Regulatory Impact Statement

Legislative improvements to support the public health response to COVID-19

Summary: Problem and Proposed Approach

Problem Definition

The COVID-19 Public Health Response Act 2020 (the Act) provides the legal framework for addressing the COVID-19 pandemic and delivering the Government's COVID-19 Elimination Strategy. The Act allows the Minister for COVID-19 Response (or the Director-General of Health in specified circumstances) to make orders to give effect to the public health response to COVID-19.

The Act has been working well to date and no significant changes to the legislative framework are proposed. However, officials in multiple agencies have identified possible amendments as a result of experience using the Act and its subordinate legislation over the past nine months.

The proposed amendments aim to strengthen empowerment provisions and to implement some technical and legal fixes, to ensure the Act is fit-for-purpose in supporting the prevention and risk of outbreak or spread of COVID-19 in 2021 and beyond.

Regulatory Impact Statement approach

This Regulatory Impact Statement (RIS) covers the proposed legislative changes that support improvements to the COVID-19 public health response. These proposals are within the responsibility of the Ministry of Health (the Ministry).

There is an associated separate RIS prepared by the Ministry of Business, Innovation and Employment (MBIE) that covers the proposed legislative changes relating to the operation of MIQFs.

Summary of Preferred Option

The preferred option is to amend the primary legislation to:

- extend the term of the Act;
- amend the empowerment provisions for orders to provide clarity and improve flexibility to:
    - revisit the term 'things' to remove repetition and confusion;
    - extend the definition of 'things' and actions to cover 'goods', and other terms to ensure an appropriate scope;
    - insert a deeming provision to ensure any goods prohibited under a COVID-19 Order are treated as "prohibited imports" for the purposes of the Customs and Excise Act 2018;
    - expand the purpose for which Orders can be made;
    - allow for material to be incorporated by reference; and
    - change Alert Level boundary descriptions;
- provide for the management of COVID-19 testing laboratories;
- strengthen the infringement regime; and
- improve delegated decision making.

Section B: Summary Impacts: Benefits and costs

Who are the main expected beneficiaries and what is the nature of the expected benefit?

Implementation of the Government's Elimination Strategy for COVID-19 is dependent on maintaining a responsive and supportive legislative framework. Benefits of the Act to date have been significant, for example:

- Community outbreaks have been managed quickly, minimising public health impact and reducing hospitalisations and deaths.
- While the economic impact of lockdowns has been substantial, businesses and trade have been able to resume more quickly than has been the case in other countries where lockdowns have continued for extended periods.
- Health inequities for Māori and Pasifika peoples, the elderly and other high-risk people have been minimised.

The existing legislation has been working well and no significant policy amendments are proposed. Rather, the proposed changes will broadly benefit the entire population of New Zealand by ensuring the Act is in place for as long as it is needed, and that the legislation is future-proofed, flexible and responsive.

While the Act may not be enduring for a long time period, it is also important to ensure that at the point of repeal the Act reflects New Zealand's best legislative framework for responding to a pandemic. The Act can then be used as a template or blueprint as a starting point for future legislation to address other pandemics, should it be needed.

Where do the costs fall?

Most of the proposed amendments will have no direct financial costs because the changes are enabling in nature, or simply provide technical/legal fixes.

Two proposals (expanding the purpose for which orders can be made, and the effective management of laboratory testing) could result in additional costs to the Crown, the public and/or business. A full cost assessment would be undertaken should a COVID-19 Public Health Order (Order) be proposed using the new provisions.

The further development of the infringement regime will purposely impose costs onto non-compliant individuals or businesses. The magnitude of the impact will be scaled so that the regime sits well in context of other infringement regimes in New Zealand. The intention is that the degree of penalty would be commensurate with the degree of non-compliance. A broader but more nuanced infringement regime could lessen the need to escalate enforcement to the Court's, hence reducing demands on that system.

We know that infringement fees have a greater impact on lower socio-economic groups, and that financial penalties are inherently inequitable given they have a proportionately larger impact on lower socio-economic households. These impacts will be carefully considered before finalising the secondary legislation.

Non-monetised costs

The Ministry recognises that the exercise of powers under the Act have significant non-monetised costs, particularly in relation to human rights implications under the Bill of Rights Act 1990 (BORA). Rights engaged include liberty, expression, freedom of assembly, movement (including the right of a citizen to enter New Zealand), and freedom from unreasonable search and seizure.

