology Ethics and Community Consultative Committee (GTECCC)', *OGTR* (Web Page, 8 July 2021) <https://ogtr.gov.au/committee/gteccc>.
[68] *GTA* (n 2) s 108. See OGTR, *Gene Technology Ethics and Community Consultative Committee* (Report, 16 September 2025).
[69] *GT Regulations* (n 22) pts 4–5.
[70] Ibid pt 7 div 3.
[71] Tribe (n 19) 26.
[72] 'Food Safety Supervisor', *Food Standards Australia New Zealand* (Web Page, 3 February 2022) <https://www.foodstandards.gov.au/business/food-safety/fact-sheets/food-safety-supervisor>.
[73] Therapeutic Goods Administration, *Pharmacovigilance responsibilities of medicine sponsors: Australian recommendations and requirements* (Report, August 2023) 24.
[74] 'Human Research Ethics Committee', *National Health and Medical Research Council* (Web Page) <https://www.nhmrc.gov.au/research-policy/ethics/human-research-ethics-committees>.

coordinating the preparation and implementation of RARMPs.[75] The Regulator has issued guidance documents regarding this in-house risk management, establishing requirements such as a breadth of expertise and the need for at least one external member within the IBC (ie, without formal association to the organisation in question), as well as specific requirements for the type of genetic manipulation that may be conducted.[76]

(c) Political support: Ministers Meeting and Standing Committee

To facilitate the scheme's practical operation, the *GT Agreement* provides for the creation of the Gene Technology Ministers Meeting ('Ministers Meeting'). This body is composed of one government minister from each jurisdiction (federal, state, and territory), and engages in tasks including advising on the composition of the Regulator, initiating reviews of the scheme, and issuing administrative guidelines to manage the Regulator's activities.[77] The Gene Technology Standing Committee ('Standing Committee') provides high-level support to the Ministers Meeting and is similarly composed of senior government officials.

The work of these two bodies is more political in nature than that of the Technical Committee, Ethics Committee, and IBCs, as it extends to facilitating jurisdictional coordination, drafting policy frameworks, and maintaining ministerial presence in the Regulator's actions.[78] However, the Ministers Meeting and Standing Committee are not involved directly in RARMP applications, ensuring that these bodies do not politicise the central work of the Regulator.

4 *Review, Public Participation, and Accountability*

A key feature of the scheme is that it contains robust mechanisms for review, public participation, and accountability. Legislative review begins with the Standing Committee, which is mandated under the *GT Agreement* to initiate review at least every five years, and *must* invite public submissions as well as draw on consultation with the expert Technical and Ethics Committees, the

[75] 'Organisation Accreditation Requirements', *OGTR* (Web Page, 26 March 2024) <https://www.ogtr.gov.au/about-approval-process/organisation-accreditation-requirements>.
[76] See OGTR, *Explanatory Information on the Guidelines for Accreditation of Organisations* (Guidance Document, 18 April 2013).
[77] 'Gene Technology Ministers Meeting', *National Gene Technology Scheme* (Web Page, 20 September 2024) <https://www.genetechnology.gov.au/about-the-national-scheme/how-it-works/ministers-meeting>.
[78] Ibid; Australian Government, 'Gene Technology Ministers' Meeting' (Communiqué, 20 July 2021) 2; Australian Government, 'Gene Technology Ministers' Meeting' (Communiqué, 11 December 2020) 2.

Regulator, and other industry or scientific groups as deemed relevant.[79] Depending on the type of review being conducted, periods of consultation are held and published on the Federal Government consultation hub before action plans are drafted.[80] Types of review initiated include revising guidance frameworks for risk analysis plans, technical reviews of the *GT Regulations*, and independent reviews of the *GTA*.

One of the most notable reviews was commenced in 2017 and is still in the process of implementation. The task of this substantial 'Third Review' included future-proofing the gene technology scheme against technological developments and assessing its ongoing effectiveness.[81] To manage this review, an expert panel was established, guided by the Standing Committee, which conducted several public consultations to identify key issues and inform action plans and strategies for implementation.

Across three different consultation phases, nearly 160 submissions were received, drawing input from private industry, research institutions, and consumers.[82] Upon finalising the recommendations, further consultation periods were held between 2020 and 2024 to construct a framework that would best implement the review and drafted amendments, with public support for attempts to reduce the prescriptiveness of the *GTA* and shift some technical considerations to delegated legislation.[83]

While new legislation is not anticipated until the end of 2025, a key feature of the scheme's review process is a sustained focus on public engagement. Requests for submissions are published on the Federal Government consultation hub. In addition, and of its own initiative, the Regulator regularly commissions surveys on community attitudes towards gene technology, integrating findings into

---

[79] *GT Agreement* (n 23) [21(h)], [44]–[45].

[80] 'Consultation Finder: National Gene Technology Scheme', *Australian Government Department of Health and Aged Care* (Web Page, 2023) <https://consultations.health.gov.au/consultation_finder>.

[81] '2017 Review: Terms of Reference', *National Gene Technology Scheme* (Web Page, 2017) <https://www.genetechnology.gov.au/resources/publications/2017-review-terms-reference>.

[82] Australian Government, National Gene Technology Scheme, *Third Review of the Gene Technology Scheme* (Preliminary Report, March 2018) VIII.

[83] See generally Australian Government, National Gene Technology Scheme, *Modernising and future-proofing the National Gene Technology Scheme: Proposed regulatory framework to support implementation of the Third Review of the Scheme* (Consultation Regulation Impact Statement, December 2020); 'Proposed Amendments to the Gene Technology Act 2000', *OGTR* (Web Page, 18 October 2024) <https://www.genetechnology.gov.au/reviews-and-consultations/current/proposed-amendments-gene-technology-act-2000>.

various review and policy documents.[84] On a more specific level, the Regulator is *mandated* to maintain periods of open consultation with the public for individual RARMPs. [85]

There are also indirect avenues for public participation through, for example, parliamentary scrutiny in stages of legislative review. Evidence of this is seen in the 'Technical Review' of the *GT Regulations* held between 2016 and 2019. This review addressed new advances in gene technology, including self-directed nuclease techniques, and sought to amend the regulatory status of certain modification techniques no longer considered GMOs (termed 'SDN-1').[86] Following the tabling of proposed amendments in the Federal Parliament, a non-majority party (the Greens) that supported organic farmers expressed concerns that it would be increasingly difficult to guarantee GMO-free markets following deregulation of GM plants modified using SDN-1.[87] In the Greens' submission, the Regulator had insufficiently consulted with farmers on the importance of both organic farming and Australia's 'clean' market reputation, with a focus exclusively on the technical and health aspects of gene technology.[88]

While initially this call for disallowance of the amendments was rejected,[89] after public scrutiny and activism concerning the ambiguities of modern GMO classifications,[90] the legislative item proposing to deregulate certain techniques was repealed a year later.[91] Regardless of the merits, this example illustrates how

---

[84] See, eg, Craig Cormick and Rob Mercer, *Community Attitudes to Gene Technology* (Report, October 2017); *OGTR Retrospective Report* (n 21).
[85] *GTA* (n 2) s 52(2)(c)(d).
[86] Australian Government, 'Explanatory Statement to Gene Technology *Amendment* (2019 Measures No 1) (Cth)', *Federal Register of Legislation* (Web Page) <https://www.legislation.gov.au/F2019L00573/latest/text /explanatory-statement>; Lauren John and Artemis Kirkinis, 'From Lab to Pasture to Plate: Amendments to the National Gene Technology Scheme', *Allens* (Blog Post, 11 August 2019) <https://www.allens.com.au/insights-news/insights/2019/08/from-lab-to-pasture-to-plate-amendments-to-the-national-gene-technology-scheme/>.
[87] Commonwealth, *Parliamentary Debates*, Senate, 13 November 2019, 3758–3766.
[88] Ibid.
[89] Ibid.
[90] 'Open Letter to Parliament: Gene Editing Deregulation Undermines Brand Australia', *OBE Organic* (Web Page, 2019) <https://www.obeorganic.com/open-letter-to-parliament-gene-editing-deregulation-undermines-brand-australia/>; 'The Gene Technology Amendment Puts Australian Families at Risk of Eating Untested, Unlabelled Genetically Modified Foods, Including Animals', *Slow Food* (Web Page, 2019) <https://www.slowfood.com/blog-and-news/the-gene-technology-amendment-puts-australian-families-at-risk-of-eating-untested-unlabeled-genetically-modified-foods-including-animals/>; 'Keep GM Animals Off Our Farms', *Friends of the Earth Australia* (Web Page, 2019) <https://www.foe.org.au/keep_gm_animals_off_our_farms>.
[91] OGTR, *Regulatory Adjustments Made in Response to 20 years of Innovation in Gene Technology* (Report, 2021) 8; OGTR, *Decision Regulation Impact Statement: Amendments to the Gene Technology Regulations 2001* (2021) 10.

the scheme has been reformed through parliamentary scrutiny and community input.[92] There are further direct mechanisms of accountability in place, such as legislative mandates for the Regulator to draft annual activity reports.[93] These reports are tabled in parliament and must include detailed information on budget activities, monitoring and enforcement updates, and operational performance matters.[94]

Further down the chain of regulation, the Regulator also monitors the activities of IBCs — the accredited organisations that conduct in-house risk assessment of GMOs. The Regulator requires annual reporting from each IBC, monitored in line with publicly accessible guidance detailing the processes of auditing, routine inspections, and spot checks.[95] Licence holders, who are often commercial sponsors in a therapeutic context,[96] therefore uphold risk management practices through local IBCs which are in turn accountable to the Regulator.

Having laid out the processes and bodies involved in regulating gene technology in Australia, the next section turns to AI in a different jurisdictional context, the EU.

