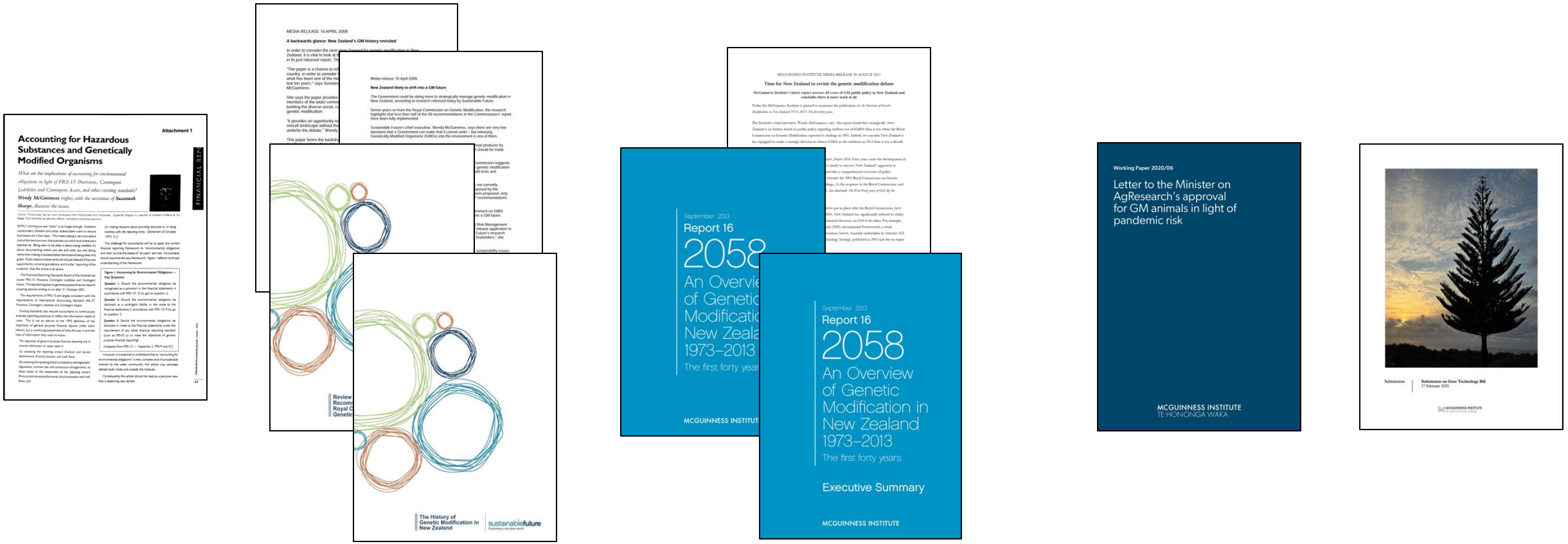
Gene Technology Bill

MARCH 2025

MCGUINNESS INSTITUTE

A: Background

Timeline of McGuinness Institute Publications on Genetic Engineering, Genetic Modification and Gene Technology



2002 2008 2013 2020 2025

The First Forty Years of GM: By the Numbers

In 1988 New Zealand undertook its first outdoor experiment. The following two pages represent GM data from 1988 to June 2013 unless otherwise indicated. There are limitations to this information, as explained in the appendices. Sources: See Appendices 1, 9, 14, 15

Types of animal tested

Types of plant tested

Also tested: Canola, Barley, Kiwifruit, *Lisianthus*, Maize, Norway Spruce Trees, Peas, Petunia, Rapeseed, Sugarbeet, Tamarillo, White Clover

Inputs

53 Outdoor experiments completed

6 Outdoor experiments approved but not commenced
(2 AgResearch, 2 Pioneer NZ Ltd, 1 Carter Holt Harvey, 1 Plant & Food)

2 Outdoor experiments currently operating
(Scion, AgResearch)

0 Outdoor experiments declined by ERMA/EPA
(from 1998)

2 Outdoor experiment with current approval commenced but not operating
(GMF99001 and GMF99005 are part of the same programme run by Scion. Approval expires in 2020 and 2019 respectively)

Process

11 Incidents of outdoor experiments

52 Reported incidents involving GMOs

1 Outdoor experiment shut down
(Shut down by Plant & Food Research, formerly NZ Institute for Crop & Food Research, two years into a 10-year consent after a biosecurity breach)