The proposed amendments would not introduce any new human right impacts, rather they would result in continuance of current impacts. The Ministry considers that the human rights impacts imposed by the legislation (including its extension and amendments) are demonstrably justified on the following basis:

- the Epidemic Preparedness (COVID-19) Notice 2020 remains in force providing a clear statement of Government's concern of high rates of COVID-19 related illness, permanent disability and death;
- rapid and decisive response actions are New Zealand's best chance to avoid needing to further escalate or prolong the Alert Level framework (with corresponding greater limitations on rights and freedoms)
- every new order or amendment is supported by a "RIA-Lite" process that assesses costs, benefits and other impacts;
- avoiding COVID-19 specific health inequities for Māori and Pasifika peoples, the elderly and other high-risk people, and those living in socioeconomic deprivation;
- applying control measures that are more flexible and able to provide tailored/targeted responses;
- amending the Act to make technical changes is consistent with BORA because limitations on people's rights must be prescribed in law; and
- learning from this global pandemic and international responses how best to respond to this and other pandemics or significant global events of the future.

This analysis is supported by a Ministry of Justice BORA assessment.

What are the likely risks and unintended impacts? how significant are they and how will they be minimised or mitigated?

The dynamic and fast-paced nature of the COVID-19 response means that there is a risk that the Act will provide inadequate flexibility to address future issues that might arise. However, reviews are frequent, and proposals are expected to use secondary legislation as much as possible to maximise flexibility.

The shared responsibility for the proposed amendments between MBIE and the Ministry does carry a small risk of creating a legislative framework that is not as unified as possible. This is mitigated by joint design and development processes and the drafting process managed by the Parliamentary Counsel Office.

Section C: Evidence certainty and quality assurance

Agency rating of evidence certainty?

The Ministry considers that the rating of evidence certainty for the proposals is strong. The amendments have been informed by the experience of officials from multiple agencies working with the legislation since it came into force in May 2020.

More broadly, a strong public health evidence base has informed the development of the Act and associated orders. This is provided through the Ministry's public health team, based on the most up-to-date and robust evidence.

Quality Assurance Reviewing Agency:

MBIE and the Ministry of Health

Quality Assurance Assessment:

Partially meets the quality assurance criteria

Reviewer comments and recommendations

A joint Ministry of Health and Ministry of Business, Innovation and Employment panel has reviewed the Impact Statement titled "Legislative improvements to support the public health response to COVID-19", produced by the Ministry of Health and dated May 2021.

The panel considers that the Impact Statement partially meets the quality assurance criteria.

The Impact Statement is clear, concise and complete. This RIS has identified a range of feasible options in terms of the legislative proposals.

Due to the short timeframes allowed for the development of the regulatory proposals, there was limited consultation outside of government. Thus, the RIS only partially meets requirements in this area.

Impact Statement: Legislative improvements to support the public health response to COVID-19

Section 1: General information

1.1 Purpose

This statement has been produced to accompany a Cabinet paper that seeks Cabinet's approval to amend the Act. The Ministry of Health is solely responsible for the analysis and advice set out in this Regulatory Impact Statement, except as otherwise explicitly indicated.

1.2 Key Limitations or Constraints on Analysis

The analysis in this RIS is subject to several constraints:

- the urgency of the issues associated with managing a global pandemic mean there has been limited time to develop proposals on matters that have significant implications for all New Zealanders;
- there is a lack of modern precedent for legislation of this type;
- the dynamic nature of COVID-19 means that legislation needs to balance flexibility with limits on the significant powers that the Act provides; and
- timeframes have not allowed for standard consultation on the proposals to be undertaken (the Ministry expects that this will occur during the select committee process).

Section 2: Problem definition and objectives

2.1 What is the current state within which action is proposed?

The current state is that of a global pandemic. As the global statistics are in a state of constant flux, we refer to the following World Health Organisation website which provides a *Daily COVID-19 Dashboard* of the impacts of the pandemic: https://covid19.who.int/table

After the first wave of infections in the first half of 2020, new strains that are more transmissible have caused resurgences that are impacting many countries, notably England, USA, Brazil, India and South Africa.

New Zealand has thus far been successful in reducing the impact of the COVID-19 pandemic, suffering few deaths per capita and able to pursue a strategy of eliminating the disease, rather than simply trying to "flatten the curve" and limit its impact.

New Zealand has implemented a COVID-19 Elimination Strategy, supported by the following four pillars:

- Keep It Out;
- Prepare For It;
- Stamp It Out; and

- Manage the Impact.

While the rollout of vaccination programmes has raised hope that the peak of the pandemic may be over, COVID-19 is likely to be a prevalent public health concern for months, if not years, to come. The public health measures contained in the Act, therefore, will remain relevant for the immediate future as we safely but progressively open New Zealand's borders.

The Act was designed to reflect the existing emergency powers available in the Health Act 1956 (which allow for a range of measures to be undertaken for the purpose of preventing the outbreak or spread of infectious diseases) while establishing a fit-for-purpose legal framework for specifically managing the unprecedented circumstances of the COVID-19 pandemic.

As a main response tool, the Act provides for the Minister responsible for administering the Act, or the Director-General of Health (in urgent circumstances), to make COVID-19 Public Health Orders (Orders) that require classes of people to undertake actions, or refrain from actions, in order to support of the public health response to COVID-19 and the Elimination Strategy.