B *Artificial Intelligence Act*

First proposed by the European Commission in 2021, the European *AIA* entered into force on 1 August 2024.[97] The *AIA* has a complex relationship with existing EU instruments, including data privacy regulations,[98] and the 'New Legislative Framework', an existing suite of legislation aimed to improve product safety for specific classes of goods entering the European internal market.[99] An example of these regulated goods are Medical Devices, which include AI-powered health

---

[92] See generally Kerry Ross, 'Providing "Thoughtful Feedback": Public Participation in the Regulation of Australia's First Genetically Modified Food Crop' (2007) 34(3) *Science and Public Policy* 216.
[93] *GTA* (n 2) pt 9 div 5.
[94] Ibid.
[95] OGTR, *Operations of the Gene Technology Regulator Annual Report 2022–23* (13 September 2023) 13.
[96] O'Sullivan et al, '20 Years of Legislation' (n 5) 8.
[97] As a result of staggered implementation and delays, many provisions have only come into force in 2025, with others not expected until 2026 and beyond.
[98] *Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the Protection of Natural Persons with Regard to the Processing of Personal Data and on the Free Movement of Such Data and repealing Directive 95/46/EC (General Data Protection Regulation),* [2016] OJ L 119/1.
[99] 'New Legislative Framework', *European Commission* (Web Page) <https://single-market-economy.ec.europa.eu/single-market/goods/new-legislative-framework_en>.

tools considered 'software'.[100] The *AIA*, having the nature of a regulation, is directly applicable to EU Member States.

The *AIA* is a horizontal framework, meaning it applies broadly across different sectors rather than targeting a specific sector such as health-related AI systems. Within the complex regulatory ecosystem that governs these systems, the *AIA* will play an overlapping but central role. This centrality is similar to the expected framework in Australia. Therefore, this section will analyse the *AIA* and the broader framework only to the extent it is relevant for comparison with the *GTA* (Part III), and for the lessons it showcases for Australia (Part IV).

The *AIA* defines the subject of the Act — an 'AI system' — as a machine-based system 'designed to operate with varying levels of autonomy' that may exhibit adaptiveness and that 'infers, from the input it receives, how to generate outputs', such as predictions, content, and decisions.[101] As this definition is quite involved, recital 12 of the *AIA* refines several terms. For example, 'autonomy' indicates 'some degree of independence of actions from human involvement', and 'adaptiveness' indicates 'self-learning capabilities, allowing the system to change while in use'.[102]

Definitional questions were extensively debated in the drafting stages of the *AIA*,[103] and an important objective of this debate was to 'future-proof' the Act with a 'technology-neutral' definition.[104] The final definition attempts to strike a balance between legal certainty and flexibility regarding a fast-evolving technology.[105]

To oversee implementation of the *AIA*, the Act establishes the 'AI Office' within the European Commission. The AI Office is tasked with monitoring AI markets, providing guidelines and spaces for innovation, and, in particular, enforcing

---

[100] Medical Devices in the EU are regulated under the *Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC* [2017] OJ L 117/5 ('*EU Medical Devices Regulation*').
[101] *AIA* (n 14) art 3(1).
[102] Ibid recital 12.
[103] Martin Ebers et al, 'The European Commission's Proposal for an Artificial Intelligence Act: A Critical Assessment by Members of the Robotics and AI Law Society (RAILS)' (2021) 4(4) *The Impact of Artificial Intelligence on Law* 589, 591.
[104] European Commission, '*Explanatory Memorandum to COM (2021) 206 final*' (21 April 2024) 3, 12.
[105] Ibid 18; *AIA* (n 14) recital 12. See generally Dan Svantesson, 'The European Union Artificial Intelligence Act: Potential Implications for Australia' (2022) 47(1) *Alternative Law Journal* 4.

requirements on 'general purpose AI systems'.[106] It will also oversee international cooperation and stakeholder engagement by working with Member States and Commission agencies with relevant competences such as the European Centre for Algorithm Transparency.

1 *Regulatory Objective, the Risk-Based Approach, and GPAI Models*

(a) Regulatory objective

The *AIA* has two express objectives. The first is protective — to ensure 'a high level of protection of health, safety [and] fundamental rights enshrined in the Charter'.[107] The 'Charter' refers to the Charter of Fundamental Rights of the European Union, and enshrines human rights, including the rights to protection of data,[108] to non-discrimination,[109] and to freedom of expression.[110] Alongside this, the *AIA*'s second objective is to promote the development of AI technologies — to 'support innovation', 'improve the functioning of the internal market', and 'promote uptake of human-centric and trustworthy AI'.[111] In a health context, this is an attempt to mitigate potentially harmful wellbeing and health effects at both an individual and population level, while permitting AI technologies to enhance health outcomes.[112]

A distinct influence of the New Legislative Framework on the *AIA* is that the *AIA* conceives AI systems as consumer-facing products, with analogies to product safety principles in terms of mechanisms for approval and regulation.[113] If a product entering the European Internal Market is deemed a 'Medical Device' — ie any instrument or tool intended for a specific medical purpose — it must meet safety standards and is subject to regulatory oversight proportionate to risk level as laid out in sector-specific legislation.[114] Despite capturing a much broader scope of AI-powered products beyond Medical Devices, the *AIA* adopts a similar risk-based approach and envisages the overlap of some regulatory bodies.[115] The

---

[106] See Decision C/2024/390, *Establishing the European Artificial Intelligence Office* (2024) ('*EU Decision Establishing the AI Office*').
[107] *AIA* (n 14) art 1.
[108] Ibid art 8.
[109] Ibid art 21.
[110] Ibid art 11.
[111] Ibid art 1.
[112] Jelena Schmidt et al, 'Mapping the Regulatory Landscape for Artificial Intelligence in Health Within the European Union (2024) 7(1) *NPJ Digital Medicine* 1.
[113] Edwards (n 20) 5–10.
[114] See, eg, *EU Medical Devices Regulation* (n 100).
[115] See Emmanouil P Vardas et al, 'Medicine, Healthcare and the AI Act: Gaps, Challenges and Future Implications' (2025) 6(4) *European Heart Journal: Digital Health* 833; Health Action International (n 20) 16–17.

implications and importance of this consumer-facing product influence will be explained below and throughout Part III.

(b) The risk-based approach

To regulate AI systems, the *AIA* adopts a risk-based approach,[116] distinguishing four categories into which any given AI system might fall: minimal risk, limited risk, unacceptable risk, and high-risk.

AI systems that fall within the 'minimal risk' category, such as email spam filters, are unregulated under the *AIA* on the basis that they are considered relatively uncontroversial.[117] In a health context, minimal risk systems might include those performing administrative tasks or automating non-patient facing processes such as billing.[118] 'Limited risk' systems, a tier above, include systems that interact with natural persons, for example wellbeing chatbots, AI systems producing medical deepfakes, or apps promoting health goals.[119] Limited risk systems are subject to disclosure obligations to ensure consumers are aware they are interacting with an AI.[120] Systems that pose 'unacceptable risk' are defined to include those that perform social scoring functions for uses such as health benefits, exploit vulnerabilities of natural persons, use biometric identification in publicly accessible spaces, or deploy 'subliminal techniques beyond a person's consciousness'.[121]

The bulk of the *AIA*'s text deals with the fourth category, 'high-risk systems'. High-risk systems either (1) are 'intended to be used as a safety component' of a product falling under sectoral product safety legislation[122] (eg, an AI system embedded in a Medical Device);[123] (2) are themselves a regulated product; or (3) fall within a list of eight application areas prescribed under the Act (eg, uses in

[116] This is explicitly stated in recital 14 of the *AIA* (n 14).
[117] European Commission, 'High Level Summary of the AI Act', *EU Artificial Intelligence Act* (Web Page, 27 February 2024) <https://artificialintelligenceact.eu/high-level-summary/>. Low-risk systems are not dealt with in the *AIA*: see 'Shaping European's Digital Future', *European Commission* (Web Page, 8 August 2024) <https://digital-strategy.ec.europa.eu/en/policies/regulatory-framework-ai>.
[118] Hannah van Kolfschooten and Janneke van Oirschot, 'The EU Artificial Intelligence Act (2024): Implications for Healthcare' (2024) 149 *Health Policy* 2.
[119] Ibid 2.
[120] *AIA* (n 14) art 50.
[121] Ibid art 5; Health Action International (n 20) 11.
[122] *AIA* (n 14) art 6(1) (a) and annex II.
[123] Ibid annex I pt (2) and (11).

education, employment, or emergency response services such as medical aid).[124] A more detailed analysis of high-risk systems will be provided below.

Importantly, decisions to categorise AI systems into one of the four specified risk categories are made by providers of AI (ie, organisations or individuals developing or applying AI systems),[125] rather than by an external or independent body such as the Regulator in the gene technology context. AI providers are the principal responsible subject under the *AIA*, and are typically private technology companies, although increasingly providers may include hospitals or healthcare organisations developing their own AI systems.[126] Actors further down the supply chain such as deployers and distributors of AI (eg, healthcare professionals) are given some, limited, responsibilities,[127] while importers and end-users (eg, patients) have no responsibilities.

