The Hon Jason Clare MP
Minister for Education

Reference: MC24-001567

Senator Dean Smith
Chair
Senate Scrutiny of Bills Committee
Suite 1.111
Parliament House
CANBERRA ACT 2600

By email: scrutiny.sen@aph.gov.au

Dear Senator

Thank you for your correspondence of 28 March 2024 on behalf of the Senate Standing Committee for the Scrutiny of Bills, regarding the *Australian Research Council Amendment (Review Response) Bill 2023* (the Bill).

On 21 March 2024, the Bill passed both Houses of Parliament and received Royal Assent on 28 March 2024.

I understand the Senate Scrutiny of Bills Committee has queried whether section 11A of the *Australian Research Council Act 2001* (the Act) can be further amended to provide the independent review report of the Australian Research Council Board, to which this section refers, be tabled in each House of the Parliament.

The recent amendments to the Act are the result of rigorous scrutiny and debate through both Houses of Parliament. I am therefore disinclined to facilitate this further amendment to the Act.

The Australian Government will follow its usual processes in ensuring that the findings of the independent review are publicly disclosed through an appropriate Government response.

[redacted] information is of assistance.

[redacted]

JASON CLARE

11 / 4 / 2024

[redacted]

Attorney-General

Reference: MC24-002011

Senator Dean Smith
Chair
Senate Scrutiny of Bills Committee
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Parliament House
CANBERRA ACT 2600

By email: Scrutiny.Sen@aph.gov.au

Dear Chair

I refer to the request of the Senate Standing Committee for the Scrutiny of Bills in Digest 3 of 2024 dated 28 February 2024, for further information in relation to the Administrative Review Tribunal (Consequential and Transitional Provisions No.2) Bill 2024 (**Consequential and Transitional Bill 2).**

I appreciate the time the Committee has taken to consider the Bills, and thank the Committee for the opportunity to address the comments raised in its initial scrutiny. Please see attached my response to the questions raised by the Committee.

Finally, noting this response includes matters within the portfolio responsibilities of the Minister for Agriculture, Fisheries and Forestry, Senator the Hon Murray Watt, I have copied him into this correspondence.

I trust this information is of assistance.

Yours sincerely

[redacted]

THE HON MARK DREYFUS KC MP
3 / 4 /2024

Encl. Response to the Committee's questions on the Bills

CC. *Senator the Hon Murray Watt, Minister for Agriculture, Fisheries and Forestry*

Response to Senate Standing Committee on the Scrutiny of Bills
Scrutiny Digest 3 of 2024

The Senate Standing Committee on the Scrutiny of Bills (the Committee) has requested my further advice in relation to the Administrative Review Tribunal (Consequential and Transitional Provisions No.2) Bill 2024 (Consequential and Transitional Bill 2). The Committee's observations are set out in the Scrutiny Digest 3 of 2024.

I note that the Consequential and Transitional Bill 2 forms part of the package of Bills that would abolish the Administrative Appeals Tribunal (AAT) and establish the Administrative Review Tribunal (the Tribunal), a new federal administrative review body that is user-focused, efficient, accessible, independent and fair. The Committee's initial scrutiny comments on the Administrative Review Tribunal Bill 2023 (ART Bill) and the Administrative Review Tribunal (Consequential and Transitional Provisions No. 1) Bill 2023 (Consequential and Transitional Bill 1) are set out in the Scrutiny Digest 2 of 2024. My response to these comments was provided to the Committee on 15 March 2024.

Limitation of Judicial Review

1.8 The committee requests the Attorney-General's advice as to why it is necessary and appropriate for decisions made by the Administrative Review Tribunal in its intelligence and security jurisdictional area to be exempted from review under the *Administrative Decisions (Judicial Review) Act 1977* with limited exceptions.

The amendments to paragraph (y) in Schedule 1 of the *Administrative Decisions (Judicial Review) Act 1977* (ADJR Act) generally maintain the effect of the existing law with respect to the reviews in the Intelligence and Security jurisdictional area. Judicial review of decisions by the Intelligence and Security jurisdictional area remains available under section 39B of the *Judiciary Act 1903* and under section 75(v) of the Constitution, if a party seeks a review on grounds beyond those enabled under clause 172 of the ART Bill.

It is widely accepted that some administrative decisions should not be subject to judicial review. The Administrative Review Council, in its 2012 report 'Federal Judicial Review in Australia' articulated the following principles as justifying exemption from the ADJR Act:

- review is also not available under section 39B of the *Judiciary Act 1903*
- the decision relates to the deployment or discipline of defence force members
- a well-established alternative scheme already exists, which is as accessible and effective as ADJR Act review
- review has the potential to fragment or frustrate another legal process which is already underway
- ADJR Act review could pose a risk to personal safety, or
- the decision has a strong link with other constitutional considerations, and as such, is more appropriate to be considered via constitutional review.

The Council also considered that national security 'may justify an exemption, but should not be used as a blanket justification'.

The Government considers that each of the decisions made by the Intelligence and Security jurisdictional area (under clause 134(1) of the ART Bill) are appropriately excluded by new paragraph (y) of the ADJR Act. The relevant decisions are:

- criminal intelligence assessments
- foreign acquisitions and takeovers decisions
- security assessments
- security clearance decisions, or
- security clearance suitability assessments.

As noted in the Government's response to the Committee's observations set out in Scrutiny Digest 2 of 2024, 'intelligence and security decisions' as defined in clause 4 of the ART Bill inherently, and exclusively, will relate to and rely on sensitive information which must be protected. These decisions can include sensitive information relevant to agency capabilities or ongoing investigations and will involve matters of high policy importance, like national security, where judgements are more appropriately made by the executive arm of the government.

The Administrative Review Council considered the ADJR Act exemption of decisions of the former Security Appeals Division of the Administrative Appeals Tribunal in its 2012 report 'Federal Judicial Review in Australia'. It concluded that the exemption was appropriate and ought to be retained 'given the concern about protection of national security information (which is subject to particular controls in the Security Appeals Division), and the fact that review is

available via s 44 [of the *Administrative Appeals Tribunal Act 1975* (AAT Act)] and s 39B [of the *Judiciary Act 1903*].'

The Government considers that, although the types of decisions considered by the Security Appeals Division (which in turn became the Security Division, and will continue as the Intelligence and Security jurisdictional area) have widened (at the time of the ARC's consideration, only security assessment reviews were conducted in the Security Appeals Division), the fundamental considerations underpinning the exemption remains. All matters which must be heard in the Intelligence and Security jurisdictional area by the operation of clause 134(1) of the ART Bill inherently involve highly sensitive intelligence and criminal intelligence information, which must be protected using special procedures in the Tribunal (which are retained from the Security Division). These matters are able to be appealed to the Federal Court of Australia through clause 172 of the ART Bill (which is equivalent to s 44 of the AAT Act), ensuring that parties can seek judicial review of Tribunal decisions.

Availability of independent merits review

1.15 The committee therefore requests the Attorney-General's advice as to:

- **Whether more detailed advice can be provided as to the risk that subsections 105.51(5) and (7) of the Criminal Code could [be] construed as vesting federal judicial power on the Administrative Review Tribunal;**
- **Whether consideration was given to alternative constructions that would preserve the right of a person to seek independent merits review (for instance by consideration of alternative remedies that could be ordered by the Administrative Review Tribunal in relation to preventative detention orders); and**
- **If an alternative construction is not possible or otherwise appropriate, whether the removal of independent merits review warrants consideration of whether review under the *Administrative Decisions (Judicial Review) Act 1977* should be provided in respect of decisions made under Division 105 of the Criminal Code relating to preventative detention order.**

A Preventative Detention Order (PDO) allows a person to be taken into custody for the purposes of either preventing a terrorist attack that is capable of being carried out, and could occur within the next 14 days, or preserving evidence of, or relating to, a recent terrorist act. An initial PDO lasts up to 24 hours, and a continued PDO, which may be given upon approval of an issuing authority, can extend the detention by a further 24 hours.

The proposed amendments in the Consequential and Transitional Bill 2 would leave decisions with respect to the validity or otherwise of PDO decisions, and the ordering of any compensation, entirely within the purview of the courts. Removing an administrative review avenue in relation to PDO decisions will not affect an individual's ability to seek the voiding of such a decision or a compensation payment, as these remedies are available through, and better determined by, processes of judicial review.

I would note generally that the power to award a grant of compensation is a power usually reserved for the courts, and is not typically a function of an administrative review body.

Providing only for judicial review of PDO decisions is appropriate as it reflects the seriousness and extraordinary nature of PDO decisions, and the courts' expertise in handling such matters. A PDO is made in the context of preventing or responding to terrorist activities, and findings in relation to the validity of a PDO decision and/or whether there has been wrongful detention will

inherently involve the determination of legal rights. Such a determination is more appropriately made by a Court. While a PDO decision is a category of administrative decision, it is made in a national security and law-enforcement context. The Court is more suited to conduct a review of such matters.

In practice, review of PDO decision could only occur after the PDO has ceased in effect, given its short-term nature. As such, the ability of the Tribunal to provide appropriate remedy through review of a PDO decision is effectively limited. Under clause 105 of the ART Bill, the Tribunal may make a decision to affirm the decision on review, remit it to the original decision-maker for reconsideration, substitute a new decision or vary the decision. It does not have the power to grant any other form of relief. Arguably, the only effective remedy in circumstances where a PDO has been wrongly issued is compensation, as a new or different decision (which is ordinarily what an administrative tribunal would issue, but not an avenue currently available to the AAT in relation to PDO decisions under the Criminal Code) will not be of any practical effect once the PDO has ceased to operate.