Amendments to the Act are necessary to:

- reflect our evolving understanding of the virus;
- ensure effective roll-out of policy decisions;
- respond to operational issues and required enhancements;
- cater for the likely future shift towards ongoing management and control of COVID-19, particularly in the context of effective vaccinations; and
- address minor and technical drafting issues.

2.2 What regulatory system(s) are already in place?

The Prime Minister of New Zealand gave notice declaring that the effects of the outbreak of COVID-19 are likely to significantly disrupt or continue to disrupt essential governmental and business activity in New Zealand. This notice, the Epidemic Preparedness (COVID-19) Notice 2020, was made pursuant to section 5 of the Epidemic Preparedness Act 2006 on 25 March 2020. The notice provides the 'trigger' for the response actions taken to eliminate COVID-19.

The Health Act 1956, the Epidemic Preparedness Act 2006, and the Civil Defence Emergency Management Act 2002 were used for the initial responses. Despite the relative success of those initial responses, there were clearly ambiguities and weaknesses that arose from such a complex use of laws.

In May 2020 the Government decided as a matter of urgency to fast-track a new law to improve the COVID-19 response by having it managed under one Act. The COVID-19 Public Health Response Act 2020 received the Royal assent on 13 May 2020.

The Ministry of Health is the lead agency for the COVID-19 health response and administers the Act. The Ministry of Business Innovation and Employment (MBIE) has operational responsibility for the management of Managed Isolation and Quarantine Facilities (MIQFs), relying on the Ministry of Health for public health advice and the

support of multiple agencies to ensure the effective operation of the MIQF system.

Orders made under the Act are the primary tool for the COVID-19 response. They allow for a timely and tailored response to COVID-19 which takes into account the contagious nature and potential for asymptomatic transmission of COVID-19. Orders are made by the Minister for COVID-19 Response, and by the Director-General of Health where urgent action is warranted. To date, all orders have been made by the Minister of Health or the Minister for COVID-19 Response.

There are six primary orders made under the Act that support the public health response to COVID-19. They are:

- the COVID-19 Public Health Response (Alert Level Requirements) Order 2020 (Alert Level Requirements Order) – specifying the Alert Level framework that applies at any given time to a given area, and what is, or is not, acceptable activity;
- the COVID-19 Public Health Response (Air Border) Order (No 2) 2020 (Air Border Order) – placing requirements on persons arriving by air (including aircrew), including requirements to enter a MIQF, and setting out the predeparture testing regime;
- the COVID-19 Public Health Response (Maritime Border) Order (No 2) 2020 (Maritime Border Order) – placing requirements on persons arriving by sea, including requirements to enter a MIQF, what is acceptable activity when a ship is docked at port, and allowances for replacement crews;
- the COVID-19 Public Health Response (Isolation and Quarantine) Order 2020 (Isolation and Quarantine Order) – setting out the requirements for people who enter MIQF, including conditions for release from MIQF;
- the COVID-19 Public Health Response (Required Testing) Order 2020 (Required Testing Order) – requiring specific border workers to get tested for COVID-19 regularly and for record keeping; and
- the COVID-19 Public Health Response (Point-of-care Tests) Order 2021 (Point of Care Testing Order) – prohibiting the importation, manufacture, sale, use etc of a point-of-care COVID-19 test unless authorised or exempt.

2.3 What is the policy problem or opportunity associated with the proposed changes?

As stated above, the Act has been working well to date. However, officials in multiple agencies have identified possible improvements having used the Act and its subordinate legislation over the past nine months. These amendments aim to strengthen and broaden empowerment provisions, and to implement some technical/legal fixes.

The proposed changes will help ensure the Act remains fit-for-purpose in supporting the prevention and risk of outbreak or spread of COVID-19 in New Zealand in 2021 and beyond.

Additionally, while the Act may not be enduring for a long time period, it is important to ensure that at the point of repeal the Act reflects New Zealand's best legislative

framework for responding to a pandemic. The Act can then be used as a template or blueprint as a starting point for future legislation to address other pandemics, should it be needed.

2.4 What do stakeholders think about the problem?

Proposals have been tested with the broad technical expertise base within the Ministry of Health, MBIE and other key agencies with responsibility for the COVID-19 response. Initial consultation has also been undertaken with other agencies within government who have an interest in the proposed amendments.

Due to the continuing time pressures associated with the COVID-19 response, wider consultation on the proposed changes has not yet been undertaken. However, the public will have an opportunity to comment on the proposed amendments through the Select Committee process. In addition, officials are proposing to undertake targeted consultation with key stakeholders ("critical friends") during the Bill drafting stage to ensure the workability of draft provisions and test the impacts of them. The key stakeholders that will be consulted include (at a minimum):

- iwi with MIQF in their rohu;
- District Health Boards; and
- unions representing employees of MIQFs.

Officials remain cognisant of the need to ensure each additional measure (e.g. orders made under the Act) is necessary, and that it is implemented in a fair and proportionate way, to retain public and business support.