(c) GPAI models

The *AIA* also distinguishes a particular sub-category of AI systems: *general purpose AI systems* ('GPAI'), which are defined to have capacities to 'serve a variety of purposes',[128] and are typically used as pre-trained adaptable models for further application in specialised systems.[129] In practice, this is intended to cover AI systems such as large language models ('LLM') like GPT-4, developed by established technology firms like OpenAI.[130] This includes a rapidly growing market driven by "health-focused" tech companies training LLMs with sensitive health data to make, for example, AI summarisation tools such as ambient scribes for clinical consults or automated referral generators.[131]

The *AIA* further categorises GPAIs into those that do and do not present systemic risks. GPAIs with 'systemic risks' include systems with high-impact capabilities (ie, computing power exceeding a legislated amount) or similar capabilities, 'as decided by the Commission' subject to consideration of established criteria.[132]

---

[124] Ibid art 2 and annex III s (3) and (4).
[125] Ibid art 8.
[126] Kolfschooten and Oirschot (n 118) n 3.
[127] *AIA* (n 14) arts 24, 26.
[128] Ibid art 3.
[129] Future of Life Institute, *General Purpose AI and the AI Act* (Report, May 2022) 3.
[130] Ibid.
[131] See generally Stephen Gilbert et al, 'Large Language Model AI Chatbots Require Approval as Medical Devices' (2023) 29(10) *Nat Med* 2396. In Australia see, eg, 'The AI medical scribe for all clinicians', *Heidi Health* (Web Page, 2025) <https://www.heidihealth.com/au>; *Lyrebird Health* (Web Page, 2025) <https://www.lyrebirdhealth.com/au>.
[132] *AIA* (n 14) art 51(1), annex XIII.

These criteria include data set size and quality, projected impact on the internal market due to reach, and number of end-users.[133]

All providers of GPAIs are required to keep — and provide to the AI Office if requested — technical documentation to comply with the European Copyright Directive,[134] and to provide certain publicly available information via a template produced by the AI Office.[135] Additional obligations are imposed for GPAI models with systemic risks, including extra testing and mitigation measures, as well as reporting 'serious incidents' to the AI Office.[136] 'Serious incident' is defined to include death or serious harm to health, serious harm to the environment, or infringement on fundamental rights.[137]

(d) In-depth analysis of high-risk systems

High-risk systems are the main focus of the *AIA*. The central obligation on providers of these systems is to establish a 'risk management' system.[138] This includes risk assessment to identify and evaluate risks arising through both intended use and foreseeable misuse of the AI system, as well as the 'adoption of appropriate and targeted' measures to manage risk.[139]

In addition, the *AIA* imposes six other requirements. At a high level, these include requirements on data governance and training, technical documentation, record keeping, transparency, human oversight, and accuracy, robustness and cybersecurity.[140] If, further down the AI supply chain, an importer, distributor, or deployer of an AI system makes a substantial modification (ie, a change not foreseen or planned in original risk assessment),[141] then they are deemed 'providers' for the purposes of complying with high-risk obligations.[142] This ensures that any AI systems posing new or unforeseen risks re-enter regulatory cycles.

AI providers demonstrate compliance with the requirements detailed above through a 'conformity assessment' ('CA'). CAs are conducted in one of two ways:

---

[133] Ibid.
[134] *Directive (EU) 2019/790 of the European Parliament and of the Council of 17 April 2019 on Copyright and Related Rights in the Digital Single Market and Amending Directives 96/9/EC and 2001/29/EC* OJ L 130.
[135] *AIA* (n 14) art 51(1)(d).
[136] Ibid art 55(1).
[137] Ibid art 3(49).
[138] Ibid art 9.
[139] Ibid art 9(2)(a)–(b).
[140] European Commission, 'High Level Summary of the AI Act' (n 117).
[141] Defined in art 3 of the *AIA* (n 14).
[142] Ibid art 25.

either by a 'Notified Body'[143] or through internal (self) assessment. A Notified Body must be established under domestic laws and is required to satisfy legislated requirements under the *AIA*.[144] Similarly, under product safety legislation, Notified Bodies must perform CAs for developers of Medical Devices.[145] Given that the majority of high-risk health-related AI systems will be classed as Medical Devices — likely as medical software[146] — the *AIA* envisages that the existing Notified Bodies for Medical Devices will perform CAs for high-risk AI systems.[147] It is still unclear how this overlap will function in practice as the *AIA* continues to take effect.[148] However, once a CA is completed, AI providers must draft a declaration of conformity which will be marked with a 'CE' mark to designate satisfaction of European product safety standards permitting free internal market movement.[149]

2 *Regulatory Features and Actors: Harmonised Standards, Post-Market Obligations and the AI Office.*

A key feature of the *AIA* is the use of harmonised standards. These are outsourced to European Standardisation Bodies,[150] and the *AIA* envisages that these standards will provide consistent and certain technical requirements for high-risk AI systems regarding underspecified legislated obligations (eg, where references are made to implement 'appropriate measures').[151] Compliance with the standards creates a presumption of conformity.[152] As for GPAI systems, the AI Office is mandated to produce a 'Code of Practice' detailing, for example, the adequate level of detail in content disclosures.[153] This Code, along with many

[143] For a list of these bodies, see 'Single Market Compliance Space: Notified bodies (NANDO)', *European Commission* (Web Page) <https://webgate.ec.europa.eu/single-market-compliance-space/notified-bodies>.
[144] *AIA* (n 14) art 31; *Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC*.
[145] *EU Medical Devices Regulation* (n 100) art 52.
[146] Ibid, ch III, r 11.
[147] See Vardas et al (n 115).
[148] Stephen Gilbert, 'The EU Passes the AI Act and its Implications for Digital Medicine are Unclear' (2024) 135(1) *NPJ Digital Medicine* 1, 1–3.
[149] *AIA* (n 14) art 48.
[150] Most relevant are CEN (European Committee for Standardisation) and CENELEC (European Committee for Electrotechnical Standardisation).
[151] 'Standard Setting', *EU Artificial Intelligence Act* (Web Page, updated June 2025) <https://artificialintelligenceact.eu/standard-setting/>.
[152] *AIA* (n 14) art 40.
[153] Ibid art 56.

standards, has been delayed until 2026,[154] but once published, adherence to it will grant a presumption of conformity to AI providers.

Though standards and codes assist in harmonising practice to some extent, the principal regulatory burden under the *AIA* rests on providers. Other actors in the AI supply chain also have some limited responsibilities. For example, distributors making AI systems available on the market are mandated to ensure providers have complied with CE certification, and to prevent distribution in the event of suspected non-compliance.[155]

Regarding post-market obligations, providers must also establish models to continuously collect, document, and analyse performance data from their AI systems.[156] This practice functions alongside 'Market Surveillance Authorities' — bodies that reside within Member States and conduct the majority of compliance investigations and enforcement actions pursuant to existing EU product regulations.[157] If during enforcement stages Member States engage in cross-jurisdictional 'joint investigations', the AI Office may provide coordinating assistance.[158] Specifically for GPAI models, the AI Office can conduct compliance evaluations as well as receive and review downstream complaints for non-compliance.[159]

One of the distinct functions of the AI Office is to promote innovation and efficient uptake of AI systems (the *AIA*'s second objective).[160] It achieves this by coordinating the implementation of 'regulatory sandboxes', which are 'controlled environments' for 'safely' testing and developing AI systems.[161] AI systems may cycle through several phases of a sandbox during development, before approaching the pre-market regulatory measures described above. The *AIA* mandates that implementing sandboxes is the responsibility of Member State authorities, which will provide one member each to compose the AI Board.[162] The

---

[154] 'EU Could Water Down AI Act amid Pressure from Trump and Big Tech', *The Guardian* (online, 7 November 2025) <https://www.theguardian.com/world/2025/nov/07/european-commissio n- ai-artificial-intelligence-act-trump-administration-tech-business>.
[155] *AIA* (n 14) art 24.
[156] Ibid ch 4 art 72.
[157] Ibid art 74; *Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on Market Surveillance and Compliance of Products* OJ L 169, 25 June 2019, 1–44.
[158] *AIA* (n 14) art 74(11).
[159] *EU Decision Establishing the AI Office* (n 106) 3–5.
[160] *AIA* (n 14) art 2(2); *EU Decision Establishing the AI Office* (n 106).
[161] *AIA* (n 14) art 57.
[162] Ibid arts 57, 65.

AI Board and AI Office are mandated to encourage information sharing and best practice guidance for sandboxes.[163]

The exact composition of the AI Office is not specified in the *AIA*. However, the Commission has published an organisational structure, including five units with technical expertise in robotics, compliance, safety, innovation, and societal good, as well as two advisors, one 'Scientific' and one 'International Affairs'.[164] The *AIA* also requires the establishment of a panel composed of members with 'scientific' and 'technical' expertise on AI to be selected by the Commission.[165] The functions of this panel are to advise the AI Office on matters including systemic risks of GPAI systems, general matters of post-market enforcement, and developing 'tools and templates'.[166]

3 *Review, Public Participation, and Accountability*

Understanding the drafting history of the *AIA* can be difficult, given many of the decisions on risk, categories, and definitions were internalised in the complexities of trialogue negotiations between Member States and the Commission. Leading scholars have described many consequential decisions within the *AIA* as having, from an outward perspective, 'little or no justification'.[167] The lawmaking process can nevertheless be traced to some extent. High-risk systems, for example, were identified in part by phases of public consultation on a drafting paper.[168] This process was also informed by private expert webinars, online conferences, literature reviews by government and non-government organisations, and documents produced by Commission expert groups.[169] Sectoral considerations led to domains such as healthcare being recognised as high-stakes, and despite consultations indicating that sectoral specific legislation was preferred, a horizontal framework was ultimately decided on.[170]

Specific provisions in the *AIA* address review and amendment of the Act. Using high-risk systems as an example, if the Commission seeks to add a new group to

---

[163] Ibid art 57.
[164] 'The AI Office: Structure and Functions', *European Commission* (Web Page, 2024) <https://digital-strategy.ec.europa.eu/en/policies/ai-office#ecl-inpage-the-structure-of-the-ai-office>.
[165] *AIA* (n 14) art 68.
[166] Ibid art 68.
[167] Edwards (n 20) 12.
[168] See European Commission, *White Paper on Artificial Intelligence*: *A European Approach to Excellence and Trust* (White Paper, 19 February 2020).
[169] Ljupcho Grozdanovski and Jérôme De Cooman, 'On The Obsolescence of Empirical Knowledge in Defining The Risk/Rights-based Approach to AI Regulation in The European Union' (2023) 49(2) *Rutgers Computer and Technology Law Journal* 207, 236–240.
[170] Ibid.

the AIA's established list, it must consider a range of legislated factors.[171] There is also a general power to create delegated legislation to supplement the *AIA*, provided procedural requirements are met, including consulting specific expert groups, and exposing the delegated legislation to parliamentary scrutiny.[172] Accountability in the *AIA* can also be partially traced across the lifecycle of an AI system from development to end-users. Providers of high-risk systems must address the documentation and disclosure requirements detailed above.