As such, it is the Government's position that a Court remains better suited to providing a tailored and appropriate review of the PDO decision.

It is also not appropriate for PDOs to be subject to the ADJR Act. In accordance with the Administrative Review Council's '*What decisions should be subject to merit review?*', national security decisions may be appropriately exempted from the ADJR Act. PDO decisions are likely to be made on the basis of sensitive classified information, and with regard to operational matters not appropriate for public dissemination.

Notwithstanding that ADJR review is not available for PDO decisions, judicial review of these decisions is provided for in:

- sections 105.51 (Legal Proceedings in Relation to PDOs) and 105.52 (Jurisdiction of State and Territory Courts) of the *Criminal Code Act 1995*,
- section 39B of the *Judiciary Act 1903* (Original Jurisdiction of the Federal Court of Australia), and
- section 75(v) of the Constitution (Original jurisdiction of the High Court).

Limitations on Merit Review – Application timeframes

1.19 The committee requests the Attorney-General's advice as to why it is necessary and appropriate for item 54 of Schedule 1 to the bill to remove the Administrative Review Tribunal's discretion to extend the application timeframe for review of decisions under the *Wine Act 2013*.

Item 54 of Schedule 1 to the Consequential and Transitional Bill 2 provides that the Tribunal may not grant an extension of time for applications to review a final determination under Part VIB of the *Wine Australia Act 2013* (Wine Australia Act). This continues the status quo for review of these decisions.

A final determination of a geographical indication under subdivision E of Division 4 of Part VIB of the Wine Australia Act identifies wine goods as originating in a country, or in a region or locality in that country, where a quality, reputation or other characteristic of the goods is essentially attributable to their geographical origin (section 4, Wine Australia Act). For example, a final determination could result in the registration of a particular region as a geographical indication, such as 'Barossa Valley' or 'Canberra District', which may become well known in the industry and among the general public.

It is necessary and appropriate to impose a time limitation on the application for review of these decisions, including by preventing the Tribunal from granting an extension of time. In this way, the legislation ensures appropriate certainty in relation to final determinations of geographical indications. Noting that review of these decisions may be sought by any person whose interests are affected by the decision (clause 17 of the ART Bill), enabling open-ended time periods for review of the decisions could lead to review being conducted long after registration of the geographical indication.

Given the time it takes to grow grapes, and to make wine, certainty regarding registered geographical indications is fundamental to the efficacy of the Australian grape and wine industry. This is particularly the case for producers conducting business activities within the boundaries of a registered geographical indication. For example, a grower must be certain that they are growing grapes within the boundaries of a particular geographical indication to ensure that wine produced from such grapes will obtain the expected market access and value. Moreover, for specific export markets that require wine goods to be described and presented with registered geographical indications, uncertainty in relation to geographical indications may pose barriers to market access for Australian wine. Removing this certainty would create inherent unfairness for stakeholders whose livelihoods often depend on it.

Finally, removing this time limitation, by retaining the Tribunal's standard discretion to extend application timeframes, would undermine the objects and purpose of the geographical indication framework and the Label Integrity Program established under the Wine Australia Act. The Label Integrity Program ensures the truth – and reputation for truthfulness – of statements made on wine labels, or made for commercial purposes in other ways, about the vintage, variety or geographical indication of wine manufactured in Australia (section 39A of the Wine Australia Act).

SENATOR THE HON MURRAY WATT
MINISTER FOR AGRICULTURE, FISHERIES AND FORESTRY
MINISTER FOR EMERGENCY MANAGEMENT

MC24-002188

Senator Dean Smith
Chair
Senate Scrutiny of Bills Committee
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Dear Senator Dean

Agriculture (Biosecurity Protection) Charges Bill 2024
Agriculture (Biosecurity Protection) Levies Bill 2024
Agriculture (Biosecurity Protection) Levies and Charges Collection Bill 2024

I refer to email correspondence of 20 March 2024 from the Secretary of the Senate Scrutiny of Bills Committee about issues raised on the above Bills in *Scrutiny Digest 4 of 2024*.

The Department of Agriculture, Fisheries and Forestry has considered these matters and a detailed response is attached.

Yours sincerely

[redacted]

MURRAY WATT 15 / 4 /2024

Enc

ATTACHMENT

Response to Senate Standing Committee for the Scrutiny of Bills

Agriculture (Biosecurity Protection) Charges Bill 2024
Agriculture (Biosecurity Protection) Levies Bill 2024

Charges and levies in delegated legislation

The Committee has brought to the attention of senators the appropriateness of allowing the rates of charges and levies to be specified in, or worked out in accordance with the regulations.

As detailed in the Explanatory Memorandum, the rates will be specified in disallowable regulations made by the Governor-General.

I believe it is appropriate for the rates to be specified in the regulations as they would be a disallowable legislative instruments under the *Legislation Act 2003*, which would ensure appropriate Parliamentary oversight. The regulations would not be exempt from sunsetting under the Imposition Acts.

Incorporation of external materials as existing from time to time

The Committee has sought further information about whether material incorporated from time to time will be made freely and readily available to all persons interested in the law, including individuals not in the industries concerned.

I confirm that where the rules would incorporate such documents, the explanatory statements would, in accordance with paragraph 15J(2)(c) of the *Legislation Act 2003*, contain a description of the relevant incorporated material and indicate how it may be obtained.

The material incorporated from time to time will be made freely and readily available to all persons interested in the law, including individuals not in the industries concerned. The explanatory statements would include website details on where the documents could be obtained; specify the Australian public libraries where the material is available; or include relevant extracts, in full, from the incorporated documents.

Agriculture (Biosecurity Protection) Levies and Charges Collection Bill 2024

Broad delegation of administrative powers – coercive powers; infringement notices

The Committee has indicated that it considers that it would be appropriate for the bill to be amended to expressly provide that only employees with the appropriate skills, experience or training should be designated compliance officers or persons assisting compliance officers. However, for the reasons set out below, I do not consider it necessary to amend the bill to expressly require this.

The exercise of administrative power is subject to extensive scrutiny and accountability requirements and the explanatory memorandum extensively addresses the appropriateness of delegating the relevant powers. In particular, in line with departmental practice in relation to compliance officers who have powers and functions under the Regulatory Powers Act, it is intended that the Secretary would appoint APS employees who have relevant experience and training and are required to undertake appropriate training prior to exercising powers under the legislation.

Further, as noted in the explanatory memorandum, it is intended that compliance officers currently appointed by the Secretary under the Primary Industries Levies and Charges Collection legislation would be appointed under the biosecurity protection levy legislation. These officers that are specialised staff, of whom there are currently around 20 officers, who carry out compliance activities in relation to the existing agricultural levy system.

Additionally, officers assisting compliance officers will be supervised and directed by the abovementioned experienced compliance officers to ensure the correct and appropriate use of their powers. Further, the provisions in Division 5 of Part 4 expressly limit any actions taken in executing a monitoring or investigation warrant against things by such persons to what is necessary and reasonable in the circumstances. The Regulatory Powers Act also requires that such persons must act in accordance with a direction given to them by the authorised person.

I note that the Committee has welcomed the above information in the explanatory memorandum addressing the intended experience, training and supervision of officers delegated administrative powers under the Bill and that appointment of a team of appropriately trained compliance officers is essential to the effective and efficient operation of the compliance regime for the collection of biosecurity protection levies and charges.

Reversal of the evidential burden of proof

The Committee has sought further information about why it is proposed to use an offence-specific defence for the criminal offence in subclause 40(1) relating to unlawful disclosure of information by entrusted persons; and the appropriateness of the reversal of the burden of proof, including whether the provisions could be drafted differently.

A person commits an offence against subclause 40(1) or contravenes the civil penalty provision in subclause 40(2) of the Bill if:

- the person is, or has been, an entrusted person; and
- the person has obtained or generated information in the course of or for the purposes of:
    - administering the Act or the rules or monitoring compliance with the Act or the rules; or
    - assisting another person to administer the Act or the rules or monitor compliance with the Act or the rules; and
- the information is of a kind covered by subclause (3) (protected information); and
- the person uses or discloses the information.

Information covered by subclause (3) includes commercially sensitive information the disclosure of which could reasonably be expected to found an action by a person (other than the Commonwealth) for breach of a duty of confidence.

Subclause 40(4) provides that the offence or civil penalty does not apply if the use or disclosure of the information is required or authorised by the Collection Bill or another law of the Commonwealth or a prescribed law of a State or Territory. The reversal of the evidential burden in relation to the matters in subclause 40(4) is appropriate and justified on the basis that the relevant matter is peculiarly within the knowledge of the defendant and it would be both significantly more difficult and costly for the prosecution to disprove rather than for the defendant to establish the matter.

The reversal of the evidential burden in relation to the matters in subclause 40(4) is appropriate and justified on the basis that the relevant matter is peculiarly within the knowledge of the defendant and it would be both significantly more difficult and costly for the prosecution to disprove rather than for the defendant to establish the matter.

Subsection 40(4) notes that an entrusted person bears the evidential burden of proof to demonstrate that the use or disclosure was permitted. Consistent with Part 4.3.2 of the *Guide to Framing Commonwealth Offences* (the Guide), this offence-specific burden requires only an evidential burden of proof, and does not impose any legal burden. An evidential burden is easier for a defendant to discharge, and does not completely displace the prosecutor's burden (it only defers that burden).

An entrusted person will be peculiarly aware of the reasons for the use or disclosure of protected information. Where it may not be clear to other people why certain information was used and if the use or disclosure was authorised, the entrusted person should easily be able to point to records indicating why it was appropriate for them to use and/or disclose that information. This explanation could be readily provided by the entrusted person.