The Act and associated legislative instruments (including any amendments) will continue to undergo significant scrutiny, for example:

- the Ministry evaluates the Act and Orders against the Elimination Strategy as part of an ongoing internal review process for both existing and proposed measures (for example, the issue with sub-delegation was identified in the process of making the pre-departure testing and quarantine-free travel orders);
- other agencies with responsibility under the Act (e.g. MBIE) undertake regular reviews of how the Act is operating with respect to their areas of responsibility;
- the Act and associated legislative instruments are subject to review by the Regulations Review Committee, which ensures detailed parliamentary oversight of secondary legislation issued under the Act;
- many decisions and actions taken under the Act are subject to review by the courts, Ombudsmen's Office, and in some cases the Health and Disability and Privacy Commissioners; and
- strong public and media interest ensure there is a high degree of public scrutiny of actions taken under the Act.

2.5 What are the objectives sought in relation to the identified problem?

The following table sets out the problem, objective and proposed solution for each of the amendments.

Proposal	Problem	Objective	Proposed solution
Extending the term of the Act	The Act will expire on 13 May 2022, but it is likely that the powers in the Act will be needed beyond this period. Should the Act be allowed to expire, we would have to rely on the limited depth of the generic provisions of the Health Act to implement the COVID-19 Elimination Strategy. There are potentially significant costs for the country if our response is weak because of not having appropriately tailored legislative empowerment.	The objective of this proposal is to ensure the Act is in place for as long as necessary. However, the executive powers in the Act are significant with respect to the imposition on the rights of freedoms of New Zealanders, so should not be in place longer than is necessary (to do so could also create legal risk as Courts may see the impositions as being inappropriate for a "business as usual" operating model).	Amend section 3 to provide for an extension of one year (to 13 May 2023). To ensure the Act is not in place longer than necessary, it is recommended that provision be made for the Act to be able to be repealed, in whole or in part, by Order in Council. This process is much simpler and faster than having to go through a full legislative process when the provisions of the Act are no longer required.
Changes to section 11 – Revisit the term 'things'	Sections 11(1)(b) and 11(3) provide conflicting and circular wording for the definition of "things". The definition also affects section 12.	Ensure clarity and scope of the definition of 'things' in the Act.	Amend the definition of 'things' to address the repetition and circular nature of the current approach.
Changes to section 11 – Extending the definition of 'things' and actions allowing the coverage of goods and other terms	It is not explicit that the term 'things' covers such as 'goods', 'products' 'businesses', 'records', 'equipment', and 'supplies'. This has a flow-on effect for agencies whose legislation links to the definition of 'things' in the Act (for example Customs New Zealand in relation to enforcing prohibited imports). This lack of clarity creates some legal risk.	Provide clarity about the intent of the provision and remove any legal risk for government agencies that use the definition in the Act for regulatory purposes.	Provide for the term 'things' to cover goods and other terms. It is also recommended that the Act includes a deeming provision which ensures any goods prohibited under a COVID-19 Order are treated as "prohibited imports" for the purposes of the Customs and Excise Act 2018.
Changes to section 11 – Expand the purpose for which Orders can be made	The empowering provisions for Orders and the purpose of the Act do not fully embrace the evolving response needed to deliver a wider range of outcomes for an enduring COVID-19 response.	The objective of this proposal is to ensure the long-term workability of the Act.	Amend section 11 and possibly sections 4 and 9 to align the criteria with the purpose of the Act and encompass enabling Orders to reflect a broader range of outcomes sought.

Proposal	Problem	Objective	Proposed solution
Changes to section 11 – Incorporate material by reference	There is no provision for incorporating material in an order by reference.	The objective of this proposal is to reduce administration burden and allow for improved effectiveness and futureproofing. For example, if NZ gets a "travel passport" or any other cross-country standards or App solutions, the Orders can refer to the latest version of them as being acceptable for the purposes detailed in the order, without having to amend the order every time the specifications change.	Allow for incorporation of material by reference in orders and Gazetting that information.
Changes to section 11 – changes to Alert Level boundary descriptions	Section 10 requires that urgent Alert Level orders only apply to a single territorial authority's boundary. This inflexibility has resulted in impractical boundaries which have little or no relevance to the needed control of community transmissions and spread of COVID-19. This has resulted in difficulties for people living in these areas and issues with enforcement.	Ensure boundaries can be defined in the most pragmatic way to allow for sensible location and enforcement of restrictions across boundaries.	Remove the limitation that urgent orders apply only to a single territorial authority's boundary, and allow an Alert Level boundary to be defined in the most pragmatic way (e.g. using geographical features, the roading network, GPS coordinates and other precise and clear means).
Effective management of laboratory testing	There is no explicit power in the Act to manage laboratories and the test methodologies used, yet these are an important service supporting the COVID-19 response. This raises: • potential issues with the quality of the testing • concerns about the lack of integration with the national network laboratories, which means they are not currently required to notify all test results and input into the national testing repository; and • concerns about potential competition over access to laboratory consumables, which are in short supply globally.	To ensure appropriate management of laboratory testing, results and consumables, should it be required.	Include a provision to place requirements on testing laboratories including: • regulating quality control and minimum standards in relation to testing; • requiring integration of COVID-19 test results into the public health system (i.e. require notification of results and input into the national testing repository); and • managing the supply of testing consumables.