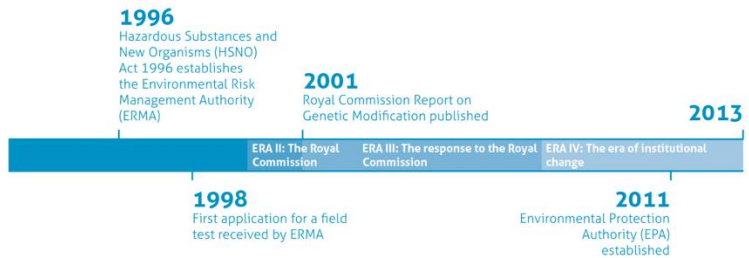
7 Trespasses or acts of vandalism on outdoor experiments

Outputs

59 GM ingredients approved for sale in New Zealand and Australia

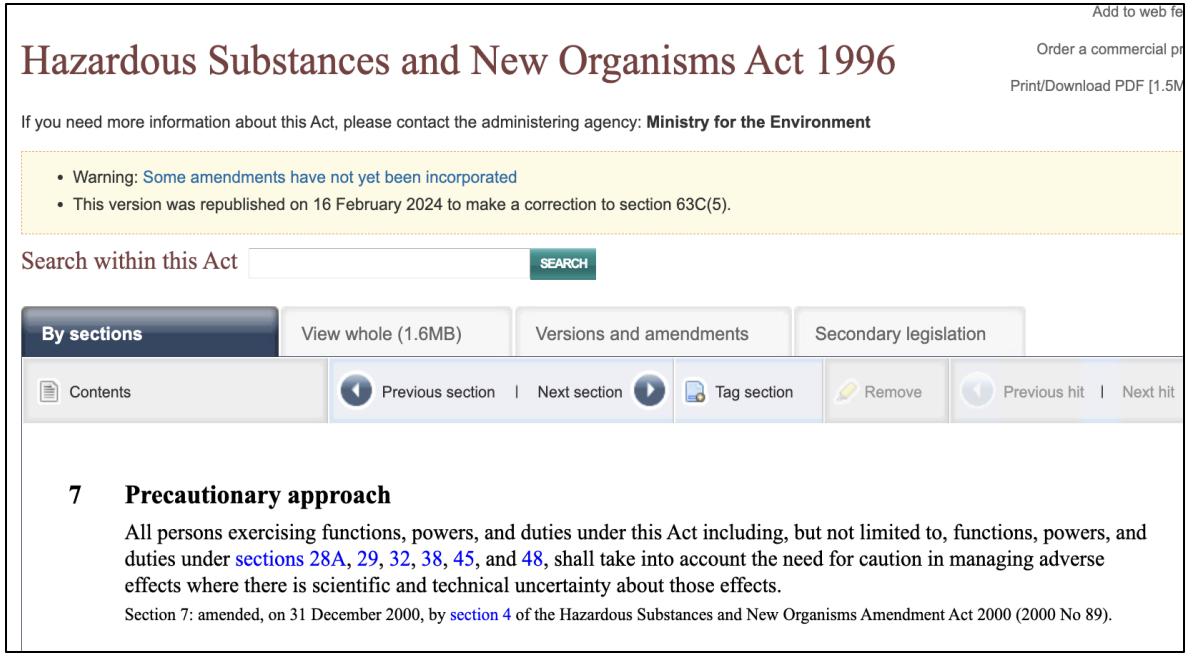
0 Commercialised GM crops grown in New Zealand

1 Imported GMO application approved for conditional release
(vaccine for equine [horse] flu – not used to date)



B: Key Suggestions

1. Add back in a precautionary approach
2. Add back in the methodology (could be a refresh of the Hazardous Substances and New Organisms (Methodology) Order 1998)
3. Take into account the intersection of gene technology and unknown capabilities (in particular AI).
4. Take into account the possibility of foreign investors undertaking risks in NZ that they cannot do in their own country
5. Align GM policy with exports/trade agreements
6. Pandemic risk: Ensure labs are regularly and independently reviewed and reported upon.



B2: Cont.
Schedule (from Hazardous Substances and New Organisms (Methodology) Order 1998)
Methodology for making decisions under Part 5 of Act

Information used by Authority

8 The information used by the Authority when considering an application must be relevant and appropriate to the scale and significance of the risks, costs, and benefits associated with the substance or organism.