In addition, requiring the entrusted person to adduce evidence helps narrow the scope of the issue. The breadth of the exclusion (that is, the use or disclosure is authorised by the Act, another law of the Commonwealth or a prescribed state or territory law) is such that if the prosecution had to prove beyond a reasonable doubt that the use or disclosure was not authorised, it would undermine the ability to prosecute the offence.

The prosecution may have to go to significant lengths to identify the reasons for the use or disclosure of information, as it may be difficult to identify the actual reason that information was used or disclosed. It would then have to go to significant lengths to identify where there is any law, other than the Act, that may have authorised the disclosure. In addition to the time and cost implications for the prosecution, it may also impose significant time and expense on the employers of entrusted persons.

If subclause 40(4) were amended to provide that the use or disclosure was not required or authorised by law as an element of the offence, the Commonwealth would have to prove that there is no Commonwealth law, or prescribed State or Territory law, in existence that could have required or authorised the use or disclosure. In practice, this limits the effectiveness of the provisions in protecting individuals from the unauthorised disclosure of protected information by making it impractical to prosecute the offence.

Further, the provision also is consistent with subclause 45(4) of the Primary Industries Levies and Charges Collection Bill 2023 and clause 81 of the Primary Industries Levies and Charges Disbursement Bill 2023, as well as provisions in other portfolio legislation namely, section 580 of the *Biosecurity Act 2015* and section 397G of the *Export Control Act 2020*. I consider it to be appropriate to provide the same level of protection for information gathered under this Bill rather than the lesser standard that would be achieved by re-drafting the provision.

Automated decision-making

The Committee has sought further information about what kinds of decisions would be likely to be considered appropriate for automated decision making and how much discretion would be involved in automated decisions. The Committee has also asked whether consideration has been given to prohibiting certain decisions from being prescribed by the rules, and how automated decision-making processes would comply with administrative law requirements.

The Collection Bill has been developed in such a way as to align collection arrangements with relevant collection arrangements under the Primary Industries Collection Legislation, where possible. In doing so, the Bill has been framed to provide contemporary, flexible and efficient legislation to better support the collection of the biosecurity protection levy in the future.

I consider it necessary and appropriate for the BPL Collection Bill to establish a framework which could, in future, allow for the use of computer programs to make decisions to support the efficient and effective administration of the Collection Bill to future proof the legislation, noting that any such future use could only occur through the making of disallowable legislative instruments that would be subject to appropriate Parliamentary oversight.

What kinds of decisions are likely to be considered appropriate for automated decision-making and the level of discretion involved in such automated decisions

The kinds of decisions that may be considered appropriate for automated decision-making in the future are those where no discretion is involved in the making of such automated decisions. For example, those that involve an objective calculation set out in legislation. At this stage, however, there is no intention to specify automated decisions.

Whether consideration has been given to prohibiting decisions listed in proposed clauses 43 and 44 from being prescribed by the rules as being decisions to which automated decision-making apply

Appropriate safeguards concerning automated decision-making are provided for in the Bill.

Firstly, any such automated decision would be specified in a legislative instrument that would be subject to the consultation requirements under section 17 of the *Legislation Act 2003* (Legislation Act). Appropriate consultation would certainly include consultation with affected levy industries, levy payers and collection agents as to how the automation of such decisions might affect them.

These legislative instruments would not be exempt from disallowance under section 44 of the Legislation Act. Therefore, they could be closely examined by the Senate Standing Committee for the Scrutiny of Delegated Legislation and potentially be disallowed under section 42 of the Legislation Act.

Subclause 49(1) of the Bill prohibits the delegation by the Secretary of the powers provided for by subclauses 48(1) and 48(2), in addition to the Secretary's rule-making power provided for by subclause 55(1) of the Bill. As these powers could only be exercised by the Secretary personally, they would always be exercised with the level of accountability that comes with that role.

Clause 44 of the Bill would provide that decisions made by the Secretary personally are reviewable by the Administrative Appeals Tribunal.

Subclause 48(4) of the Bill would provide that the Secretary may make a decision in substitution for an automated decision where the Secretary considers the automated decision is not the correct or preferable decision.

Finally, as the Collection Bill does not oblige the Secretary to automate decisions, they would retain the discretion not to automate decisions they considered more appropriate to be made by a decision-maker.

For these reasons, I do not propose to prohibit particular decisions under the Collection Bill from being prescribed in the rules.

Whether consideration has been given to how automated decision-making processes will comply with administrative law requirements (for example, the requirement to consider relevant matters and the rule against the fettering of discretionary power)

Whether consideration has been given to the Ombudsman's report Automated Decision-making: Better practice guide and the recommendations in paragraph 17.1 of the report of the Royal Commission into the Robodebt Scheme

The department has intentionally developed a legal framework that is consistent with other provisions on the Commonwealth statute book in which automation of government services can operate.

If decisions are automated in the future, in line with recommendation 17.1 of the Royal Commission into the Robodebt Scheme:

- the department would ensure that there is a clear path for those affected by decisions to seek review;
- departmental websites would contain information advising that automated decision-making is used and would explain in plain language how the process works; and
- the Department would make available business rules and algorithms to enable independent expert scrutiny.

The department has considered the Commonwealth Ombudsman's report, *Automated Decision-making: Better Practice Guide* in the development of the provision, particularly in relation to how such automation would comply with administrative law requirements, such as procedural fairness, internal and external review rights, the requirement to consider relevant matters, and the rule against fettering of discretionary power.

<u>Incorporation of external materials as existing from time to time</u>

The Committee has sought further information about whether material incorporated from time to time will be made freely and readily available to all persons interested in the law, including individuals not in the industries concerned.

I can confirm that where the rules would incorporate such documents, the explanatory statements would, in accordance with paragraph 15J(2)(c) of the *Legislation Act* 2003, contain a description of the relevant incorporated material and indicate how it may be obtained.

I note the material incorporated from time to time will be made freely and readily available to all persons interested in the law, including individuals not in the industries concerned. The explanatory statements would include website details on where the documents could be obtained; or specify the Australian public libraries where the material is available; or include relevant extracts, in full, from the incorporated documents.

Attorney-General

Reference: MC24-002010

Senator Dean Smith
Chair
Standing Committee of the Scrutiny of Bills
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CANBERRA ACT 2600

By email: Scrutiny.Sen@aph.gov.au

Dear Chair

Thank you for the Senate Scrutiny of Bills Committee's correspondence of 28 February 2024 regarding the Committee's assessment of the Crimes Amendment (Strengthening the Criminal Justice Response to Sexual Violence) Bill 2024.

I appreciate the time the Committee has taken to review the Bill, and have enclosed my response to the Committee's questions for its consideration.

I trust my response is of assistance.

Yours sincerely

[redacted]

THE HON MARK DREYFUS KC MP
25/3/2024

Encl. *Response to the Committee's questions on the Bill*

Response to the Senate Standing Committee on the Scrutiny of Bills

Scrutiny Digest 3 of 2024

The Senate Standing Committee on the Scrutiny of Bills (Committee) has requested the Attorney-General's further advice in relation to the Crimes Amendment (Strengthening the Criminal Justice Response to Sexual Violence) Bill 2024 (Bill). These matters are set out in the Scrutiny Digest 3 of 2024.

The following information is provided in response to the Committee's request for further advice on the Bill, noting the Bill is concurrently being considered by the Senate Standing Committee on Legal and Constitutional Affairs (SSCLCA). The Government will consider any recommendations for proposed amendments to the Bill in conjunction with any recommendations from the SSCLCA.

Committee Comments - Procedural fairness

1.102 The committee requests the Attorney-General's advice as to:

a) what impact (if any) proposed subsection 15YDG(1) could have on the right of an accused person to a fair hearing, including whether there are any safeguards contained elsewhere in the bill; and

b) **if the operation of proposed subsection 15YDG(1) could impact on the fair hearing rights of an accused person, whether further detail can be provided of the way in which the trial rights of an accused person have been balanced in the bill with the policy intent of protecting vulnerable witnesses from being re-traumatised by re-providing evidence.**

The intention of section 15YDG is to prevent vulnerable persons from being required to provide evidence further to that provided in an evidence recording hearing, unless specific circumstances are met. This is to reduce the level of trauma that may be occasioned should the vulnerable witness be required to give evidence multiple times on the same issue or issues, for example, where a re-trial is ordered. The defendant's fair hearing rights are preserved through appropriate criminal procedure safeguards.

Section 15YDG only applies in narrow circumstances:

- Firstly, Part IAD of the Crimes Act only applies in relation to certain people (being vulnerable adults, children, and select special witnesses) in relation to certain offences under section 15Y. These offences and persons have been identified as those which have the greatest potential for re-traumatisation during the criminal trial process given the nature of the alleged offending. This ensures that Part IAD is appropriately targeted and does not apply in relation to proceedings where the risk of traumatisation is less likely.

- Secondly, where Part IAD of the Crimes Act applies, section 15YDB requires that the court may only order an evidence recording hearing if it is satisfied that it is in the interests of justice to do so. The court has the power to limit or expand the evidence recording hearing to evidence in chief, cross examination, and/or re-examination as the court deems fit. In ordering an evidence recording proceeding, the court must take into account whether the defendant has sufficient time to prepare for the evidence recording hearing and that the defendant's legal representation is available for the hearing.

- Thirdly, section 15YDG does not prohibit a vulnerable person from being required to give evidence in addition to evidence in an evidence recording hearing. Rather, section 15YDG necessitates that the court is satisfied that there is probative value in the vulnerable person being required to give further evidence. It is open to the court to allow the admission of additional evidence under paragraphs 15YDG(1)(a)-(c) in circumstances where it is necessary to a) clarify the vulnerable person's evidence; b) give proper consideration to information or material that has since come to light; or c) it is in the interests of justice to do so. The 'interests of justice' is not prescriptive, but is intended to ensure that the court and, if applicable, jury, have available to it all relevant information in order to make an informed assessment of the evidence.