Proposal	Problem	Objective	Proposed solution
	While it is possible to use a section 11 order to regulate some of these matters, it is not possible to impose differential regulation on private and public laboratories which may be appropriate (particularly with respect to supply of consumables should there be a significant COVID-19 outbreak in New Zealand).		
Strengthening the infringement regime	A weak offence and penalty regime could undermine New Zealand's response and potentially risks failure of the COVID-19 Elimination Strategy. The current approach to compliance with Orders and requirements within them is to educate and support individuals to meet the requirements, rather than punish them for not complying. However, there are concerns that current infringement fee of $300 may not deter more serious breaches as effectively as it could. For example, an individual bringing an apple into New Zealand through the air border in breach of bio-security legislation may be subject to an infringement fee of $400. Yet if they breach the pre-departure testing requirement and risk bringing COVID-19 into the country, that fee is only $300.	The objective of the infringement regime is to ensure compliance with the requirements set out in Orders to help New Zealand respond to the global COVID-19 pandemic. The infringement regime should provide a meaningful disincentive for non-compliant behaviours is in place that reflects New Zealand's national interest and public health imperatives. It should also provide for ongoing flexibility of the regime so that it will not require any further changes to support the COVID-19 response over the life of the Act.	Amend the Act to increase the maximum infringement fee to $1,000 for an individual (currently $300), and to increase the court-imposed infringement fine to a maximum of $3,000 for an individual (currently $1,000). To ensure sure the infringement penalties are proportionate both to the risk posed by non-compliance and the resources available to an individual versus a body corporate to meet infringement penalties, a new fee of $3,000 and a court-imposed infringement fine of up to $9,000 is proposed for body corporates. Secondary legislation is also recommended to enable different fees to be set depending on the gravity of the infringement offence and whether there is repeat offending. Infringement fees have a greater impact on lower socio-economic groups. These impacts will be carefully considered before finalising the secondary legislation.
Improve delegated decision-making	An issue has been identified regarding the empowerment provision in section 12(1)(d) of the Act. That section provides a power for a COVID-19 order to sub-delegate to any person or class of persons (including the Director-General of Health). It also confirms that the sub-delegated power is a	Ensure the Act allows for responsible and time-critical decision-making in relation to the issuing of orders under the Act.	Amend the sub-delegation authority to better provide for the Director-General of Health to make necessary and rapid decisions (orders?) based on public health risk. The ability for the Minister to sub-delegate to the Director

Proposal	Problem	Objective	Proposed solution
	power to grant an exemption or authorise a specified activity that would otherwise be prohibited by the Order. Essentially, the issue is that under the current sub-delegation authority the Director-General of Health is only empowered to say who is exempt from the requirements in any given Order – not who they would apply to. This issue arose through the establishment of pre-departure testing requirements in the Air Border Order, as at the time of making the Order, it applied to the United Kingdom and the United States, but it was anticipated that other countries would be added. Given the speed with which those changes would need to be made (within hours of becoming aware of a spike in cases in departing countries) it would be inefficient to require an amendment to the Order itself to include those new countries (noting that the standard time frame for making or amending an Order is 6 weeks). A similar issue arose in the drafting of the amendments setting up the quarantine-free travel bubble with Australia, leading to a difficult drafting process and amendments that are more complicated than they would otherwise need to be. For decisions that may need to be made or changed at short notice, it is preferred that they be delegated to the Director-General of Health rather than the Minister for COVID-19 Response, to enable this agility of response.		General could be perceived as reducing transparency and accountability for decision-making on matters that could result in potentially significant implications for New Zealanders. This is an inherent trade-off with responsiveness of decision-making. We also note that the Director General's role is a statutory appointment which comes with significant powers under the Act and other legislation.

Section 3: Option identification

3.1 What options are available to address the problem?

Four options have been identified to address the problems outlined above:

- Option 1: Status quo
- Option 2: Amend primary legislation (preferred option) l
- Option 3: Use secondary legislation (e.g. Orders)
- Option 4: Use of non-regulatory levers (e.g. contracts and influence)

3.2 What criteria, in addition to monetary costs and benefits have been used to assess the likely impacts of the options under consideration?