9 When evaluating the information provided by an applicant (including prescribed information and any additional information) so as to achieve the purpose of the Act, the Authority must—

(a) recognise risks, costs, benefits, and other impacts associated with the substance or organism in an application which relate to the safeguarding of the life-supporting capacity of air, water, soil, and ecosystems, and provide for this principle; and

(b) recognise and provide for the principle of maintenance and enhancement of the capacity of people and communities to provide for—

(i) their own economic, social, and cultural wellbeing; and

(ii) the reasonably foreseeable needs of future generations; and

(c) take into account risks, costs, benefits, and other impacts associated with the substance or organism in an application which relate to—

(i) the sustainability of all native and valued introduced flora and fauna; and

(ii) the intrinsic value of ecosystems; and

(iii) public health; and

(iv) the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, wāhi tapu, valued flora and fauna, and other taonga; and

(v) the economic and related benefits to be derived from the use of a particular hazardous substance or new organism; and

(vi) New Zealand's international obligations.

10 Where an application relates to a new organism, the Authority must also evaluate the information provided on the risks, costs, benefits, and any other impacts which relate to—

(a) the significant displacement of any native species within its natural habitat:

(b) the significant deterioration of natural habitats:

(c) the significant adverse effects on human health and safety:

(d) significant adverse effects on New Zealand's inherent genetic diversity:

(e) the ability of the organism to establish an undesirable self-sustaining population anywhere in New Zealand:

(f) the ease with which the organism could be eradicated if it established an undesirable self-sustaining population:

(g) the ability to cause disease, be parasitic, or become a vector for human, animal, or plant disease.

11 Where an application relates to a hazardous substance, the Authority must also evaluate information which addresses the effects of the substance through its life cycle and the risks, costs, and benefits flowing from the following characteristics associated with the substance:

(a) explosiveness:

(b) flammability:

(c) capacity to oxidise:

(d) corrosiveness:

(e) toxicity (including chronic toxicity):

(f) eco-toxicity with or without bio-accumulation:

(g) any 1 or more of the above properties generated when the substance comes into contact with air or water.

B2: Cont.
Schedule (from Hazardous Substances and New Organisms (Methodology) Order 1998)
Methodology for making decisions under Part 5 of Act

Evaluation of risks, costs, and benefits

12 When evaluating assessment of risks associated with the substance or organism in an application, the Authority must take into account—

(a) the nature of the adverse effects; and

(b) the probability of occurrence and the magnitude of each adverse effect; and

(c) ~~the risk assessed as a combination of the magnitude of the adverse effect and the probability of its occurrence;~~ and

(d) ~~the options and proposals for managing the risks identified, and~~

(e) the uncertainty bounds on the information contained in the assessment expressed quantitatively where possible, but otherwise through narrative statements.

13 When evaluating the assessments of costs and benefits associated with the substance or organism in an application, the Authority must take into account—

(a) the costs and benefits associated with the application and whether the costs and benefits are monetary or non-monetary; and

(b) the magnitude or expected value of the costs and benefits and the uncertainty bounds on the expected value; and

(c) the distributional effects of the costs and benefits over time, space, and groups in the community.

14 The costs and benefits are those that relate to New Zealand and that would arise as a consequence of approving the application.

B2: Cont.
Schedule (from Hazardous Substances and New Organisms (Methodology) Order 1998)
Methodology for making decisions under Part 5 of Act

Decision-making

21 Decisions by the Authority must be in accordance with the specific requirements of the Act and the regulations made under the Act.

22(1) The Authority must evaluate risks, costs, and, where applicable, benefits, taking into account—
- (a) the nature and characteristics of the substance or organism; and
- (b) the applicant's assessments and, where applicable, proposals for the management of the risks concerned; and
- (c) any submissions received; and
- (d) the reviews prepared by the chief executive or any expert appointed by the Authority or the chief executive.

(2) Subclause (1) does not limit any discretion that the Authority may have under the Act.

23 The Authority may, in accordance with section 58 of the Act, obtain further information in order to gain a sufficient understanding of the actual or potential effects caused by the substance or organism and the means of managing those effects.

24 The Authority, its chief executive, its staff, and any appointed expert must use recognised risk identification, assessment, evaluation, and management techniques.

25(1) When evaluating risks, the Authority must begin with a consideration of the scientific evidence relating to the application and take into account the degree of uncertainty attaching to that evidence.