Upon market entry, parts of these documents are subject to public scrutiny, as the *AIA* requires providers to list their systems in a public database alongside technical data.[173] Downstream users of systems who suspect non-compliance with the *AIA* must not distribute high-risk systems to the market.[174] A significant and widely acknowledged limitation of the *AIA* relates to people impacted by AI systems (eg, patients facing discrimination from an AI-enabled decision), who are provided with no mechanisms for recourse under the Act itself.[175]

In recognising that AI systems naturally present difficulties in establishing chains of accountability,[176] the *AIA* has some focus on disclosure requirements and information sharing practices within supply chains. This includes the establishment of government regulatory sandboxes that work to streamline AI systems through testing mechanisms, maintaining close rapport with providers.[177]

Overall, the *AIA* establishes a predominantly decentralised regulatory approach, with some coordination by the AI Office and regional standards bodies. Most responsibility resides with providers to both assess and implement responses to the risks associated with AI systems, and overlap is expected with the Notified Bodies for Medical Device regulation. Further reflecting the pro-industry orientation of the Act, opportunities for public input into regulatory processes are limited.

---

[171] *AIA* (n 14) art 7.
[172] Ibid art 97.
[173] Ibid art 71.
[174] Ibid art 24.
[175] Jeremias Adams-Prassl, 'Regulating Algorithms at Work: Lessons for a "European Approach to Artificial Intelligence"' (2022) 13(1) *European Labour Law Journal* 30, 49; Michael Veale and Frederik Zuiderveen Borgesius, 'Demystifying the Draft EU Artificial Intelligence Act: Analysing the Good, the Bad, and the Unclear Elements of the Proposed Approach' (2021) 22(4) *Computer Law Review International* 97, 112.
[176] Jennifer Cobbe, Michael Veale and Jatinder Singh, 'Understanding Accountability in Algorithmic Supply Chains' in *FAccT '23: Proceedings of the 2023 ACM Conference on Fairness, Accountability, and Transparency* (12 June 2023) 1186–1197 <https:doi.org/10.1145/3593013.3594073>.
[177] *AIA* (n 14) art 60 annex III, art 13.

III COMPARING THE *GTA* AND THE *AIA*

This part will compare the *GTA* and the *AIA* as two instruments regulating specific technologies that present both known and indeterminate risks in the high-stakes health sector, which manage this challenge in distinct and interesting ways. It focuses on four of the most significant points of comparison between the two Acts: (1) regulatory objectives; (2) regulatory triggers; (3) risk categorisation and decision-making; and (4) mechanisms for accountability, public participation, and review.

A *Regulatory Objectives*

The regulatory objectives of the *AIA* and *GTA* are notably different. The *GTA*'s exclusive focus is to 'protect the health and safety of people, and to protect the environment'.[178] The *AIA* partly shares this focus — to protect the health, safety, and fundamental rights of people — however, in addition, it explicitly promotes innovation, AI uptake, and improved market functioning.[179] It is therefore baked into the *AIA*'s regulatory approach that the protection of health, safety, and fundamental rights may be superseded by pro-AI market considerations. This approach seems to undermine the Act's protective objective and, indeed, the very nature of fundamental rights protections.

Express support for this pro-industry regulatory approach can be found in explanatory reports accompanying the *AIA*, stating the Act's regulatory intention to only intervene when 'strictly needed in a way that minimises the burden for economic operators'.[180] This is reflected in the *AIA*'s risk-based model, with each regulated category resulting from 'drafting compromises' that weigh the risks posed by AI systems against promised benefits, including improved health outcomes, efficiency, and market gains.[181]

This is illustrated clearly by the category of 'minimal risk' AI systems, which, by virtue of being unregulated under the *AIA*, demonstrate that the promise of economic and efficiency gains outweigh any 'minimal' level of risk presented. While some scholars have described this compromise as reasonable given risk is

---

[178] *GTA* (n 2) s 3.
[179] *AIA* (n 14) art 1.
[180] European Commission, 'Communication on Fostering a European approach to artificial intelligence' (21 April 2021) [4].
[181] Johanna Chamberlain, 'The Risk-Based Approach of the European Union's Proposed Artificial Intelligence Regulation: Some Comments from a Tort Law Perspective' (2023) 14(1) *European Journal of Risk Regulation* 1, 1.

'practically never completely avoidable',[182] there have also been critiques that such a minimal degree of regulation is unacceptable in the face of unpredictable risk to health, safety, and fundamental rights.[183]

The dual objectives of the *AIA* are in stark contrast to the *GTA*'s single precautionary objective. The *GTA*'s regulatory starting position is that *all* dealings with GMOs are prohibited until permitted, regardless of their promise or predicted (even potentially negligible) levels of risk.[184] Only once dealings undergo the approval process described in Part II (eg, centralised, detailed risk assessment and licence application with ongoing obligations) can a GMO be dealt with.

At a sub-structural level, the *GTA*'s category of 'exempt dealing' can be analogised to the *AIA*'s 'minimal risk' category (eg, an AI-based system performing administrative functions in healthcare). Recalling from Part II, exempt dealings are, for example, uses of GMOs that align with methods of basic molecular biology.[185] These are listed in the *GT Regulations* as dealings that can be undertaken without a licence provided specified criteria are met, demonstrating that the gene technology scheme retains conditional oversight even of unlicensed use of gene technology. Unlike the *AIA*, the *GTA* does not presume certain uses of gene technology to be so low-risk as to not require regulation — even when that might deprive the market of a GMO of great benefit in the high-stakes context of health.

B *Regulatory Triggers*

Comparing the design of the *AIA* and the *GTA* highlights a key functional difference between the Acts, that is, the feature that triggers regulation. The *GTA* regulates dealings that may lead to GMOs, rather than GMOs themselves. This means GMOs are not only regulated as products, when there is a vaccine or modified crop ready for market, but also in early stages of research and development. Contrastingly, the *AIA* regulates AI systems as products, meaning regulation is only triggered if a developed product is proposing to enter the Internal Market. In short, the *GTA* uses a 'process trigger', while the *AIA* uses a 'product trigger'. At an international comparative level, European gene technology regulation also uses a process

---

[182] Ibid 7.
[183] See Edwards (n 20).
[184] 'How We Regulate Genetically Modified Organisms (GMOs)', *OGTR* (Web Page, 4 September 2024) <https://www.ogtr.gov.au/about-ogtr/how-we-regulate-genetically-modified-organisms-gmos>.
[185] Tribe (n 19) 26.

trigger, whereas Canada is an example of a jurisdiction that employs a product trigger, regulating GMOs through assessing new traits in developed GMOs as products.[186]

The *GTA*'s third statutory review considered the merits of a process trigger against a product trigger, finding that the existing approach increases the scope of the regulatory scheme in desirable ways.[187] Regulating the full process of GMO development captures a broader range of activities, allowing 'products that do not yet have a history of safe use to be monitored'.[188] Reviews of the gene technology legislative scheme have found that technological developments have historically moved faster than regulation,[189] which, in accordance with public sentiment towards gene technologies, justifies a 'regulatory scheme with a broad scope'.[190]

While it is typically gene technology rather than AI literature that uses this product and process trigger terminology,[191] it is useful to apply here given the calls to adopt a more conservative framework that captures unforeseen risk through a large scope.[192] This terminology also assists in understanding the influence of European product safety legislation on the *AIA*. As argued by leading scholars in this area, this influence has led to the *AIA* conceiving AI systems as a tangible product,[193] creating a distinction between 'risks to rights' or pro-rights thinking — which is similar to what is observed in the *GTA* and promotes the *AIA*'s protective objective — and 'product safety' or pro-industry thinking.[194]

This explains the critiqued absence from the *AIA* of the precautionary principle,[195] which is common in health-focused regulatory models and appears in the *GTA*'s explanatory documents as necessary for protection of health risks throughout development cycles.[196] Health-related AI applications, particularly in

---

[186] 'Regulating Agricultural Biotechnology', *Canadian Food Inspection Agency* (Web Page, 2023) <https://inspection.canada.ca/en/plant-varieties/plants-novel-traits/general-public/regulating-agricultural-biotechnology>.
[187] Recommendation 8 in the *Gene Technology Scheme Third Review Report* (n 30) 10, 36.
[188] Ibid 37.
[189] This was a finding in a legislative review of the gene technology scheme conducted by Allen Consulting Group: see Allen Consulting, *Review of the Gene Technology Act 2000* (Final Report, 2011) 6–7.
[190] Recommendation 8 in the *Third Review of the Gene Technology Scheme* (n 30) 10, 36.
[191] Thygesen (n 31) 65.
[192] Veale and Borgesius (n 175) 97; *Interim Discussion Paper* (n 10) 15.
[193] Veale and Borgesius (n 175) 97; Edwards (n 20) 5.
[194] Tobias Mahler, 'Between Risk Management and Proportionality: The Risk-Based Approach in the EU's Artificial Intelligence Act Proposal' [2022] *The Swedish Law and Informatics Research Institute* 247, 265.
[195] Health Action International (n 20) 14.
[196] *Senate Report on Gene-Tech Bill 2000* (n 4) 23, 32; *Risk Analysis Guidance Framework* (n 35) 9.

high-risk contexts, often follow similar product development to therapeutics that involve GMOs, including laboratory research, clinical trials, performance studies, and access to sensitive patient data. Despite this, the *AIA*'s pro-industry regulatory starting point focuses on post-market compliance as opposed to pre-market approval. While the *AIA* requires risk management systems prior to market entry as part of a system's 'lifecycle',[197] third party oversight is not present at this stage.