We used four criteria in addition to costs and benefits to evaluate these proposals:

1. **Effectiveness** – able to achieve the objectives of the proposal.
2. **Proportionality** – there are limited restrictions on individual rights and appropriate safeguards.
3. **Durability** – flexible to respond to and develop in changing COVID-19 environment.
4. **Transparency** – it is clear what the rules are, and when, how and whom they apply to; it is clear who decision makers are, how they make their decisions

In the analysis tables for each section below, the performance of each option against these four criteria is assessed using the below key:

++	much better than the status quo
+	better than the status quo
0	about the same as the status quo
-	worse than the status quo
- -	much worse than the status quo

3.3 What other options have been ruled out of scope, or not considered, and why?

The original triage process to assess the amendments that would comprise the Bill identified some minor matters that could be addressed with non-regulatory options, including through section 11 orders, directions from enforcement officers and guidance. Where these solutions were feasible, they were implemented and the potential amendment withdrawn. The remaining issues that have been identified require legislative change.

Section 4: Impact Analysis for Main Options

Proposal: Extend the term of the Act				
Objective sought: To ensure the Act is in place for as long as necessary				
Criteria	**Option 1: Status quo**	**Option 2: Amend primary legislation (preferred option)**	**Option 3: Use of Orders**	**Option 4: Use of non-regulatory levers**
Effectiveness – would it achieve the outcome sought	- - Should the Act be allowed to expire, we would need to rely on the limited depth of the BAU provisions of existing legislation (such as the Health Act) which would not provide an adequate legislative framework for responding to COVID-19.	++ The only way to extend the term of the Act is to amend the primary legislation.	- - It is not possible to extend the term of the Act using a section 11 order.	- - It is not possible to extend the Act using non-regulatory levers.
Proportionality – there are limited restrictions on individual rights and appropriate safeguards.	**0**	**0** Extending the term of the Act would continue current restrictions rather than imposing new ones.	N/A	N/A
Durability – flexible to respond to and develop in changing COVID-19 environment.	- - Relying on BAU legislation would provide less flexibility in responding to the COVID-19 environment than extending the Act.	++ Provision would be made for the Act to be able to be repealed, in whole or in part, by Order in Council (which is simpler and faster than a full legislative process).	N/A	N/A
Transparency – it is clear what the rules are, and when, how and whom they apply to; it is clear who decision makers are, how they make their decisions	- - Relying on BAU legislation would provide less transparency than extending the Act.	**0**.	N/A	N/A
Overall assessment	**Not preferred**	**Preferred option**	**Not preferred**	**Not preferred**

Proposal: Changes to section 11 orders – various				
Objective sought: To ensure the framework for orders can continue to respond to the dynamic COVID-19 environment, and to make technical changes to improve the Act				
Criteria	**Option 1: Status quo**	**Option 2: Amend primary legislation (preferred option)**	**Option 3: Use of Orders**	**Option 4: Use of non-regulatory levers**
Effectiveness – would it achieve the outcome sought	**0**	++ The proposed amendments will future-proof the legislation and ensure flexibility.	- - It is not possible to use a section 11 order for most changes proposed. It is possible to allow Orders to cover wider range of purposes without expressly providing for it in the primary legislation, however, this will be open to legal challenge and could result in Order being struck down.	- - It is not possible to use non-regulatory levers for this purpose.
Proportionality – there are limited restrictions on individual rights and appropriate safeguards.	**0**	**0** Extending the purpose for which orders can be made could result in additional restrictions on rights, but any restrictions would be proportional to public health risk and other relevant considerations. Setting out restrictions in primary legislation is consistent with BORA.	N/A	N/A
Durability – flexible to respond to and develop in changing COVID-19 environment.	**0**	++ The orders framework will be more flexible and able to respond to the changing environment.	N/A	N/A
Transparency – it is clear what the rules are, and when, how and whom they apply to; it is clear who decision makers are, how they make their decisions	**0**	++ Most of the proposed changes to section 11 orders are intended to increase transparency and clarity.	N/A	N/A
Overall assessment	**Not preferred**	**Preferred option**	**Not preferred**	**Not preferred**

Proposal: Effective management of COVID-19 laboratory testing				
Objective sought: To ensure appropriate management of laboratory testing, results and consumables.				
Criteria	**Option 1: Status quo**	**Option 2: Amend primary legislation (preferred option)**	**Option 3: Use of section 11 order**	**Option 4: Use of non-regulatory levers**
Effectiveness – would it achieve the outcome sought	- Some regulation of laboratory testing is possible using a section 11 order, but no differential regulation between public and private laboratories is possible under current provisions.	++ This proposal will ensure flexibility in the legislation to make orders to effectively manage laboratory testing if required.	- Some regulation of laboratory testing is possible using a section 11 order, but no differential regulation between public and private laboratories is possible under current provisions.	- - It is possible to enter into agreement or Memoranda of Understanding with laboratories; however, this would take considerable length of time and the outcome is not guaranteed, particularly with private market laboratories. It is also likely financial compensation would be expected.
Proportionality – there are limited restrictions on individual rights and appropriate safeguards.	**0**	- There may be restrictions on private laboratories should an order be made (impact would be assessed at that time).	N/A	**0**
Durability – flexible to respond to and develop in changing COVID-19 environment.	**0**	++ This proposal will ensure flexibility to make orders to effectively manage laboratory testing if required.	N/A	**0**
Transparency – it is clear what the rules are, and when, how and whom they apply to; it is clear who decision makers are, how they make their decisions	**0**	++ Ensuring appropriate legislative authority is in place to regulate laboratory testing provides maximum transparency about who the decision-maker is and what their powers are.	N/A	- - This option would be less transparent, as the agreements would be considered commercially sensitive.
Overall assessment	**Not preferred**	**Preferred option**	**Not preferred**	**Not preferred**