(2) Where evidence relating to an application refers to other values and matters relevant to Part 2 of the Act, including the relationship of Māori culture and traditions with their ancestral lands and taonga, the Authority must also consider the values and other matters in that evidence.

26 Taking into account the measures available (if any) for risk management, the Authority may approve an application where a substance or organism poses negligible risks to the environment and human health and safety if it is evident that the benefits associated with that substance or organism outweigh the costs.

27(1) Where clause 26 does not apply, the Authority must take into account the extent to which the risks and any costs associated with that substance or organism may be outweighed by benefits.

(2) Where an application is for a new organism and that organism causes any of the effects in section 36 of the Act, clause 26 and subclause (1) do not apply and the Authority must decline the application.

28(1) The Authority may, from time to time, issue explanatory material relating to the calculation of monetary and non-monetary costs and benefits.

(2) Explanatory material issued under this clause does not form part of the methodology.

B2: Cont.
Schedule (from Hazardous Substances and New Organisms (Methodology) Order 1998)
Methodology for making decisions under Part 5 of Act

Uncertainty

29 Where the Authority encounters scientific and technical uncertainty relating to the potential adverse effects of a substance or organism, or where there is disputed scientific or technical information, the Authority—

(a) must determine the materiality and significance to the application of the uncertainty or dispute taking into account the extent of agreement on the scope and meaning of the scientific evidence; and

(b) may, where the uncertainty or dispute is material or significant, facilitate discussion between the parties concerned to clarify the uncertainty or dispute.

30 Where any scientific or technical uncertainty or dispute is not resolved to the Authority's satisfaction during its consideration of the application, the Authority must take into account the need for caution in managing the adverse effects of the substance or (to the extent provided for under the Act) the organism concerned.

31 Where the Authority considers that uncertainty arises from an absence of information, or inconclusive or contradictory information, or information from an unreliable source, the Authority may request the applicant to provide further information in accordance with section 58 of the Act and must take full account of any additional information provided.

32 Where the Authority considers there is uncertainty in relation to costs, benefits, and risks (including, where applicable, the scope for managing those risks), the Authority must attempt to establish the range of uncertainty and must take into account the probability of the costs, benefits, and risks being either more or less than the levels given in evidence.

Approach to risk

33 When considering applications, the Authority must have regard to the extent to which the following risk characteristics exist:

(a) exposure to the risk is involuntary:

(b) the risk will persist over time:

(c) the risk is subject to uncontrollable spread and is likely to extend its effects beyond the immediate location of incidence:

(d) the potential adverse effects are irreversible:

(e) the risk is not known or understood by the general public and there is little experience or understanding of possible measures for managing the potential adverse effects.

B2: Cont.
Schedule (from Hazardous Substances and New Organisms (Methodology) Order 1998)
Methodology for making decisions under Part 5 of Act

Presentation of decisions

36(1) The Authority must publicly notify its decision.

(2) When giving its decision to the applicant and to those persons who have made submissions, the Authority must—

(a) ~~state whether the application is approved, with or without controls, or declined; and~~

(b) state the criteria in the Act and in this methodology relied on by the Authority in reaching its decision; and

(c) ~~where the application relates to a hazardous substance and is approved,~~ state the classification of the substance and—