In addition to the above, the defendant's fair hearing rights are protected by safeguards in the Bill which ensure the defendant and their legal representative are able to properly engage with and interrogate evidence given by a vulnerable person. These include that:

- The defendant must be able to see and hear the vulnerable person (if the vulnerable person is appearing remotely), or be able to hear the vulnerable person (if the vulnerable person is in the same room) (section 15YDC(1)); and
- The defendant and their legal representation must be given reasonable access to the original recording in order to view or listen to it, including if this is required on more than one occasion (section 15YDF).

Committee Comments – Reversal of the evidential burden of proof

1.116 The committee requests the Attorney-General's advice as to:

a) whether the reversed evidential burden defences are justified in reference to the Guide to Framing Commonwealth Offences; and
b) whether the bill could be amended to remove the reversed evidential burdens by, for example, inserting the defences as elements to the offence.

15YR(1) of the Crimes Act provides that a person commits an offence if they publish any matter which identifies a vulnerable person in relation to a proceeding as being a child witness, child compliant or vulnerable compliant (who is not the defendant), or the matter is likely to lead to the vulnerable person being identified as such a person, and the court did not grant leave for the publication to occur.

The purpose of the offence in subsection 15YR(1) is to protect the privacy of a vulnerable person by creating a broad prohibition on the publication of any matter that identifies, or is likely to identify, the vulnerable person (identifying material). Attaching a criminal offence to such a publication recognises the harm that could be caused to a vulnerable person should such a publication occur. That harm eventuates through a significant breach of a vulnerable person's privacy which increases the risk of re-traumatisation. There are exemptions to the offence in subsection 15YR(2). These exemptions recognise that there are legitimate circumstances in which publication may be warranted. As the Committee has noted, the exemptions are drafted as reversed evidential burden defences.

Chapter 4 of the *Guide to Framing Commonwealth Offences, Infringements Notices and Enforcement Powers* (the Guide) provides guidance on when offence-specific defences may be appropriate. This includes where the information required to prove the existence of one of the prescribed defences would be peculiarly within the knowledge of the defendant, and/or it would be significantly more difficult and costly for the prosecution to disprove than for the defendant to establish the matter.

There are five offence-specific defences in subsection 15YR(2) that may apply as a defence to the offence in subsection 15TR(1). These offence-specific defences have been deliberately framed to ensure that lawful publication requires consideration by the publisher of the information of whether an exemption to the general prohibition applies. Offence-specific defences in section 15YR are the appropriate mechanism to protect vulnerable people from unauthorised publication of identifying material, while ensuring that there are limited carve-outs for legitimate publication. Each defence in subsection 15YR(2) falls within circumstances that Chapter 4 of the Guide considers may be appropriate for an offence-specific defence to apply.

In the new defences to the offence in subsection 15YR(1) being introduced by this Bill (being those in paragraphs 15YR(2)(c)-(e)), the consent of the vulnerable person is a central tenet. Paragraphs 15YR(2)(d) and 15YR(2)(e) each require the publishing person to obtain the consent of the vulnerable person, and the publication must be in accordance with the consent provided. This defence recognises that there is a strong public interest in allowing third parties (such as media outlets) to publish identifying information about vulnerable persons, however this should only occur with that person's consent. It is appropriate for this to be an offence-specific defence as obtaining the consent is an active action of the defendant and is something of which they would have a particular knowledge.

Paragraph 15YR(2)(c), being the other new defence introduced by the Bill, provides a defence where the vulnerable person identified is deceased. This new defence responds to stakeholder feedback. Paragraph 15YR(2)(c) recognises that publishing identifying material of a person who is deceased does not raise the same issues of re-traumatisation of the vulnerable person, and there are legitimate public interest reasons why persons may wish to publish this information. This defence is offence-specific as there is an expectation that this would be a central consideration in a decision to publish identifying information by the publishing person, and that that material fact is something that the defendant could easily adduce.

The defences in paragraphs 15YR(2)(a) and 15YR(2)(b) are existing defences to the offence in subsection 15YR(1). The Bill restructures these defences to ensure they operate effectively with the updated section 15YR, but they operate in substantially the same manner. The defences in paragraphs 15YR(2)(a) and 15YR(2)(b) recognise that a vulnerable person may need to be identified in documents either in that legal proceeding, or in other legal proceedings. Demonstrating that these documents were prepared for an authorised purpose is something that a defendant would have particular knowledge of and would be in a position superior to the prosecution to prove. This is further bolstered in that in the preparation of documents in relation to legal proceedings, legal professional privilege would likely present a significant barrier to the prosecution's ability to satisfy the element beyond reasonable doubt. By contrast, a defendant would be well placed to discharge an evidential burden without infringing privilege.

THE HON RICHARD MARLES MP
DEPUTY PRIME MINISTER
MINISTER FOR DEFENCE

Ref No: MC24-000962

Senator Dean Smith
Chair
Senate Standing Committee for the Scrutiny of Bills
Parliament House
CANBERRA ACT 2600

Dear Chair Dean

I write regarding the Defence Trade Controls Amendment Bill 2024. The Senate Scrutiny of Bills Committee previously sought my advice on a number of matters in relation to this Bill, including the level of delegation of the Minister's powers and functions provided for in the Bill.

In my response to the Committee of 14 March 2024 I provided further advice on how the proposed delegation would work in practice, including the training provided to delegates and the limited circumstances under which this delegation would be made. Specifically I advised the Committee that non-SES officers would only be delegated the power to approve low risk and low complexity permits. I also committed that this matter would be addressed in the Parliamentary debate on the Bill.

Accordingly, I draw the Committee's attention to the second reading speech by the Minister for Finance and Manager of Government Business in the Senate, Senator the Hon Katy Gallagher, on the Bill's introduction into the Senate, which can be found at page 26 of the published Hansard proof for Thursday 21 March 2024. I have enclosed a copy to this letter.

I trust this information is of assistance to the Committee and thank the Committee for its work on the Bill.

Yours sincerely,

[redacted]

RICHARD MARLES

18/4/24

This Bill will also enable the Minister for Defence to determine, by legislative instrument, a class of former Defence staff members who are not required to apply for an authorisation.

The class may be determined by the type of work previously performed by the Defence staff member and the period of time that has elapsed since the performance of that work.

Following the introduction of this Bill last year, the Deputy Prime Minister referred the Bill to the Parliamentary Joint Committee on Intelligence and Security. On the 14 March 2024, the Committee published its report and made five recommendations. The Government thanks the Committee for its timely consideration of the Bill.

The Bill also amends the Criminal Code to ensure consistency between the operation of this Bill and section 83.3 of the Criminal Code Act 1995 which establishes an offence for providing military-style training to a foreign government principal.

These amendments clarify that if a person is exempt from the new offences in the Safeguarding Australia's Military Secrets Bill, that the person will also be exempt from section 83.3 of the Criminal Code for the same conduct.

The Safeguarding Australia's Military Secrets Bill is not intended to prevent Australians from working overseas or with all foreign governments or militaries.

Rather, the legislative intent is to prevent individuals with knowledge of sensitive Defence information from training or working for certain foreign militaries or governments where that activity would put Australia's national security at risk.

This Bill will ensure individuals in possession of sensitive Defence information who want to undertake these activities first seek authorisation to do so. This is to ensure their activities are not damaging Australia's national interests.

This Bill will enable the Minister for Defence, or their delegate, to consider each request for authorisation on a case-by-case basis.

The Bill provides individuals the ability to seek internal or external merits review of certain decisions made under this authorisation framework.

Authorisations may be granted subject to conditions and may be cancelled, suspended or varied in certain circumstances.

An authorisation will be refused if the Minister, or their delegate, reasonably believes that the performance of the work or training by the individual would prejudice the security, defence or international relations of Australia.

The measures in this Bill are serious but necessary. The importance of protecting our nation's secrets and sensitive information cannot be overstated.

The protection of our nation's secrets and sensitive information through this Bill is central to preserving Australia's national security and to keeping Australians safe.

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DEFENCE TRADE CONTROLS AMENDMENT BILL 2024

In the complex and challenging strategic environment we face today, preventing our defence technologies, capabilities and information from falling into the hands of our adversaries is paramount.

To keep pace with these challenges, it is essential that Australia has a robust protective security framework.

Australia's export control system is a key element of our protective security framework.

It is designed to prevent military goods and technologies being transferred to foreign individuals or entities in ways that prejudice Australia's interests.

It will also streamline the transfer of defence goods and technology among Australia, the United Kingdom and the United States to enhance advanced scientific, technological and industrial cooperation.

This is critical legislation.

This Bill strengthens Australia's existing export control system by enhancing protections around the supply of controlled goods and technology listed on the Defence and Strategic Goods List (DSGL) within and outside of Australia.

It bolsters Australia's national security, better protects our technology advantage, and safeguards Australia's technology and information, as well as that of our partners.

And it will increase the innovation ecosystem with like-minded partners and support our collective ability to pull innovation through to capability, at scale and at speed.

The reforms are expected to provide an estimated net benefit to the economy of $614 million over 10 years.

The reduction in regulation through the national exemption for export permits to the US and the UK would benefit $5 billion of the almost $9 billion in annual defence exports.

These exemptions would also mean that almost a third of the 3,000 export permit applications currently assessed annually are no longer required.

Australia is not making these reforms alone.

The United Kingdom and the United States are also reviewing their export control frameworks to support the creation of a licence-free environment between AUKUS partners.