Proposal: Strengthening the infringement regime				
Objective sought: ensure compliance with the requirements set out in Orders to help New Zealand respond to the global COVID-19 pandemic.				
Criteria	**Option 1: Status quo**	**Option 2: Amend primary legislation (preferred option)**	**Option 3: Use of section 11 order**	**Option 4: Use of non-regulatory levers**
Effectiveness – would it achieve the outcome sought	- Existing penalties may be too low to deter serious infringements. No distinction in penalties for individuals and body corporates.	++ Increased penalties likely to provide additional deterrent effect, particularly for serious infringements. Differential penalty regime for individuals and body corporates reflects the level of risk and ability to pay. Secondary legislation would allow for consideration of different penalty levels for serious and/or repeat offending.	- - It is not possible to use a section 11 order for this purpose.	- While education and support about requirements is the first approach to enforcement, it is important that this is backed up by a robust penalty framework for those who are unwilling to comply.
Proportionality – there are limited restrictions on individual rights and appropriate safeguards.	**0** Existing safeguards (e.g. appeal rights) would remain in place.	**0** No additional restrictions are proposed. Existing safeguards (e.g. appeal rights) would remain in place.	N/A	**0**
Durability – flexible to respond to and develop in changing COVID-19 environment.	**0**	+ Secondary legislation will allow for consideration of different levels for serious and/or repeat offending.	N/A	- Education and influence are unlikely to be adequate to address serious and/or repeat offending.
Transparency – it is clear what the rules are, and when, how and whom they apply to; it is clear who decision makers are, how they make their decisions	**0**	+ Infringement regimes should be clearly set out in legislation	N/A	**0**
Overall assessment	**Not preferred**	**Preferred option**	**Not preferred**	**Not preferred**

Proposal: Improved delegated decision-making				
Objective sought: Ensure the Act allows for responsible and time-critical decision-making in relation to the issuing of orders under the Act.				
Criteria	**Option 1: Status quo**	**Option 2: Amend primary legislation (preferred option)**	**Option 3: Use of section 11 order**	**Option 4: Use of non-regulatory levers**
Effectiveness – would it achieve the outcome sought	**0**	++ The proposed amendment would allow for time-critical decision-making on orders to be delegated by the Minister.	- - It is not possible to use a section 11 order for this purpose.	- - It is not possible to use a non-regulatory levers for this purpose.
Proportionality – there are limited restrictions on individual rights and appropriate safeguards.	**0**	**0** No restrictions on individuals are proposed, existing safeguards remain in place.	N/A	N/A
Durability – flexible to respond to and develop in changing COVID-19 environment.	**0**	++ Would enable time-critical decision-making for urgent orders to enable agility of response.	N/A	N/A
Transparency – it is clear what the rules are, and when, how and whom they apply to; it is clear who decision makers are, how they make their decisions	**0**	- Sub-delegation of decision-making from the Minister could be seen as reducing transparency (this is an inherent trade-off with responsiveness of decision-making).	N/A	N/A
Overall assessment	**Not preferred**	**Preferred option**	**Not preferred**	**Not preferred**

Section 5: Conclusions

5.1 What option, or combination of options is likely to best address the problem, meet the policy objectives and deliver the highest net benefits?

Legislative amendment is the best solution to address the range of fixes and improvements that have been identified. As set out in the tables above, it is not possible for the proposed changes to be implemented in any other way (e.g. through making a section 11 order).

Quick and balanced responses under the Act have delivered significant net public health and social benefits for New Zealand relative to the rest of the world, and this will be enhanced by futureproofing the Act at this stage. The dynamic nature of the COVID-19 response environment means that significant legislative flexibility and speed is required to deliver a sound and proportionate public health response.

Not all circumstances, scientific knowledge, and optimal public health response measures were known at the time of drafting the Act in 2020. We also cannot foresee the ways the COVID-19 response will change in the future. Designing the Act to enable the making of the public health responses via section 11 orders and other subordinate legislation, provides the flexibility required.

Improving the Act so that it reflects New Zealand's best legislative framework for responding to a pandemic will also provide a blueprint for future legislation to address any other global pandemics should it be needed.