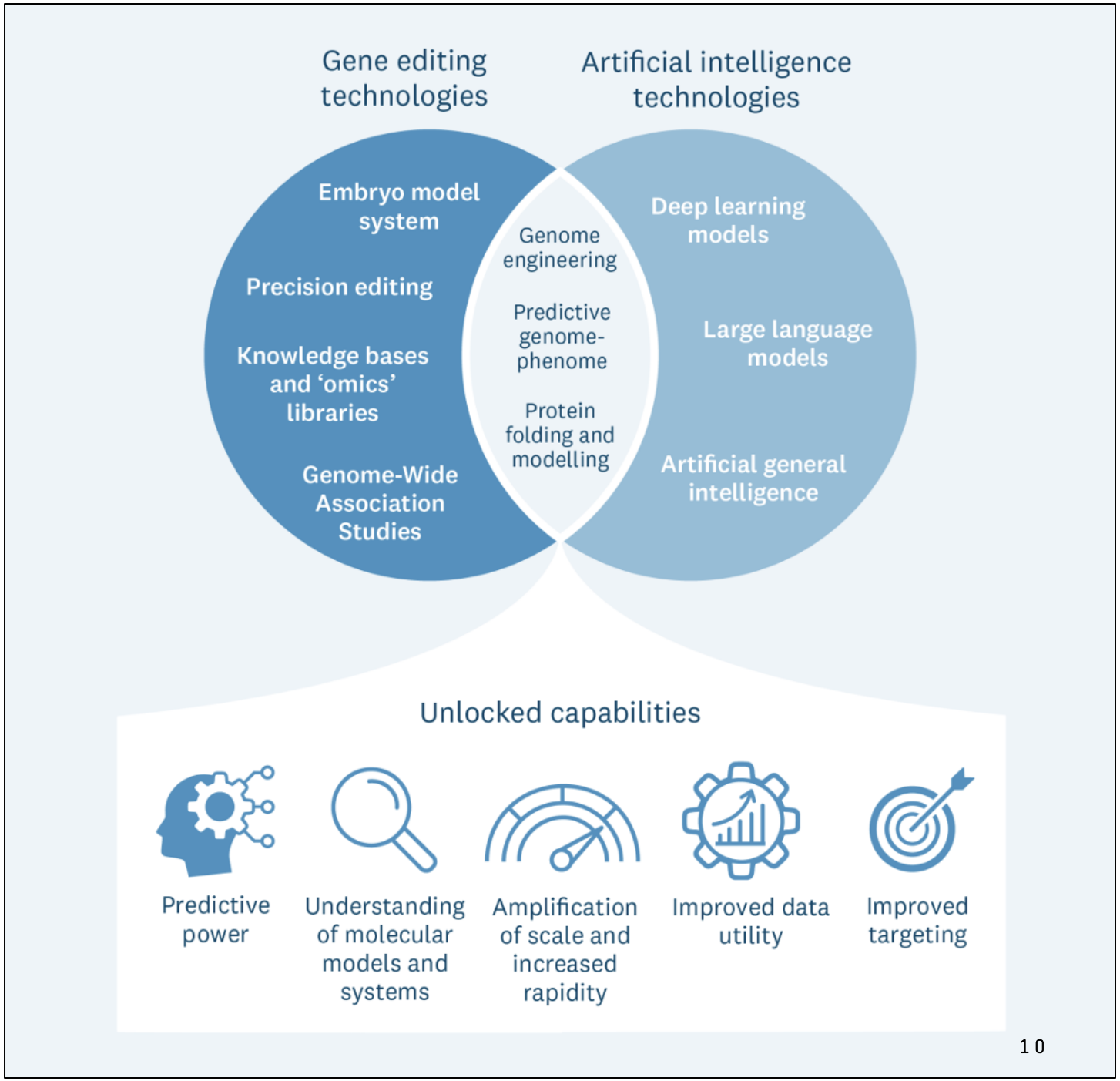
(i) whether the controls specified in the regulations for that classification have been attached to the substance; or

(ii) whether those controls have been varied by the Authority and attached to the substance; and

(d) where the application is approved and relates to a new organism or hazardous substance in containment, state the controls attached to that approval in accordance with Schedule 3 of the Act; and

(e) state the reasons for the Authority's decision.