On 15 December 2023, the United States Congress passed groundbreaking legislation to give Australia and the United Kingdom a full national exemption from US export control regulations.

This is a generational reform that will be fundamental to enabling AUKUS and creating a licence-free environment.

Australia's access to this national exemption will require Australia to have implemented an export control system that is comparable to the US and have implemented a reciprocal national exemption from its export controls for the US.

This Bill, coupled with the Defence Amendment (Safeguarding Australia's Military Secrets), achieves an export control framework that is fit-for-purpose and ensures we are able to access to the US national exemption.

The Bill achieves this by amending the *Defence Trade Controls Act 2012* in four ways.

First, it regulates the supply of military and dual-use DSGL technology, as defined in the DSGL, to non-exempt foreign persons within Australia.

Second, it regulates the supply of goods and technology listed in Part 1 of the DSGL and the 'Sensitive' and 'Very Sensitive' Lists in Part 2 of the DSGL, that were previously exported or supplied from Australia, from a foreign country to another country, or within the same foreign country.

Third, it regulates the provision of DSGL services related to Part 1 of the DSGL to foreign persons or entities outside of Australia.

Fourth, it creates a licence-free environment for the supply of DSGL goods and technology and the provision of DSGL services from Australia to the United Kingdom and the United States.

To give effect to these changes, the Bill creates new offences with appropriate penalties and exemptions.

The Bill includes a number of exceptions to the three new offences to streamline trade with international partners, beyond the UK and the US.

The exceptions seek to reduce the compliance burden faced by the industry, higher education and research sectors whilst ensuring the controls adequately address Australia's national security requirements.

Following the introduction of this Bill in the House last year, the Bill was referred to the Senate Foreign Affairs, Defence and Trade Legislation Committee.

On 15 March 2024, the Committee published its final report and made nine recommendations, ultimately recommending that the Senate pass the bill without delay.

The Government thanks the Committee for its consideration of the Bill, as well as those who made submissions and gave evidence to assist the Committee in its work.

As a result of this inquiry and the co-design process undertaken with stakeholders a number of amendments were made to the Bill in the House.

These amendments include enshrining certain exemptions to the offences created by the Bill into the primary legislation rather than regulations, giving those that may be impacted by the legislative framework greater certainty.

The Bill is appropriately targeted to strike a balance between protecting our national security while supporting economic prosperity through international exports.

Australia's export control regime is a permissive system designed to permit the responsible transfer of controlled goods and technology—these reforms do not change this underlying principle.

To assist the efficient administration of this scheme, the Bill allows for the delegation of the authority to, in limited circumstances, decide and issue permits to Australian Public Service Executive Level 1 (EL1) officers.

As the Deputy Prime Minister outlined to the Senate Scrutiny of Bills Committee, this will be limited to the assessment and approval of low risk and low complexity applications. Defence will ensure that EL1 officers exercising this delegation will have the appropriate training and experience to make such a decision.

These reforms are not intended to prevent foreign nationals from working with Australia on DSGL goods or technologies.

They are not intended to prevent foreign students or academics from engaging with Australian academic institutions.

Rather, the intent of the Bill is to prevent sensitive defence goods and technologies from being passed to foreign individuals or governments in a manner that may harm Australia's interests.

The exceptions to the offences contained in the Bill intend to narrow the scope of the Bill to those activities and technologies that could prejudice the security, defence and international relations of Australia.

This ensures Australia cultivates research and innovation and streamlines trade with international partners beyond AUKUS.

This Bill and the licence-free environment will ensure Australia, the United Kingdom and the United States can collaborate, innovate and trade at the speed and scale required to meet the challenging strategic circumstances.

These reforms represent a significant opportunity to unlock the benefits of AUKUS, helping establish a seamless industrial base between Australia, the United States and the United Kingdom.

This is central to preserving Australia's national security and to keeping Australians safe.

Debate adjourned.

Senator the Hon Katy Gallagher

Minister for Finance
Minister for Women
Minister for the Public Service
Senator for the Australian Capital Territory

REF: MS24-000254

Senator Dean Smith
Chair
Senate Scrutiny of Bills Committee
Parliament House
CANBERRA ACT 2600

25 MAR 2024

Dear Senator Dean Smith

I refer to a further request for advice from the Senate Scrutiny of Bills Committee (the committee) on 21 March 2024 relating to the Financial Framework (Supplementary Powers) Amendment Bill 2024 (the Bill).

The committee requests my further advice in relation to when and how the need for the amendments proposed by the Bill and the retrospective validation of past uses of the power under section 32B became apparent during the Department of Finance's review of the operation of the *Financial Framework (Supplementary powers) (FFSP) Act 1997*.

I can advise that the FFSP framework, comprising of the FFSP Act and the FFSP Regulations is the subject of regular and ongoing review by my department as part of core business to ensure it remains fit for purpose.

For example,

- In 2013, legislative amendments were made to ensure that government spending continued to be supported to reflect machinery of government changes. The amendments resulted in an addition of a new Schedule 1AB to the Regulations[1].
- In 2018, over 160 items that no longer required legislative authority were repealed from the Schedules to the Regulations[2].

In relation to the Bill, over the course of 2023 as part of ongoing and regular engagement with Commonwealth entities throughout 2023, my department was made aware of a potential risk in relying on sections 32B and 39B for legislative authority.

I trust this further advice is of assistance to the committee.

Yours sincerely

[redacted]

Katy Gallagher

[redacted]

[1] F2013L02089, Explanatory Statement, Financial Management and Accountability Amendment (2013 Measures No. 1) Regulations 2013
[2] F2018L00456, Explanatory Statement, Financial Framework (Supplementary Powers) Amendment (2018 Measures No. 1) Regulations 2018

THE HON ANDREW GILES MP
MINISTER FOR IMMIGRATION, CITIZENSHIP AND MULTICULTURAL AFFAIRS

Ref No: MC24-009217

Senator Dean Smith
Chair
Senate Scrutiny of Bills Committee
Suite 1.111, Parliament House
CANBERRA ACT 2600

Dear Senator Dean

Thank you for your correspondence of 28 March 2024 concerning comments made in the Senate Standing Committee for the Scrutiny of Bills Digest No.5 of 2024 on the Migration Amendment (Removal and Other Measures) Bill 2024 and the issues the Committee has identified. I appreciate the time you have taken to bring this matter to my attention.

Before dealing with the Committee's specific concerns I take this opportunity to note that a robust legislative framework is important for the management of the migration system. There are no more important elements of the system than decisions on who may come to Australia, and who has to leave.

There is an ongoing problem that Australia faces in sending home individuals who will not cooperate with our removal efforts. Some of these people are in immigration detention, and some are in the community on temporary bridging visas. In addition there is a group of countries that will not accept individuals who are citizens of their country if that person has indicated they do not agree to go home. There are other countries who do not facilitate the return of their own citizens from Australia, as Australia does.

The amendments in this Bill are directed towards non-citizens who have come to the end of any visa application processes, and who are on a removal pathway.
This legislation brings forward new levers to give effect to the obligation under the *Migration Act 1958* to remove non-citizens who have exhausted all avenues to remain in Australia and who do not cooperate with our efforts to have them go home. As a consequence of their non-cooperation some of these non-citizens cannot currently be removed from Australia.

These changes are necessary to uphold Australia's strong immigration framework, in particular by ensuring that the Australian Government's ability to ensure that non-citizens in Australia depart when their lawful stay is exhausted. This Bill does not expand the cohort of people who are eligible for removal from Australia.

The Bill includes important safeguards and constraints in relation to the exercise of the new powers. For example, the Bill expressly provides that if a person has a protection finding relating to a particular country, then the Minister must not give that person a direction in relation to that country. Similarly, if a person has an ongoing protection visa application the Minister must not give that person a direction.

Please find in the Attachment my response to each of the Committee's concerns. I trust this will assist both the Committee and the Senate's further consideration of this Bill.

I have copied this letter to the Hon Clare O'Neil, Minister for Home Affairs and Minister for Cyber Security, and Senator, the Hon Penny Wong, Minister for Foreign Affairs.

I thank you and the Committee for raising these matters.

Yours sincerely

ANDREW GILES

6 / 5 / 2024

ATTACHMENT

I thank the Senate Standing Committee for the Scrutiny of Bills for their comments on the Migration Amendment (Removal and Other Measures) Bill 2024 in the Scrutiny of Bills Digest No. 5 of 2024 and provide the following response to each concern raised:

Undue trespass on rights and liberties – paragraphs 1.2 to 1.4

The Committee's concern here is the mechanism at proposed paragraph 199B(1)(d) to prescribe additional visas that may expand the scope of people who may be subject to removal directions. The Committee suggests that this should be done by primary legislation and not by delegated legislation, given the penalties involved for failure to comply.

There is nothing in this Bill that alters or expands the duty in section 198 of the Migration Act to remove certain unlawful non-citizens from Australia or those who may hold a visa on the basis of their pending removal or departure from Australia. This Bill does not expand the cohort of unlawful non-citizens who are liable to be removed from Australia under section 198 or those holding bridging visas on departure ground. As section 198 only applies in relation to unlawful non-citizens, prescribing a visa under proposed paragraph 199B(1)(d) would not, of itself, make the holder of that visa liable for removal from Australia.

The intention of this provision is to provide flexibility to accommodate any new visa arrangements that might be in place in the future. The prescription mechanism gives the Government flexibility to extend the application of the direction power to any new kinds of visas that might be held by people on a *removal pathway*. This might be, for example, that future visa streamlining reforms replace the complexities of current removal pathway visa arrangements with simplified visas, including where that simplification does not represent a change in policy.