Similarly, in government regulatory sandboxes, to the extent that pre-market testing is required, it is generally only optional.[198] For high-risk systems, requirements for providers to self-assess a product's 'foreseeable misuse' only engage *after* a system has been classified into a risk category. This allows providers to focus on misuse that is foreseeable through intended use of the product, rather than actual use and real-world applications.[199] This second measure has been suggested as the preferred criteria of a product's risk level, particularly when assessed externally, and reveals the overly prescriptive nature of the *AIA*.[200]

The *AIA* does impose some regulatory obligations that function similarly to the *GTA*'s pre-market-facing process trigger. Most importantly, these are data training, validation, and testing requirements for providers modelling high-risk AI systems.[201] While these have been welcomed as much-needed attempts to legislate quality metrics for training data,[202] a number of critiques note the absence of clear definitions throughout the relevant article. In particular, no definition of 'bias' and no examples of positive or negative bias are provided, despite the requirement for companies to carry out their obligations in view 'of possible biases'.[203] In a health context this ambiguity lacks 'coherent

[197] Feldstein (n 15) 8.
[198] *AIA* (n 14) art 9(7).
[199] Health Action International (n 20) 14; Felix Busch et al, 'Navigating the European Union Artificial Intelligence Act for Healthcare' (2024) 7(1) *NPJ Digital Medicine* 1, 1–3.
[200] European Consumer Voice in Standardisation ('ANEC'), *ANEC comments on the European Commission proposal for an Artificial Intelligence Act* (Position Paper, 2021) 3–6; Health Action International (n 20) 14, 19.
[201] *AIA* (n 14) art 10.
[202] Ibid; Phillip Hacker, 'A Legal Framework for AI Training Data: From First Principles to the Artificial Intelligence Act' (2021) 13(2) *Law, Innovation and Technology* 257, 297.
[203] *AIA* (n 14) art 10(2)(f); Marvin van Bekkum, 'Using Sensitive Data to De-Bias AI Systems: Article 10(5) of the EU AI Act' (2025) 56 *Computer Law & Security Review* 1, 1–9. See generally Brent Mittelstadt et al, 'The Unfairness of Fair Machine Learning: Levelling Down and Strict Egalitarianism by Default' (2023) 30(1) *Michigan Technology Law Review* 1.

coordination',[204] raising complex issues of prejudice, ground truths, and discrimination.

These issues are revisited in Part IV in light of Australia's commitment to enact AI legislation mitigating discrimination and bias. The effectiveness of these provisions is further questioned by the fact that both downstream deployers and users lack mandatory access to training data, as well as the capacity to compel changes.[205] Thus, in addition to lacking definitional clarity, the provision fails to meaningfully span regulation between pre-market research and development stages and post-market deployment.

In reality, AI systems are not a product but a 'system delivered dynamically through multiple hands',[206] with complex production lines meaning risk profiles can change depending on who may be developing or applying the technology.[207] In drawing influence from product safety legislation and framing AI systems as a 'consumer-facing' product, the *AIA* has been critiqued for overlooking this dynamic nature.[208] This suggests that a broader process trigger, as exemplified in the *GTA*, without a compromised pro-industry objective may offer considerably greater protection.

C *Risk Categorisation and Decision-Making*

Both the *GTA* and the *AIA* establish different categories of regulation, which are comparable by virtue of adjusting regulatory processes and obligations to perceived levels of risk. The most notable differences are the arbitrariness of these risk categories, the decision-makers involved, and their respective roles.

Under the *GTA*, the Regulator is always involved, and their influence may change depending on the regulatory stream. For example, the Regulator's role in an emergency dealing may simply be to advise the Minister on the manageability of risk, whereas under an intentional environmental release of a GMO the Regulator's influence is mandated and fundamental to each risk assessment plan. Under the *AIA*, the AI provider is heavily involved amidst the absence of a consistent or independent decision-maker across the regulated categories.

---

[204] Hacker (n 202) 298.
[205] Edwards (n 20) 10.
[206] Ibid 5.
[207] Glenn Cohen et al, 'The European Artificial Intelligence Strategy: Implications and Challenges for Digital Health' (2020) 2(7) *The Lancet Digital Health* 376, 376; Veale and Borgesius (n 175) 97; University of Melbourne, 'Safe and Responsible AI in Australia: Discussion Paper Response To Senate Inquiry' (Submission, August 2023) 16.
[208] Edwards (n 20) 5.

The *GTA* leaves work for the Regulator and a sophisticated network of expert bodies in each of its categories to ensure consistency and predictability — both intentionally designed attributes of the *GTA*.[209] By contrast, the *AIA* leaves private providers of minimal risk systems to meet limited disclosure obligations, and providers of high-risk systems to conduct risk assessments and meet their various data governance, training, and cybersecurity obligations.[210] While providers may be well placed to identify risks given they have 'detailed knowledge of the design and production process'[211] — a sentiment from product safety legislation — they are neither independent nor adapted to assess harms.

Even with the presence of Notified Bodies to conduct conformity assessments and technical documentation, there are significant concerns raised by scholars that these bodies — the same Notified Bodies regulating Medical Devices — may lack the necessary qualifications to regulate AI-specific risks.[212] Looking at indirect discrimination as an example of risk, this can be difficult to recognise without knowledge of the relevant characteristics of affected populations, which are often sensitive, protected, and potentially hidden in data sets.[213] Health-related AI tools expand the potential to exacerbate existing health and digital inequalities,[214] or to re-identify vulnerable demographics from aggregated data sets,[215] and these risks may go unnoticed without knowledge of the systematic inequalities being entrenched.

The prescriptive nature of the *AIA*'s risk-based categories has also been widely critiqued and is considered highly arbitrary,[216] particularly when framed against the *GTA*. Several examples can help illustrate this. Under the *AIA*, AI-powered diagnostic tools or clinical decision-making software are expected to be high-risk,[217] while AI-powered health apps, wellbeing chatbots, and administrative assistants are anticipated to be minimal risk. Apps calculating, for example, user fertility based on body temperature can change in risk category

---

[209] *Gene Technology Scheme Third Review Report* (n 30) 3.
[210] Edwards (n 20) 6–8.
[211] *Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a Common Framework for the Marketing of Products, and Repealing Council Decision 93/465/EEC* OJ L 218/82, [22].
[212] Vardas et al (n 115) 836; Health Action International (n 20) 16–17.
[213] See generally Michael Veale and Reuben Binns, 'Fairer Machine Learning in the Real World: Mitigating Discrimination without Collecting Sensitive Data' (2017) 4(2) *Big Data & Society* 4.
[214] See generally OECD, *AI in Health: Huge Potential, Huge Risks* (Policy Brief, 2024).
[215] See generally Na Liangyuan et al, 'Feasibility of Reidentifying Individuals in Large National Physical Activity Data Sets From Which Protected Health Information Has Been Removed With Use of Machine Learning' (2018) 7(8) *JAMA Network Open* 1.
[216] Edwards (n 20) 5, 11; Health Action International (n 20) 14.
[217] Vardas et al (n 115) 16–17.

depending entirely on whether their intended purpose is conception or contraception.[218]

Similarly, 'minimal risk' administrative tools built on LLMs for basic notetaking or scribe functions have the potential to hallucinate outputs, automatically populating electronic health records with inaccurate data.[219] When relied upon by clinicians, these can emerge as unintentional clinical decision-making assistants directly affecting patient outcomes — a clear description of a high-risk tool. While LLMs are expected to be regulated by the AI Office, scholars have put forward strong cases for these to be considered Medical Devices.[220]

In other words, an LLM-powered tool that is arguably minimal risk can also be imagined as a high-risk Medical Device, or a highly capable GPAI model posing systemic risks, with each categorisation carrying various regulatory implications for different actors. A blurred line emerges between risk categories, and it is unlikely that providers, typically private companies with incentives to minimise regulatory burden,[221] are equipped to identify the full range of risks at play.

The *GTA* recognises this and positions the Regulator over licence holders, typically commercial sponsors,[222] to scrutinise unpredictable risks in a more granular, high-touch way. The *GTA* addresses issues not only through the structural design of the Regulator and granular risk categorisation, but also through IBCs. These certified bodies with detailed knowledge of the specific dealings of specific organisations are well placed to monitor and liaise with the Regulator on unpredictable risks as they emerge in both research and post-market stages.[223] While applicants, supported by IBCs, may provide information to the Regulator regarding their dealing, this simply informs the Regulator's decision-making rather than permitting self-assessment.[224] Every decision is technically informed through the rigorous scrutiny of the expert Technical Committee. To ensure scope for public consideration of ethical and societal concerns, decisions on value-laden

---

[218] Health Action International (n 20) 14–15.
[219] See generally Peter Lee et al, 'Benefits, Limits, and Risks of GPT-4 as an AI Chatbot for Medicine' (2023) 388(13) *New England Journal of Medicine* 1233; Chris Stokel-Walker et al, 'What ChatGPT and Generative AI Mean for Science' (2023) *614 Nature* 214.
[220] Hugh Harvey and Mike Pogose, 'Are LLM-Based Ambient Scribes and Clinical Summarisers Medical Devices?', *Hardian Health* (Web Page, 2024) <https://www.hardianhealth.com/insights/are-llm-based-ambient-scribes-and-clinical-summarisers-medical-devices>; Gilbert (n 148) 2396.
[221] Veale and Borgesius (n 175) 97–100.
[222] O'Sullivan et al, '20 Years of Legislation' (n 5) 8.
[223] Ibid 4; Tribe (n 19) 26.
[224] See, eg, Gene Technology Technical Advisory Committee, 'GTTAC Meeting of 18 December 2023' (Communiqué, 18 December 2023) 2.

assessments are not outsourced to private standardisation bodies as in the *AIA*,[225] but draw on guidance documents following consultation with the public and the Ethics Committee. This leaves sufficient room for ethically and societally informed influence on decision-making and risk thresholds.