5.2 Summary table of costs and benefits of the preferred approach

Proposal	Preferred approach	Summary of costs and benefits
Extend the term of the Act	Amend the Act	**Costs** The exercise of powers under the Act have significant financial and non-financial costs to the Crown and the public. However, there will likely be much higher costs associated with not having appropriately tailored legislative framework. **Benefits** Quick and balanced responses under the Act have delivered significant net public health and social benefits for New Zealand relative to the rest of the world. Ensuring the Act is in place for as long as it is needed will continue these benefits. Ensuring that the Act can be repealed (in whole or in part) will ensure the legislation is not in place longer than necessary.

Proposal	Preferred approach	Summary of costs and benefits
Changes to section 11 – Revisit the term 'things' Extend the definition of 'things' and actions allowing the coverage of goods and other terms Expand the purpose for which Orders can be made Incorporate material by reference Changes to Alert Level management boundary descriptions	Amend the Act	**Costs** There may be costs for the Crown, the public and/or businesses if orders are made utilising the expanded purpose for which orders can be made. These costs would be assessed at the time any order is made. **Benefits** These amendments will: • provide clarity about intent and provide technical/legal fixes where required, reducing legal risk; • ensure we are able to respond to the dynamic nature of COVID-19; • enhance administrative efficiency (e.g. enabling material to be incorporated by reference); and • ensure appropriate and workable Alert Level Boundary management.
Effective management of COVID-19 laboratory testing	Amend the Act	**Costs** There may be modest costs to the Crown in administering any regulatory regime should this be required. There may also be administrative and other costs for public/private laboratories depending on what is proposed. These costs would be assessed at the time any order is made. **Benefits** This proposal will ensure flexibility in the legislation to make orders to effectively manage laboratory testing (if required) to ensure: • appropriate regulation of quality control and minimum standards in relation to testing; • integration of COVID-19 test results into the public health; and • management of the supply of testing consumables.
Improvement of the infringement regime	Amend the Act	**Costs** Strengthening the infringement regime will purposely impose costs onto non-compliant individuals or businesses. **Benefits** The magnitude of the impact will be scaled so that the regime sits well in context of other infringement regimes in New Zealand. The intention is

Proposal	Preferred approach	Summary of costs and benefits
		that the degree of penalty would be commensurate with the degree of non-compliance. It is intended that increasing the penalty levels for infringements will provide a more appropriate deterrent to non-compliance, particularly for more serious or repeat offending. A broader but more nuanced infringement regime could lessen the need to escalate enforcement to the Court's, hence reducing demands on that system.
Improve delegated decision- making	Amend the Act	**Costs** There are no costs directly associated with this amendment. Sub-delegation of decision-making from the Minister could be seen as reducing transparency. This is an inherent trade-off with responsiveness of decision-making (see benefits below). **Benefits** Would enable time-critical decision-making for urgent orders to enable agility of response.

Section 6: Implementation and operation

6.1 How will the new arrangements work in practice?

Some of the proposed amendments will require regulations, Orders, or other tertiary instruments to fully implement what is intended. Some of these will be introduced soon after the legislation commences (e.g. regulations for infringement offences) while others would follow should the instrument be required.

Whenever any COVID-19 response measure is being considered, the Ministry assesses the manner and timing of implementation in light of the public health urgency and broader impacts in terms of BORA, and economic and social well-being.

6.2 What are the implementation risks?

There are limited implementation risks associated with the proposed amendments as they do not involve any significant policy changes to the current approach.

Implementation risks could arise when developing tertiary instruments (e.g. Orders). However, these matters will be considered when the proposal is being developed. Any implementation risks will be identified and mitigated in consultation with the government agencies that have responsibility and accountability for implementation, and where possible/appropriate with the individuals and organisations that will be impacted by any proposed change.

Section 7: Monitoring, evaluation and review

7.1 How will the impact of the new arrangements be monitored?

The Act and associated legislative instruments (including any amendments) will continue to undergo significant monitoring, as set out below.

- The Ministry evaluates the Act and Orders against the Elimination Strategy as part of an ongoing internal review process for both existing and proposed measures (for example, the issue with sub-delegation was identified in the process of making the pre-departure testing and quarantine-free travel orders).
- Other agencies with responsibility under the Act (e.g. MBIE) undertake regular reviews of how the Act is operating with respect to their areas of responsibility.
- The provisions of the Act are dependent on continuation of the Epidemic Preparedness (COVID-19) Notice 2020, which provides a clear statement of Government's concern of high rates of COVID-19 related illness, permanent disability and death.
- The Act and associated legislative instruments are subject to review by the Regulations Review Committee, which ensures detailed parliamentary oversight of secondary legislation issued under the Act.
- The Government's Elimination Strategy, implemented under the Act, is subject to regular review by the Health Select Committee.
- Many decisions and actions taken under the Act are subject to review by the courts, Ombudsmen's Office, and in some cases the Health and Disability and Privacy Commissioners.
- Strong public and media interest ensure there is a high degree of public scrutiny of actions taken under the Act.

7.2 When and how will the new arrangements be reviewed?

The Act (including the new arrangements) will continue to be reviewed and monitored both formally and informally as outlined above.