Non-citizens who have exhausted all avenues to remain in Australia, are expected to depart voluntarily or otherwise be liable for removal as unlawful non-citizens under section 198 of the Migration Act. The power at subsection 199B(1)(d) is intended to provide appropriate flexibility – and parliamentary oversight, as any regulations are disallowable – should another type of visa be determined in future to be the most appropriate visa for non-citizens to maintain lawful status in the community while making arrangements to depart or be removed from Australia, in the same way the BVR is currently used for this purpose.

Undue trespass on rights and liberties – paragraph 1.5

The Committee's concern here is that the legislation should provide a minimum time in which a non-citizen has to comply with a direction to cooperate on removal. The committee suggests 60 days would be appropriate.

I appreciate the Committee's concern, but in context these directions are given to people who have already come to the end of any visa application processes, who are on a removal pathway and who have not cooperated with efforts to remove them from Australia. It is imperative that individuals who are on a removal pathway cannot be allowed to frustrate the Government and the Australian people by refusing to cooperate with their removal from Australia.

A removal pathway non-citizen must act on a direction lawfully within a reasonable timeframe. Minimum timeframes will differ case by case and so a default 60 days would not be appropriate in every scenario. Applying a minimum timeframe would also add to the time involved to bring these matters to a conclusion, and in some cases would add to periods of detention of unlawful non-citizens.

In practice, directions given to a removal pathway non-citizen would provide a rational and reasonable time for compliance. For example, a direction may involve a relatively less time consuming process such as a signature on a passport application. Longer timeframes may be required for the making of an appointment and attending an interview at a foreign country's embassy or consulate. In every case the Minister or delegate would consider the circumstances of the removal pathway non-citizen and what is proposed to be required of them in the direction, and would set the timing for compliance accordingly.

In every case clear information on the obligation of the non-citizen to comply and relevant time-frames would be provided to that non-citizen, including the potential consequences of non-compliance. These timeframes would always be reasonable, as the intention is to gain the cooperation of the person and to effect their removal from Australia, not to seek their punishment.

Undue trespass on rights and liberties – paragraphs 1.6 to 1.8

The Committee's concern here is imposition of a high maximum penalty and a mandatory minimum sentence for non-compliance with a direction given to a removal pathway non-citizen.

As noted in the Explanatory Memorandum to the Bill, the objective of a mandatory minimum sentence is to provide a strong deterrent to non-cooperation by non-citizens with a direction given by the Minister under proposed section 199C. The maximum available penalty of 5 years' imprisonment is intended to provide an effective deterrent to the commission of the offence in section 199E.

It reflects the seriousness of the offence in the context of the integrity of Australia's migration system, where a removal pathway non-citizen does not cooperate with, or otherwise frustrates, legitimate and lawful efforts to remove them in accordance with the Migration Act.

The penalty provisions are equivalent to those associated with offences recently agreed to by the Parliament in the *Migration Amendment (Bridging Visa Conditions) Act 2023* and the *Migration and Other Legislation Amendment (Bridging Visas, Serious Offenders and Other Measures) Act 2023*. The Government considers that the offence set out in this Bill is of similar gravity, given the frustration of migration law involved and the damage this causes to the integrity of Australia's migration and temporary entry programs, and the Government considers that the proposed penalties are commensurate with this.

Undue trespass on rights and liberties – paragraphs 1.9 to 1.11

The Committee's concern here is about the reasonable excuse defence set out in item 3 of Schedule 1 of the Bill at proposed subsection 199E(3), with the Committee suggesting that limiting the Minister's powers to give a Direction would be preferable to relying on a reasonable excuse defence. The Committee also comments that the breadth of the term 'reasonable excuse' may result in persons complying with directions even when it may be lawful for them to refuse to do so.

The Committee suggests that the Minister's power be limited to things where it is possible to comply, and not allow the Minister to require production of a document the person does not have.

The availability of the reasonable excuse defence reflects the Government's intention that there should be no criminal liability where the removal pathway non-citizen has a reasonable excuse for not complying with the direction. The Committee may be aware that the default fault elements in the Criminal Code apply to the offence under section 199E. Where it is not possible for a person to comply with a removal pathway direction, there would be no purpose in charging the person with the offence set out in section 199E, as the elements of the offence could not successfully be proven. In circumstances where it is possible for a person to comply with the direction, but they do not comply because they have a reasonable excuse, they will be entitled to raise that defence.

However, the Government does not accept that the lawfulness of the direction should be determined by whether, in the particular factual circumstances, the person turns out to be unable to comply with the direction or has a reasonable excuse for not doing so.

The Government believes that the Minister should be able to lawfully issue a removal pathway direction to a non-citizen in circumstances where it is not necessarily clear at the outset whether the person will be able to comply with the direction – for example, a direction that the non-citizen attend an interview with a consular official of their home country may be frustrated if the official cancels the meeting. This should not result in criminal liability for the removal pathway non-citizen, but nor should it result in the direction becoming invalid.

Undue trespass on rights and liberties – paragraphs 1.12 to 1.17

The Migration Act already provides the Minister with power to revisit protection findings of certain unlawful non-citizens, for the purpose of facilitating their removal. As set out in the Explanatory Memorandum to the Bill, current section 197D only applies to unlawful non-citizens. The proposed amendments extend this existing power to non-citizens who hold a specified bridging visa, or a visa prescribed by the Minister, as *removal pathway non-citizens*(within the meaning given by proposed s 199B(1)). Importantly, any regulations made to prescribe a visa for the purposes of s 199B(1)(d) would be a disallowable legislative instrument, and appropriately subject to parliamentary scrutiny.

The Committee's concern here is about the Minister's power to revisit protection findings for removal pathway non-citizens, with the proposed amendment at Schedule 2 Item 4 of the Bill having the effect of including holders of certain visas within the scope of section 197D of the Migration Act. The committee states it is unclear why such a provision is required, and whether procedural fairness is, or should be, in play.

I appreciate the Committee's concern, but note that the power is intended for those on a removal pathway – that is, where they have already been refused a substantive visa or their substantive visa has been cancelled on other grounds, such as on character grounds. In such cases, it may be necessary to revisit a person's protection finding where the circumstances of the person or the country in relation to which a protection finding has been made have changed and unlikey they do not hold a substantive visa. For example, the protection finding may have been made a long time ago or the conditions in a country may have significantly improved such that the person no longer faces a well-founded fear of persecution or real risk of suffering significant harm, and hence the person's removal to that country could be effected consistently with Australia's *non-refoulement* obligations.

The extension of section 197D as amended by the Bill reflects the changing landscape for migration law and immigration detention. The Committee will be aware that on 8 November 2023, in the matter of *NZYQ v Minister for Immigration, Citizenship and Multicultural Affairs & Anor* [2023] HCA 37 ('NZYQ'), the High Court ruled that indefinite detention was unconstitutional where there is no real prospect of removal of a non-citizen becoming practicable in the reasonably foreseeable future. As a result, NZYQ affected non-citizens were released from immigration detention, on a Removal Pending Bridging Visa (BVR).

Following the High Court's decision in NZYQ, the Government now faces circumstances in which this power needs to be expanded to certain non-citizens who are in the Australian community and hold a visa – particularly BVR holders. Without these amendments, the Act would not provide a means to robustly and appropriately manage a removal pathway non-citizen lawfully in the community and to arrange for their removal when this becomes practicable.

I trust the Committee will appreciate that this amendment is directed at non-citizens who have exhausted all avenues to remain in Australia, and in respect of whom the Australian Government is obliged to seek removal consistent with our *non-refoulement* obligations, including to a safe third country if the person has a protection finding. This remains the case whether the person is an unlawful non-citizen in immigration detention or is a removal pathway non-citizen in the community on a visa.

If an individual's visa is refused or cancelled, for example because the non-citizen has committed a serious crime, and they have no other valid reason to remain in Australia on a substantive visa, it is appropriate to consider whether their home country is now safe for them to return to, or whether third country removal options would need to be pursued because a protection finding would still be made in respect of the home country.

In the Government's view it is essential that there be no difference in approach to non-citizens unlawfully in Australia in immigration detention, and those who may hold a visa on the basis of their pending removal from Australia.

In relation to the exercise of revisiting a removal pathway non-citizens protection finding, I note that the Bill does nothing to change current procedural fairness requirements. The Minister or delegated decision maker exercising power under section 197D currently has an obligation under common law to afford the person procedural fairness and this will not change.

In practice this common law obligation means the Minister or the Departmental delegate must:

- give the person prior notice that a subsection 197D(2) decision may be made;
- give the person the opportunity, either in writing or at interview, to comment on any new information (including country information) that is adverse to their claims and is significant and credible and relevant to the decision being made under subsection 197D(2), and
- draw the person's attention the critical factor(s) on which the decision is likely to turn and provide them with an opportunity to respond.

When they provide this information to the person, the Minister or the Departmental delegate would:

- provide it to the person in the way that they consider appropriate in the circumstances; and
- ensure, as far as reasonably practicable, that the person understands why it is relevant to the matters under consideration.

The result is that a decision that a person, including a person who holds the specified type of bridging visa, is no longer a person in respect of whom any protection finding would be made will ensure that the person can be removed, consistently with Australia's *non-refoulement* obligations, once their bridging visa ceases.

No changes to this existing approach have been proposed in the Bill. Additionally, any decision made under this provision by the Minister is subject to merits review and a non-citizen subject of a decision under section 197D is not subject to removal until that decision is complete within the meaning of subsection 197D(6).

Importantly, as is the case under the current legislative framework, removal of a person to a country would not be lawfully available where the person's circumstances have been considered in a section 197D process, and the Minister or delegated decision-maker is satisfied that a protection finding would still be made in relation to that individual and that country, including on the basis of new claims or country information.