D *Public Participation, Accountability, and Transparency*

A critical feature drawn from Part II is the high degree of public scrutiny in the gene technology scheme. This is observed not only in stages of legislative review, where multiple phases of open consultation direct review focus, but in individual licence applications that are open for public consultation. Scholars have been critical of a distinct absence of similar measures in the *AIA*, which does not 'envisage any role for social dialogue', thereby missing an opportunity to incorporate 'on-the-ground experience' in processes such as standard setting.[226]

While there is established scope for industry lobbying and organised stakeholder participation in the *AIA*'s standard setting process,[227] scholars have called for improved 'participation rights'.[228] Given protection from high-risk systems may depend primarily on the effectiveness of standard setting, the degree to which it incorporates the high level of public debate necessary for value-laden assessments is questionable.[229]

To ensure *meaningful* public engagement in the *GTA*, review stages draw clear traceable connections between respective stages of consultation and the continually refined government approaches between preliminary papers, final reports, and action plans.[230] In contrast, the consultation period that informed the *AIA* involved more significant periods of private and political debate than public engagement.

---

[225] See generally Martin Ebers, 'Standardizing AI: The Case of the European Commission's Proposal for an Artificial Intelligence Act' in Larry A DiMatteo, Cristine Poncibò and Michel Cannarsa (eds), *The Cambridge Handbook of Artificial Intelligence: Global Perspectives on Law and Ethics* (Cambridge University Press, 2022) 321.
[226] Adams-Prassl (n 175) 49.
[227] 'Standard Setting' (n 151).
[228] Ebers (n 225) 340–7.
[229] Ibid 340.
[230] This sequence of documents is available at 'Third Review of the Gene Technology Legislation', *OGTR* (Web Page, March 2022) <https://www.genetechnology.gov.au/reviews-and-consultations/ past/2017-third-review#consultation-phases>.

To address the inherent difficulties in constructing traditional mechanisms of accountability for AI systems,[231] the *AIA* places a heavy emphasis on information sharing. Scholars have recognised that accountability in AI contexts can be maintained through sharing data sources, model accuracy, and tools to safeguard users.[232] The *AIA* promotes this through features such as a mandatory database for high-risk systems,[233] requirements to disclosure technical aspects of high-risk systems,[234] and regulatory sandboxes maintaining rapport with providers.[235]

These measures do provide a degree of accountability and transparency, which is particularly welcome in a health context given the 'ubiquitous data biases' historically ingrained across data sets,[236] as well as numerous cases of private companies mishandling health data, cyber security attacks, and disregard of patient consent.[237] Despite these measures, however, this emphasis on information sharing seemingly attempts to compensate for a stricter regulatory presence in models such as the *GTA*, permitting AI providers to meet their obligations in supposedly transparent settings without high-touch oversight of external regulatory bodies.

IV Regulatory Lessons for Australia

A *Australia's Approach*

While the Australian Government has not enacted AI-specific legislation, several key developments have brought this prospect into view. In 2019, the Department of Industry, Science and Resources ('DISR') published a voluntary set of eight 'AI Ethics Principles'.[238] These were drafted to ensure the 'responsible design,

---

[231] See Cobbe (n 176).

[232] See generally Jeannie Marie Paterson, 'Misleading AI: Regulatory Strategies for Algorithmic Transparency in Technologies Augmenting Consumer Decision-Making' (2022) 34(3) *Loyola Consumer Law Review* 558.

[233] *AIA* (n 14) art 60 annex III.

[234] *AIA* (n 14) art 13.

[235] 'Regulatory Sandboxes in the AI Act', *The Future Society* (Web Page, 2022) <https://thefuturesociety.org/workstream/regulatory-sandboxes-in-the-ai-act/>.

[236] Health Action International (n 20) 16; Trishan Panch, Heather Mattie and Rifat Atun, 'Artificial Intelligence and Algorithmic Bias: Implications for Health Systems' (2019) 9(2*) Journal of Global Health* 020318:1–5.

[237] Angie Lavoipierre, 'MediSecure reveals 12.9 million Australians had personal data stolen in cyber attack earlier this year' *Australia Broadcast Corporation* (online, 18 July 2024) <https://www.abc.net.au/news/2024-07-18/medisecure-data-cyber-hack-12-million/104112736>; Cam Wilson, 'Australia's Biggest Medical Imaging Lab is Training AI on its Scan Data. Patients Have No Idea', *Crikey* (online, 19 September 2024) <https://www.crikey.com.au/2024/09/19/patient-scan-data-train-artificial-intelligence-consent/>.

[238] Australian Government, Department of Industry, Science and Resources, *Australia's Artificial Intelligence Ethics Framework: Australia's AI Ethics Principles* (2019) ('*AI Ethics Principles*').

development and implementation of AI'. Following stakeholder consultation, they were finalised to include principles focused on reliability, transparency, accountability, social wellbeing, and fairness.[239] Australia's AI Ethics Principles have informed subsequent developments, in particular the plans towards 'Safe and Responsible AI' in Australia, first announced in June 2023.[240]

At the beginning of 2024, the DISR published an *Interim Discussion Paper* on Safe and Responsible AI.[241] A key insight from this paper was that Australia's current protections are inadequate to address risks posed by AI.[242] A non-statutory expert AI group was also established, comprised of individuals with scientific, legal, and market expertise that could provide advice to the DISR on mandatory guardrails for 'AI systems in high-risk settings'.[243]

The *Proposals Paper* subsequently released in September 2024 considered options for defining high-risk AI systems, and set out 10 'mandatory guardrails' to promote principles such as accountability and transparency.[244] Alongside this, the DISR published a *Voluntary AI Safety Standard* advising developers generally,[245] and the Office of the Australian Information Commissioner issued a guidance document on generative AI and privacy obligations.[246]

Across this set of documents, there is limited attention given to AI and health, despite promises to invest in the 'priority' healthcare sector and conduct 'gap analysis' in current protective frameworks.[247] The Government most directly addresses this in a consultation paper titled *Safe and Responsible Artificial Intelligence in Health Care Legislation and Regulation Review*, released by the Department of Health and Aged Care in September 2024.[248] This paper requests

---

[239] 'Consultation Hub: AI Ethics Principles', *Department of Industry, Science and Resources* (Web Page, 15 August 2019) <https://consult.industry.gov.au/australias-ai-ethics-framework/submissions/ list>.
[240] *Interim Discussion Paper* (n 10).
[241] Ibid.
[242] Ibid 5.
[243] 'AI Expert Group: Terms of Reference', *Department of Industry, Science and Resources* (Web Page, 2023) <https://www.industry.gov.au/science-technology-and-innovation/technology/artificial-intelligence/ai-expert-group-terms-reference>.
[244] Proposals Paper (n 11).
[245] See Australian Government, Department of Industry, Science and Resources, *Voluntary AI Safety Standard* (August 2024) ('*Voluntary Safety Standard*').
[246] Office of the Australian Information Commissioner, *Guidance on Privacy and Developing and Training Generative AI Models,* (Guidance Paper, October 2024).
[247] *Proposals Paper* (n 11) 4, 56.
[248] Australian Government, Department of Health and Aged Care, *Safe and Responsible Artificial Intelligence in Health Care Legislation and Regulation Review* (Final Report, March 2025) ('*AI in Health Care Consultation Paper*').

public comment on AI in healthcare, laying out the sector-specific risks but placing strong emphasis on the revolutionary promises of the burgeoning AI market, including the various use-cases to improve patient outcomes and reduce clinician burnout.

While healthcare-specific options for reform are presented, including the introduction of health care-specific laws and a regulatory body,[249] these are highly speculative and in contradiction to the intended horizontal AI framework laid out in other documents. While this set of documents can be difficult to navigate, taken as a whole they reveal several key points regarding Australia's intended approach that will structure discussions below.

First, the Government's underlying objective is what this article has characterised as 'prescriptive' and 'pro-industry' — to adopt a risk-based approach, with 'safe and responsible' AI uptake in 'high-risk settings' and 'unimpeded' uptake in low-risk settings.[250] To achieve this underlying objective, the Government aims to maximise opportunities presented by AI through investment and growing national capabilities, while enacting predictable legislation to support the AI market in offering 'safe and responsible' AI systems.[251]

Second, the *Interim Discussion Paper* and supplementing documents consistently refer to 'community first' regulation, emphasising the need for 'public involvement' placing people 'at the centre' of regulatory developments.[252] Potential models to achieve this are insufficiently raised in subsequent Government papers.