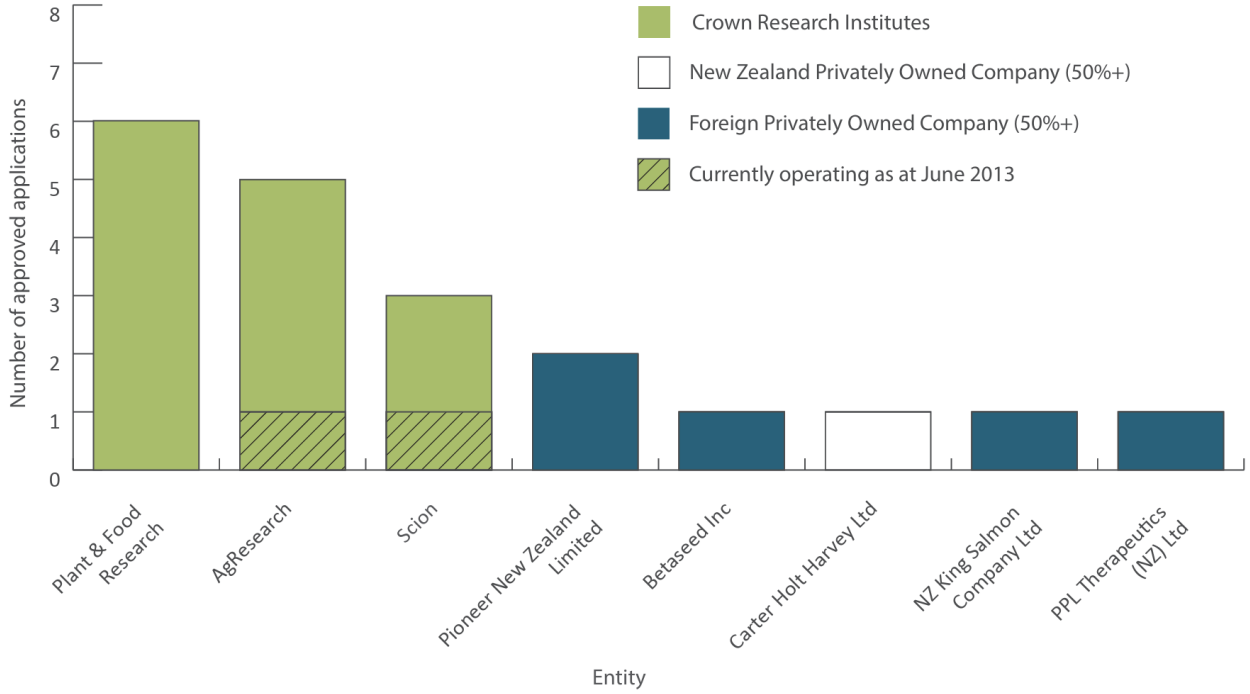
B3:
Take into account the intersection of gene technology and unknown capabilities (in particular AI).



B4:
Take into account the possibility of foreign investors undertaking risks in NZ that they cannot do in their own country

Figure 6: Approved applications for GM outdoor experiments by entity since the implementation of the HSNO Act 1998–2013