I wish to also be clear that these amendments to section 197D do not allow the Minister to revisit the protection findings of a person who holds a Protection visa, nor to the holders of other substantive visas which former protection visa holders might now hold. It only allows protection findings to be revisited for lawful removal pathway non-citizens and is an addition to the existing power relating to unlawful non-citizens.

Broad discretionary powers – paragraphs 1.20 to 1.23

The Committee's concern here is the discretion to designate countries as 'removal concern countries' with a suggestion that it should be a matter for the Parliament via primary legislation.

Although I appreciate the Committee's concern I respectfully disagree, as the Minister has to act where it is in the 'national interest' to do so. Determination of the national interest is properly a matter for the Executive, not the Legislature. The objective is to let affected countries know that the Australian Government thinks they should facilitate removal of their own citizens from Australia, consistent with international norms, and this is a lever to do so.

Taking into account all the considerations that may be in play before making a determination, such as consultations with the Prime Minister and the Minister for Foreign Affairs and whether the national interest is at stake, is not something amenable to Parliamentary debate.

Although I acknowledge the impact of this power, it is not inconsistent with other 'national interest' powers found in the Migration Act and other Commonwealth legislation.

Australia makes every effort to cooperate with other countries in the context of efforts to remove and return non-citizens to their home country where they have exhausted all lawful avenues to remain in Australia.

In practice, the Minister would consider designating a country as a 'removal concern country' only following significant diplomatic efforts and government-to-government engagement on the issues and challenges of returns. This expectation is inherent in the Minister's obligation to consult the Minister for Foreign Affairs as a statutory pre-condition to making a designation.

Where a country is designated as a 'removal concern country' there are also appropriate exemptions in the Bill to continue to allow visa applications from close family relatives of Australian citizens and permanent residents, applications for a Refugee and Humanitarian (Class XB) visa, and applications by nationals of a removal concern country who are dual nationals of that country and another country that is not a removal concern country.

The power has been designed to provide the Minister with the flexibility to impose the designation in a way that has the greatest impact on the foreign government, while minimizing impact on Australian citizens and residents. In practice, this is achieved by the Minister having the power to specify classes of people and classes of visa, by legislative instrument, to exempt them from the bar on making a valid visa application. This will also ensure that the exercise of the designation power is consistent with Australia's international obligations, or for any other purpose. These exceptions would likely include approved diplomatic and consular officers and other international representatives, returning permanent residents of Australia and other persons in respect of whom Australia may have international obligations or commitments, such as international trade obligations. To illustrate, the legislative instrument power could be used to specify the Diplomatic (Temporary) (Class TF) visa, the Temporary Work (International Relations) (Class GD) visa, or the Return (Residence) (Class BB) visa.

The Bill provides flexibility for the Minister to take into account the specific situation of the country concerned and to provide a tailored response where required, including consideration of advice from the relevant Australian government agencies. Under proposed subsection 199G(4), the Minister can also decide to allow a visa application by an individual where it is in the public interest. This is a personal power of the Minister.

Broad discretionary powers – paragraph 1.24

The Committee's concern here is whether a Minister may designate multiple countries in a single instrument, with the committee noting it might impact the efficacy of Parliamentary scrutiny.

The intention of the Government is that, should this power be exercised, countries would be individually designated. This would be a signal to the country involved, and that signal may be dissipated if multiple countries were designated simultaneously.

The responsibility of the Minister to consult before making a decision in the national interest does not diminish the responsibility to explain where necessary what has been done and why, including during Parliamentary and Committee scrutiny. As the reasons for acting in the national interest in individual cases may be different the Government takes the view that specific reasons will always be demonstrated for each country designated.

Parliamentary scrutiny – paragraphs 1.27 to .1.31

The Committee's concern here is that the Government is pressing to have the bill passed quickly.

I note the Committee's concern, however Australia's orderly and well-managed immigration program relies on the Government's ability to appropriately resolve the status of individuals with no lawful pathway to remain in Australia. The NZYQ High Court decision and the subsequent release from detention of non-citizens for whom there is no real prospect of removal from Australia becoming practicable in the reasonably foreseeable future, has necessitated a focus on removals and the challenges the Government faces in implementing a robust and effective removals program.

Put simply, the nature of a cornerstone of Australia's immigration system is changing, and the legislative scheme needs to change at the same pace.

The Hon Michelle Rowland MP

Minister for Communications
Federal Member for Greenway

MS24-000612

Senator Dean Smith
Chair of Standing Committee for the Scrutiny of Bills
Senator for Western Australia
Parliament House
CANBERRA ACT 2600

Dear Senator

Thank you for the email of 28 February 2024 from the Committee Secretary, outlining the comments of the Scrutiny of Bills Committee in Scrutiny Digest 3/24 on some proposed measures in the Telecommunications Legislation Amendment (Enhancing Consumer Safeguards and Other Measures) Bill 2023 (the Bill). I am writing to confirm the Australian Government's response to the Committee's recommendations.

I note that the Committee requested that I amend the explanatory memorandum (EM) to the Bill to include additional justification for the appropriateness of proposed subsections 360HB(4), 360HB(5), 360J(3), 360J(4), 360KB(2) and 360KB(4) of the *Telecommunications Act 1997* (the Act). I can confirm that an addendum to the EM will be issued to address this.

I also note the Committee's view that legislative instruments made under the proposed subsections should be limited to five years duration. While I understand the Committee's view, I am concerned that the proposal may reduce certainty for industry about the operation of the powers. In practice, there may be circumstances in which a timeframe longer than five years may be preferable. Accordingly, I propose that the instrument would sunset in accordance with the requirements of the *Legislation Act 2003* (that is, a maximum period of ten years), but also note that, as has been the case with previous instruments, I would provide for an earlier self-repeal date where this is appropriate. For transparency, I will include my reasoning for keeping the standard timeframe in the addendum to the EM.

Thank you for taking the time to write to me on this matter.

Yours sincerely

[redacted]

Michelle Rowland MP

23 / 4 / 2024

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The Hon Mark Butler MP
Minister for Health and Aged Care

Ref No: MC24-005007

Senator Dean Smith
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Dear Chair Dean

I refer to the Senate Scrutiny of Bills Committee (Committee) request for further information on the Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 (Bill) in Scrutiny Digest 5 of 2024.

The Committee has requested my detailed advice on aspects of the Bill as they relate to significant matters in delegated legislation, offences of strict liability and reversal of evidential burden of proof, broad discretionary power(s), enforcement notices, availability of independent merits review, seizure of assets and delegation of administrative powers and functions.

I ask that the Committee consider my responses in concert with the objects of the Bill, the reforms to the Commonwealth tobacco control framework necessary to ensure Australia meets it ongoing obligation under the World Health Organization Framework Convention on Tobacco Control (FCTC) and the broader objective to reduce the use of tobacco and nicotine products in Australia by 2030, as contained in the National Tobacco Strategy 2023-2030 (NTS).

Reforms to Commonwealth laws are needed to effectively respond to changes in the market and novel and emerging products that influence consumer behaviour and seek to undermine existing tobacco control measures. Reforms are also necessary to ensure Australia meets its ongoing obligations under the FCTC.

Article 5.2 of the FCTC requires Parties to develop appropriate policies for preventing and reducing tobacco consumption, nicotine addiction and exposure to tobacco smoke, which is linked to both reducing potential nicotine addiction from e-cigarette use and preventing tobacco future use.

The NTS was developed by all Australian governments to improve the health of all Australians by reducing tobacco use. The NTS aims to achieve a national daily smoking prevalence of less than 10% by 2025 and 5% or less by 2030 in Australia, and to prioritise tackling smoking among First Nations people to reduce the daily smoking rate to 27% or less by 2030. Consistent with these aims, there is more that can be done to reduce the preventable death and disability caused by smoking.

The primary objects of the Bill are to address the growing risk posed by vaping in Australia, particularly to youth and young adults, while preserving legitimate patient access to therapeutic vaping goods for smoking cessation and the management of nicotine dependence, where clinically appropriate.

The Bill is the centrepiece of regulatory reforms to reduce rates of vaping and prevent long-term adverse effects on population health through enhanced regulation. The reforms are proposed to be implemented through the federal cooperative scheme for therapeutic goods. By extending the operation of the *Therapeutic Goods Act 1989* (TG Act), the Bill would provide a nationally consistent approach to the regulation of vapes. Corresponding laws in each state and territory would operate to avoid regulatory gaps and achieve complete regulatory coverage, noting that Western Australia has recently introduced corresponding laws to apply the TG Act as a law of the state. The scheme will enable officers across all jurisdictions and different portfolios to exercise powers and functions to prevent unlawful trade of vapes in Australia.

The success of the reforms will not be achieved by one regulatory body alone. It will rely on the actions of multiple agencies across the Australian Government, states and territories to monitor and enforce. In support of these objects, it is proposed to include reverse evidential burdens and impose higher pecuniary penalties to support the effectiveness of the overarching regulatory approach and deter unlawful conduct. This reflects a balanced compromise between the needs of effective law enforcement and the presumption of innocence and, following careful consideration, strikes an appropriate balance that is reasonable, necessary and proportionate in pursuit of the Bill's legitimate objectives.

I trust that the enclosed information in the Annexure provides further context in relation to the matters of interest, and I thank the Committee for its consideration of this important legislation.

Thank you for writing on this matter.

Yours sincerely

[redacted]

Mark Butler

09/04/2024

Encl (2)

Annexure – Detailed response

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1 Significant matters in delegated legislation

1.1 The Senate Scrutiny of Bills Committee (the Committee) has requested advice as to why it is necessary and appropriate for the definition of a 'unit' of vaping goods (in item 10 of Schedule 1) and the quantity of a kind of vaping goods that would amount to a commercial quantity (item 6 of Schedule 1) to be left to delegated legislation.