Third, and related to the above point, the need for accountability and transparency in AI regulation is repeatedly emphasised. References are made to 'designated roles' for regulatory responsibility, publicly accessible information on AI systems, and mechanisms for information sharing.[253]

B *Learning From the GTA and the AIA*

1 *Regulatory Objectives, Decision-Making, and the Risk-Based Approach*

The *Interim Discussion Paper* targets multiple purposes. The first of these is a pro-industry 'overall objective' to maximise opportunities presented by AI.[254] In

[249] Ibid 5.
[250] *Interim Discussion Paper* (n 10) 10–14.
[251] Ibid 13.
[252] Ibid 19.
[253] Ibid 20.
[254] Ibid 19, 25.

addition, the Government emphasises the need to reliably protect against risks through ex ante legislation.[255] This creates potentially conflicting purposes. In an attempt to balance these, the Government proposes a risk-based framework, suggesting more burdensome regulation in high-risk settings and minimal regulation for low-risk systems.[256]

While 'further work' is needed to define these risk-based categories,[257] consultation phases identified a number of potential harms that will inform this work. These include discrimination from algorithmic bias, accurately locating sources of error, systemic and compounding risks, and unforeseen risks driven by rapid technological change.[258] The Government has recognised healthcare as a 'high-stakes' domain, expressing concern about the representativeness of data sets and applicability to Australian populations, in particular for protected characteristics such as race, gender, and disability.[259]

In considering what constitutes a high-risk system and the necessary guardrails to manage risk, the Government has clearly stated that adverse impacts on individual health are a factor, while also stating that not all health-related AI applications are necessarily high-risk.[260] Many explicit references are made to the *AIA* as a direct influence on the Government's policy choices, with the benefits of regulatory 'interoperability' cited as justification for mirroring the approach.[261] Similar proposed features include the range of harms identified, the dual objectives, and the risk-based approach.[262] If Australia is to draw inspiration from the *AIA* in this way, a number of cautions should be mentioned.

A risk-based model can be overly prescriptive in terms of the scope of regulated categories and proportionate obligations that are codified into legislation. As covered in Part III, many scholars faced difficulties in identifying the criteria informing this codifying process under the EU model.[263] This not only means that harms may be overlooked, but also that difficulties may be encountered in justifying the addition of future AI systems to the regulatory categories.[264]

---

[255] Ibid 12, 13, 19.
[256] Ibid 13.
[257] Ibid 14.
[258] Ibid 11.
[259] *Proposals Paper* (n 11) 21.
[260] *AI in Health Care Consultation Paper* (n 248) 3, 16.
[261] *Interim Discussion Paper* (n 10) 5, 24–5; *Proposals Paper* (n 11) 5.
[262] *Interim Discussion Paper* (n 10) 5, 15, 24.
[263] Mahler (n 194) 264.
[264] Edwards (n 20) 12.

This may be particularly important in AI contexts given the unpredictability of risk as acknowledged in the *Interim Discussion Paper*.[265] Potentially undetected at first, risks can present systemically to impact on, for example, the proficiency of health professionals or the stability of labour markets.[266] This is possible even in presumed 'low-risk' settings, as scholars have identified this potential for harm in, for example, the widespread use of chatbots,[267] despite them being predominantly unregulated in the *AIA* with only minimal obligations to disclose that a user is interacting with an AI system.[268] Envisioning a scenario in which a chatbot incorrectly directs users away from a public medical service, or perhaps fails to offer alternative platforms to less technology-literate customers, this appears to be a violation of the exact rights intended to be protected under high-risk categories.

Lessons can be drawn here from the *GTA*. In not grouping GMOs into a dichotomy of high- and low-risk, the *GTA* affords the Regulator the flexibility to maintain a reactive, high-touch decision-making presence under a granular model.[269] Consistent with the GTA's underlying process trigger, the *GTA* acknowledges unpredictability and attempts to capture risk across technology lifecycles, rather than fixing it at market release. This broader approach would enliven and give much-needed substance to the DISR's stated aspirations of 'reliability' and 'safety' through continuous monitoring across AI lifecycles.[270]

Another focus of the DISR's approach is mitigating the risk of bias and discrimination in AI use.[271] Recalling from Part III, the *AIA* imposes data training and testing obligations on providers of high-risk systems — provisions that have been critiqued for having insufficient clarity regarding quality criteria and definitions of bias.[272] In a health context, definitional clarity is particularly pertinent, as the term 'bias' may, for example, suggest health-data inaccuracies by

---

[265] *Interim Discussion Paper* (n 10) 11.
[266] Ibid 10.
[267] 'Chatbots Are Not People: Dangerous Human-Like Anthropomorphic AI', *Public Citizen* (Web Page, September 2023) <https://www.citizen.org/article/chatbots-are-not-people-dangerous-human-like-anthropomorphic-ai-report/>; 'The Chatbot Race Must Not Be Run with Blinkers', *Australian Human Rights Commission* (Web Page, February 2023) <https://humanrights.gov.au/about/news/ opinions/chatbot-race-must-not-be-run-blinkers>.
[268] *AIA* (n 14) ch 4.
[269] Ebers et al (n 103) 264; Mahler (n 194) 247.
[270] Australian Government, Department of Industry, Science and Resources, *National Assurance Framework* (21 June 2024) 4–6 ('*National Assurance Framework*').
[271] *Interim Discussion Paper* (n 10) 11.
[272] Sandra Wachter, 'Limitations and Loopholes in the EU AI Act and AI Liability Directives: What This Means for the European Union, the United States, and Beyond' (2024) 26(3) *Yale Journal of Law and Technology* 671, 687–98.

reason of poor healthcare access, historical prejudices, or simply ground-truths (eg, certain demographics being predisposed to particular illnesses).

Similarly, notions of individual versus group fairness — 'making all groups impacted by a system worse off, rather than helping disadvantaged groups' — might be interpreted by a provider as less "discriminatory", more "fair", or less "biased".[273] Extreme implications of this interpretation might include diagnosing less patients than necessary in order to meet vague legislative criteria. While definitional certainty is desired, it may be impossible in an area where the technical and ethical boundaries of concepts such as bias and discrimination are being continuously redrawn.

Critiques of the *AIA* have illustrated how mandating training, validation, and testing to be 'free of errors' is an unrealistic and potentially impossible requirement of the *AIA*.[274] The *GTA*'s less prescriptive model should be considered here. With a singular objective to ground its approach, flexible decision-making is distributed between distinct Ethics and Technical Committees, IBCs, and the Regulator across research and development stages — comparable to pre-market data training stages. In an AI context, this model would ensure 'coherent coordination'[275] between dynamic regulatory obligations and evolving standards of bias, discrimination, and data quality metrics that contain both ethical and technical considerations.

To manage such an involved regulatory scheme, questions of scalability should be considered. The *GTA*, since 2001, has approved nine inadvertent dealings and two emergency dealings, assessed 944 applications for the two main streams of intentional GMO releases, and approved just below 15,000 notifiable low-risk dealings.[276] The significant portion of these dealings have been managed by 231 active IBCs,[277] which exist in institutions ranging from universities to private research facilities.

The *GTA*'s protective approach applied in an AI context would likely curb innovation and uptake as it complicates decision-making. If rights-based AI legislation is the goal, however, with health as a priority sector, this necessitates making a strongly pro-industry objective — and concerns of overregulation —

---

[273] Ibid 689.
[274] *AIA* (n 14) art 10(3); Ebers et al (n 103) 595; Edwards (n 20) 8.
[275] This revisits terminology used to critique the AI Act in Part III: see Hacker (n 202) 298.
[276] 'What We've Approved?', *OGTR* (Web Page, 3 March 2025) <https://www.ogtr.gov.au/what-weve-approved>.
[277] As at September 2025, see 'List of Accredited Organisations', *OGTR* (Web Page, 5 September 2024) <https://www.ogtr.gov.au/what-weve-approved/accredited-organisations>.

secondary to a protective objective. In any event, the *GTA* demonstrates the possibility of accommodating innovation with timely deregulation alongside constant monitoring of evolving risk.

In 2011, reforms of the gene technology scheme led to the re-classification of genetically modified somatic cell therapies, with many clinical trials of therapeutic products no longer requiring a licence, and instead only IBC review.[278] Experts credit this as 'instrumental' in attracting clinical trials to Australia.[279] This has been contrasted with the *AIA* approach of an initial prediction with occasional amendments, and yet demonstrates the ability to balance promises of a booming market and industry pressures[280] with controlled and risk-free deregulation.

While comparative numbers for AI systems are not readily available, the DISR has estimated that around 650 AI companies are currently headquartered in Australia.[281] Given the scale and diversity of these companies, including the global reach of foreign actors, this raises questions for an AI regulatory model that reflects the *GTA*. Statutory prosecution of an IBC has never been required in the Regulator's history,[282] and between 2023 and 2024 the Regulator received and investigated 66 reports of suspected non-compliance (eg, regarding certification and licence conditions).[283] These figures are significantly below the regulatory output that might be expected of a *horizontal* AI framework. However, in line with this article's focus, scalability can be managed by taking a sector-specific approach in regard to regulatory functions that might be decentralised. There is a significant precedent for this in health-related sectors, not only under IBCs as in the *GTA* model, but also functions in food safety and pharmacovigilance. Similar to certified in-house functions that conduct and manage risk within organisations, internal AI safety bodies could assist and oversee providers and deployers of AI systems in identifying and managing health-related risks. In its early consultations, the Government listed internal review bodies as a potential

[278] O'Sullivan et al, '20 Years of Legislation' (n 5) 5–6.
[279] Ibid 7.
[280] Gabrielle O'Sullivan et al, 'Clinical Gene Technology in Australia: Building on Solid Foundations' (2022) 217(2) *The Medical Journal of Australia* 65, 67.
[281] 'Developing a National AI Capability Plan', *Department of Industry, Science and Resources* (Web Page, 2024) <https://www.industry.gov.au/news/developing-national-ai-capability-plan>.
[282] 'Overview of GMO Monitoring and Compliance', *OGTR* (Web Page, February 2022) <https://www.ogtr.gov.au/ongoing-regulatory-compliance/overview-gmo-monitoring-and-compliance>.
[283] OGTR, *Operations of the Gene Technology Regulator Annual Report 2023-2024'* (September 2024) 61.

oversight mechanism,[284] and although this has diminished in priority with the release of the *Proposals Paper*, it could involve, for example, decentralised bodies embedded in hospitals to directly interact with deployers like practitioners or public health authorities.