Source: See Appendix 10



B5:
Align GM policy with exports/trade agreements

Table 4

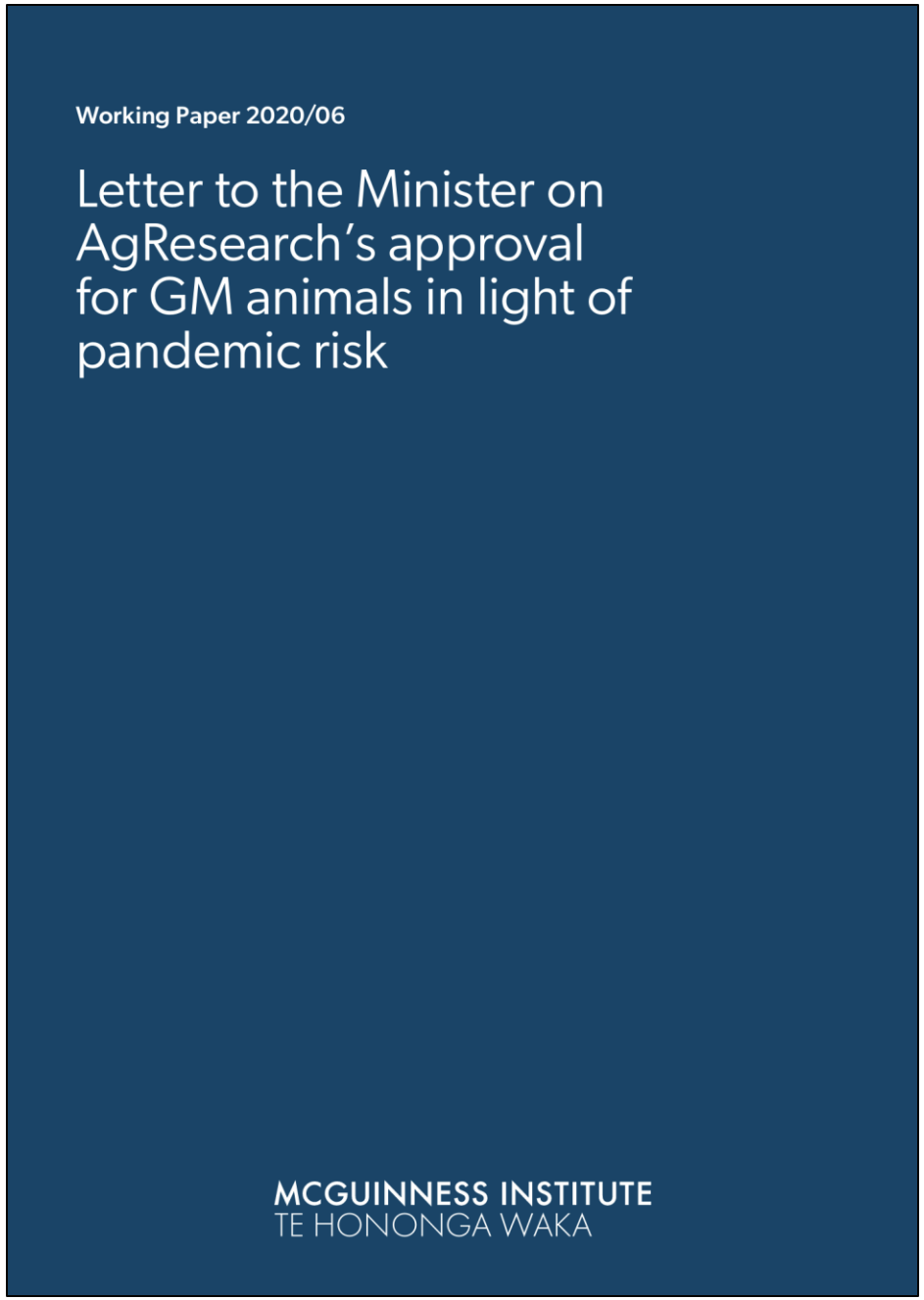
Top 25 exports

By commodity/service and destination

Quarter ended

HS/BPM6 code	Commodity/Service[1][2]	Destination	December 2023	March 2024	June 2024	September 2024	December 2024	
			NZ$(million)	NZ$(million)	NZ$(million)	NZ$(million)	NZ$(million)	% of total
0401-0406	Milk powder, butter, and cheese	China, People's Republic of	1,642	1,679	1,567	955	2,145	8
A1204	Travel	Australia	819	1,108	774	776	817	3.1
44	Logs, wood, and wood articles	China, People's Republic of	835	853	611	686	762	2.9
A1204	Travel	China, People's Republic of	503	860	566	549	730	2.7
02	Meat and edible offal	United States of America	517	618	831	506	640	2.4
02	Meat and edible offal	China, People's Republic of	690	688	522	290	602	2.3
19	Preparations of milk, cereals, flour, and starch	China, People's Republic of	411	340	416	293	490	1.8
A1204	Travel	United States of America	415	763	425	175	435	1.6
A1210	Other business services	United States of America	241	197	264	285	361	1.4
A1204	Travel	European Union 27	293	523	223	135	346	1.3
0401-0406	Milk powder, butter, and cheese	Indonesia	277	253	264	220	341	1.3
71	Precious metals, jewellery, and coins	Australia	216	204	212	230	295	1.1
0401-0406	Milk powder, butter, and cheese	Algeria	240	315	208	38	289	1.1
A1203	Transportation	Australia	251	263	223	241	279	1
0401-0406	Milk powder, butter, and cheese	Australia	257	242	227	210	279	1
02	Meat and edible offal	European Union 27	214	313	331	202	277	1
0401-0406	Milk powder, butter, and cheese	Saudi Arabia	275	211	171	216	276	1
A1210	Other business services	Australia	228	211	227	260	258	1
0401-0406	Milk powder, butter, and cheese	Malaysia	255	213	215	191	248	0.9
A1204	Travel	United Kingdom	185	456	164	102	239	0.9
0401-0406	Milk powder, butter, and cheese	United States of America	211	276	223	149	235	0.9
0401-0406	Milk powder, butter, and cheese	Thailand	235	205	146	111	219	0.8
A1208	Charges for the use of intellectual property n.i.e.	Australia	216	204	C	228	209	0.8
A1209	Telecommunications, computer, and information services	United States of America	203	184	184	200	207	0.8
2204	Wine	United States of America	264	171	164	160	200	0.7
	Total[3][4]	**All countries**	**24,329**	**25,898**	**26,186**	**22,144**	**26,664**	**100.0**

B6:
Pandemic risk: Ensure labs are regularly and independently reviewed and reported upon.



Animal Markets and Zoonotic Disease Risk A Global Synthesis of a 15 Country Study, 2024

"Eight of the 10 mammalian species who share the highest number of viruses with humans are domestic species, including pigs, cattle, horses, sheep, and goats. An estimated 80% of pathogens carried by livestock can infect other species, such as ours." (p. 86)