The *GTA* provides a worked-through approach where internal and external risk review bodies draw on both ethical and technical expertise in reporting to a regulatory body. This can be efficiently complemented by harmonised standards as contemplated by the *Interim Discussion Paper*, while also addressing scholarly cautions about the appropriateness of standards in light of value-laden and unpredictable risk assessments.

2 *Community First Regulation*

An anticipated feature of the Australian AI framework is 'community first' regulation. This concept is not defined in key documents but, as stated by the DISR, involves placing communities at the centre of the regulatory framework, building public trust, and maintaining close consultation with industry and the community.[285] Early intent to achieve this is signalled by the influence of public participation in refining the current approach. The DISR and the Department of Health and Aged Care have conducted various phases of consultation, seeking advice on gaps in current legal frameworks, and have recommended mechanisms to address these gaps.[286]

Beyond standard practices of consultation within the lawmaking process, a true community first approach requires that the public has a meaningful role within the AI regulatory framework. This is a key feature of the *GTA*, and one that has attracted widespread approval.[287] In AI contexts, public input is particularly important given AI systems move through lifecycles, with risks that change and present differently to different individuals.[288] The gene technology scheme demonstrates the particular importance of this in a high-stakes health context, providing multiple avenues for public engagement which are taken seriously in

[284] *National Assurance Framework* (n 270) 8.
[285] *Interim Discussion Paper* (n 10) 18–19.
[286] Ibid 13–15. See *AI in Health Care Consultation Paper* (n 248).
[287] Kerry (n 92) 216. See generally Richard Hindmarsh and Rosemary Du Plessis, 'GMO Regulation and Civic Participation at the "Edge of the World": The Case of Australia and New Zealand' (2008) 27(3) *New Genetics and Society* 181.
[288] *AI Ethics Principles* (n 238) 5; Michael Guihot, Anne Matthew and Nicolas Pierre Suzor, 'Nudging Robots: Innovative Solutions to Regulate Artificial Intelligence' (2017) 20(2) *Vanderbilt Journal of Entertainment & Technology Law* 385, 414.

relation to individual risk assessment plans (RARMPs), whereas the *AIA* leaves little room for this.[289]

In the DISR's *Voluntary Safety Standard*, stakeholder engagement is listed as a proposed guardrail for AI developers, with a focus on values such as diversity, inclusion, and fairness.[290] In the *Proposals Paper*, which focuses on high-risk settings specifically, stakeholder engagement does not feature as a proposed guardrail and no emphasis is placed on active consultation processes during risk assessment phases, similar to the *AIA*. The *National Assurance Framework* for AI use in government briefly, but marginally, acknowledges the need for this engagement, recognising that stakeholder views may assist when conducting impact assessments.[291] The *National Assurance Framework* also makes mention of 'co-designed' regulation,[292] but subsequent papers do not propose models for this.

This appears to be a shift away from the 'community first' terminology used to lead the national approach. If Australia is to approach AI regulation with a consistent community first attitude, it must present continuous avenues for civic input — particularly given the low levels of public trust in AI and the sensitive nature of health data.[293]

The *GTA* separates political, scientific, and ethical decision-making into different statutory bodies, and incorporates community engagement primarily as an ethical consideration feeding into its risk assessment plans. This model would function well in an AI context, given that even the most technical decisions are necessarily value-laden in the presence of fundamental rights implications.[294] As there is a strong call for human rights-based AI regulation in Australia,[295] it follows that these values should be continuously upheld and grounded in a statutory body. This would give effect to many of the Government's AI Ethics Principles, including promoting human-centred values and AI systems that benefit individuals and society.[296]

---

[289] Ebers (n 103) 595.
[290] *Voluntary Safety Standard* (n 245) 42.
[291] *National Assurance Framework* (n 270) 13.
[292] Ibid 26.
[293] Department of the Cabinet and Prime Minister, *How might artificial intelligence affect the trustworthiness of public service delivery?* (Briefing Report, 2023) 15–17.
[294] Veale and Borgesius (n 175) 105.
[295] See generally *AHRC Report on Human Rights and Technology* (n 9).
[296] *AI Ethics Principles* (n 238).

Finally, the gene technology scheme presents other replicable mechanisms for a community first approach, including the statutory nature of the Ethics Committee, the regular outsourcing of public opinion surveys, and established stages of consultation that work to openly refine policy developments and guide RARMPs.

3 *Accountability and Transparency*

Accountable and transparent regulation are intended to be central to the Government's safe and responsible AI plan. However, the vague proposal for risk categories in the *Proposals Paper* brings into question the transparency of the Australian approach, especially when positioned in contrast to the clarity of the *GTA*.

Under the *GTA*, the Regulator is a centralised source of accountability and transparency. For example, the Regulator's website breaks down complicated features of the *GTA* for the general public, listing dealings in accessible formats, and detailing communiques of all bodies informing risk decision-making. Further, the Regulator provides recourse avenues for people impacted by GMOs, and publishes RARMPs to permit public scrutiny. This ensures that rationales for decision-making are clear and accessible, both at a high level and in more detailed stages of application approval. The Australian Government proposed similar avenues as guardrails for AI in both high-risk and general contexts as well as an established Ethics Principle,[297] a welcome deviation from the *AIA* where this is insufficiently addressed.

Currently Australia supports a National AI Centre and a Responsible AI Network, ostensibly to enable sharing of best practice guides, tools, and learning modules under a collaboration of 'knowledge partners'.[298] However, the orientation of both activities is to the *business* community — not to the general public, and similarly not for the purposes of transparency and accountability. Neither body assists, for example, in supporting accountability principles such as ensuring the contestability of decisions. Presumably this is a crucial element of what constitutes 'responsible' and accountable AI — terms that are central to the national approach yet lack substantive definition in policy documents. While establishing accountability in AI contexts can present unique difficulties, this is

[297] *Proposals Paper* (n 11) 35; *Voluntary Safety Standard* (n 245) 34.

[298] 'Responsible AI Network (RAIN)', *Department of Industry, Science and Resources* (Web Page, 2023) <https://www.industry.gov.au/science-technology-and-innovation/technology/national-artificial-intelligence-centre/responsible-ai-network>.

particularly important in health contexts as products with obscured development cycles have the potential to directly influence patient outcomes.

In constructing accountability chains, scholars have recommended approaches to AI accountability that balance external oversight with internal mechanisms.[299] The Australian approach should therefore learn from both the *AIA* and *GTA*. The principal weaknesses of the *AIA* are its dependency on private providers to meet obligations, and its insufficient avenues for recourse. However, it does have the support of surveillance bodies and downstream obligations on AI deployers to report on non-compliance. Feeding substantially modified AI systems back through the regulatory cycle also recommences regulatory obligations in a way that would benefit Australia's framework.

The *GTA* again offers a more comprehensive approach with IBCs uniquely adapted to identifying health-related risks built across technological lifecycles. If a post-development product trigger is favoured in an AI context, similar bodies specialising in AI and healthcare should be established across, for example, healthcare centres or hospitals where private AI-powered tools are flourishing. Regulatory feedback loops in the *AIA* can also be learnt from and adapted to reflect the *GTA*'s high-touch approach by constructing oversight mechanisms for changes in intended and actual use of health-related AI systems to align with scholarly cautions. As demonstrated above, the *GTA*'s consistent regulatory presence could be worked into an AI context through facilitating engagement with expert internal and external bodies, accompanied by transparency and accountability obligations to address the unpredictable and high-risk nature of AI systems.

V Conclusion

As described by the Australian Human Rights Commission, Australia's current AI protection framework is 'patchwork at best'.[300] In the absence of AI-specific legislation, Australia is exposed to both the known and unknown risks of AI systems, which are exacerbated in high-stakes health contexts. Under increasing public pressure, the Australian Government has begun drafting a regulatory approach. In doing so, lessons can be sourced from both the bold first-mover

[299] See generally Robert Gorwa and Michael Veale, 'Moderating Model Marketplaces: Platform Governance Puzzles for AI Intermediaries' (2024) 16(2) *Law, Innovation and Technology* 341.
[300] 'Australia Needs AI Regulation', *Australian Human Rights Commission* (Web Page, 15 August 2023) <https://humanrights.gov.au/about/news/australia-needs-ai-regulation>.

approach of the EU's *AIA*, and Australia's sustained regulatory experience protecting from health risks under the *GTA*.

Comparisons between these regulatory models and the ways in which they approach the far-reaching consequences of two distinct emerging technologies reveal a number of fundamental lessons. At the centre are contrasting approaches to innovation, risk assessment, and fundamental rights that situate a critical decision for Australia. By signalling a clear intent to maximise the economic opportunities presented by AI, rather than adopt a public safety and pro-rights approach, the Australian Government appears to be making a calculus that weighs innovation first and foremost.

Given the unpredictability and high-risk nature of health-related AI systems, this pursuit of innovation without the sophisticated regulatory protections of the gene technology scheme would position Australia without the benefits of technically and ethically informed decision-making by independent experts, meaningful community engagement, or mechanisms for accountability. By adopting a protective objective with a trigger that prioritises pre-market regulation, Australia can regulate AI systems in a manner consistent with precautionary approaches to technologies that are yet without a history of safe use.

This grounding starting point, paired with granular risk categorisation and flexible decision-making powers, provides the foundation for a framework that regulates AI systems not as consumer-facing, tangible products, but as dynamic and unpredictable systems. This would permit risk assessment and regulatory obligations to be framed against the real-world application of AI systems, rather than their intended or predicted use. As illustrated by the *GTA*, these processes should be diversely informed by expert statutory committees, industry-embedded bodies, and the general public. Australia still has the opportunity to overcome the deficiencies identified by scholars expert in the European approach, and in doing so should draw from the rigorous structural protections of the *GTA* in order to regulate AI systems in a responsible and safe manner.