1.2 The Committee notes the importance of these definitions to the offence provisions proposed to be inserted by the Bill.

2 Definition of a 'unit' of vaping goods

Clarification

2.1 The concept of a 'unit' of vaping goods has no application to the criminal offence provisions proposed to be inserted by the Bill. Rather, it is a matter central only to the enforceability, and application, of the civil penalty provisions in the proposed new Chapter 4A relating to the importation, manufacture, supply and commercial possession of vaping goods in subclauses 41Q(3), 41QA(3), 41QB(3), 41QC(10) and 41QD(4).

2.2 The concept is intended to provide an appropriate mechanism for calculating the number of contraventions of a civil penalty provision, as an alternative to the prosecution of corresponding criminal conduct.

2.3 As a public health measure directed to discourage unlawful conduct relating to vaping goods to ultimately discourage the uptake of vaping, the definition of a 'unit' needs to be flexible and adaptable as appropriate in the circumstances. It is

proposed that a unit of vaping goods is prescribed in regulations made under the TG Act.

2.4 The regulations would be subject to appropriate parliamentary scrutiny and disallowance. This supports an approach that is adaptive to evolving public health issues, contemporary clinical and scientific evidence and changes in technology and the market more generally.

Necessary and appropriate

2.5 The intention of the new offences and civil penalty provisions is to deter unlawful conduct, arrest the alarming increase in the use of vapes in Australia, particularly among youth and young adults, and to prevent a new generation of persons being exposed to dangerous chemicals and developing nicotine dependence.

2.6 It is necessary and appropriate for the definition of a 'unit' of vaping goods (in item 10 of Schedule 1) to be prescribed by regulations having regard to:

(1) the design, development and marketing of unlawful vaping goods, which will continue to evolve following the vaping reforms; this is because the market has consistently sought to evade compliance efforts in recent years through product design and concealment; successful regulation must remain responsive to industry changes;

(2) the scientific, medical and public health understanding in relation to vaping goods, which will continue to mature, as the health impact of unlawful vapes is determined particularly with reference to nicotine concentrations and toxicities;

(3) matters specified in other delegated legislation made under the *Therapeutic Goods Act 1989* (TG Act), such as standards, which may change from time to time and materially impact the determination of a 'unit' of vaping goods.

2.7 Given the need for adaptability, it is appropriate for a 'unit' of vaping goods to be prescribed in the regulations having regard to changing scientific, medical, and public health understanding. Any incongruence with acceptable or legitimate volumes or quantities of therapeutic vaping goods would create serious difficulties for compliance and enforcement efforts.

2.8 Prescribing a 'unit' of vaping goods in delegated legislation would provide for necessary flexibility and agility to ensure that the public health risks from vaping are expeditiously managed and enforced in response to an aggressive and changing illicit market. The public health risks are significant and are explained at pages 3 to 5 of the explanatory memorandum to the Bill.

2.9 The reasoning behind the proposed approach with respect to a 'unit' of vaping goods would be included in explanatory material to the regulations. and based on further consultation, medical advice and the broader compliance and enforcement experience.

Responsive to the evolution of the illicit market

2.10 The government's experience in enforcing the existing regulatory framework has demonstrated that the illicit market is quick to adapt to the changing regulatory settings, including making alterations to the manufacturing of vaping goods.

2.11 Examples include the removal of all references to nicotine on the label of vaping goods being imported and subsequently supplied in Australia, and the deliberate mischaracterisation of vaping goods as perfume atomisers or the like.

2.12 Such steps significantly frustrate the ability for the Australian Border Force and the Therapeutic Goods Administration (TGA) to take appropriate regulatory action to prevent these goods entering Australia and making their way to retailer stores for the purpose of direct supply to the public.

2.13 Flexibility in determining a unit of vaping goods will ensure that any changes to the way that vaping goods are designed, manufactured, promoted or characterised can be appropriately responded to by ensuring that a unit of vaping goods reflects the reality of the evolving illicit market.

Responsive for public health reasons

2.14 As the Committee is aware, clause 41P provides that vaping goods are to be defined as including all their various permutations: vaping accessories, devices, and vaping substances. Vaping goods can be one, or a combination of these different permutations, and there can be different characteristics, which distinguish the goods from each other, and the objective harm of each permutation of the goods themselves.

2.15 Flexibility in determining a unit of vaping goods is critical in ensuring that the harms of the different permutations of vaping goods are internally consistent and correspond to the objective harms of each kind of vaping good.

2.16 For example, the objective harm of 20 vaping accessories could be said to correspond to the objective harm of 200ml of vaping substance. However, this assessment may change as over time, and require amendment to ensure consistency, depending on the relevant concentration or toxicity.

2.17 There may be circumstances where the objective harm may be linked to the nicotine concentration in the vaping substance, rather than the volume itself. Determining a 'unit' of each of the permutations is complex and is anticipated to evolve as the scientific and medical knowledge about, vaping goods develops and matures.

Relevance of other delegated legislation

2.18 Standards, which are disallowable legislative instruments, made under the TG Act set maximum volumes for vaping substances. These volumes are subject to change from time to time and will be relevant to determining a 'unit' of vaping goods. Prescribing 'units' in the regulations allows flexibility to amend this concept if maximum volumes in the standards are changed.

Example – traveller's exemption

2.19 An example of an analogous approach which has been specified in delegated legislation is the prescription of the quantity allowable under the traveller's exemption in regulation 5A of the *Customs (Prohibited Imports) Regulations 1956*.

2.20 This exemption allows a person travelling to Australia to bring a small quantity of vaping goods with them for use in their treatment, or someone they are caring for, who is entering Australia on the same ship or aircraft. The current maximum allowable quantity is no more than 2 vapes, 20 vaping cartridges and 200 ml of vaping liquid.

2.21 While no explanation was provided in the explanatory statement for the *Customs Legislation Amendment (*Vaping *Goods) Regulations 2023,* the volumes and quantities specified in the traveller's exemption are relatively modest and considered to be reasonable in the circumstances for the personal use of a traveller to Australia.

3 Definition of 'commercial quantity'

3.1 The Committee has sought advice as to why it is necessary and appropriate for a quantity of a kind of vaping goods that would amount to a commercial quantity (item 6 of Schedule 1) to be left to delegated legislation, noting the importance of this definition to the offence provisions proposed to be inserted by the Bill.

3.2 The Minister notes that this definition also applies to the civil penalty provisions proposed to be inserted by the Bill. However, the definition has greater significance to the offence provisions due to the cascading maximum penalties that apply under clause 41QC (possession of a commercial quantity of vaping goods). This is because the applicable offence provision and maximum penalty depends on the quantity of vaping goods found in a person's possession.

Necessary and appropriate

3.3 The Minister considers it is necessary and appropriate for a quantity of a kind of vaping goods that would amount to a commercial quantity to be prescribed in regulations to:

(1) ensure flexibility to change the quantity in line with prescribing practices of health professionals with respect to therapeutic vapes for personal use;

(2) ensure the commercial quantity is adaptive to new and emerging design specification, which could affect the types of vaping substance used, the delivery of vaping substance, the volume and concentration capacity of the vaping device and the number and types of vaping accessories available for use with vaping devices and substances;

(3) allow quantities to be amended efficiently, if necessary, in response to illicit trade of vapes to ensure that the criminal offences continue to act as a sufficient deterrent; and

(4) maintain a workable connection between a commercial quantity of vaping goods and acceptable or legitimate volumes or quantities of therapeutic vaping goods (as discussed in paragraph 2.18).

Quantity prescribed for personal use

3.4 The vaping reforms are not intended to prohibit the possession of vaping goods for personal use, provided the vapes in a person's possession are appropriately less than a commercial quantity. Accordingly, the phrase 'commercial quantity' serves as a marked distinction between commercial possession and possession for personal use.

3.5 The medical advice as to the appropriate quantity of vaping goods for personal use is evolving and differs significantly depending on the patient's individual circumstances.

3.6 By allowing for the quantities to be prescribed in the regulations, the government can more easily and quickly respond as the medical and public health advice evolves. Flexibility will be important in ensuring that by the prohibitions on commercial possession by unlawful actors in Australia are fit for purpose and achieve the regulatory objective of these measures.

3.7 The reasoning behind the proposed approach with respect to the meaning of a commercial quantity would, of course, be included in the explanatory statement to the regulations and would be based on expert public health and medical advice and the broader compliance and enforcement experience.

Analogous approach – commercial quantity of serious drugs and precursors

3.8 An example of an analogous approach where a commercial quantity of a substance has been prescribed in regulations made under primary legislation is the commercial quantity of a serious drug, controlled precursor or border-controlled precursors in the *Criminal Code Act 1995*.

3.9 Section 301.10 of the *Criminal Code Act 1995* provides that the quantity of a serious drug, controlled precursor or border-controlled precursor is prescribed. These quantities are set out in the *Criminal Code Regulations 2019* (the *Criminal Code Regulations 2002* at the time the provision was introduced).

3.10 The Minister notes that the reason provided for this approach similarly related to the need for flexibility in the face of evolving markets and emerging products. It was felt that any delay in updating quantities would be exploited by 'entrepreneurial criminals and organised crime groups'. The same arguments apply in relation to vaping goods.

Summary

3.11 For the reasons set out above, the Minister considers it is necessary and proportionate for the definition of a 'unit' of vaping goods or the quantity of a kind of vaping goods that would amount to a commercial quantity to be prescribed in regulations.

3.12 This would ensure the TG Act can address the ongoing public health risks posed by vaping in a flexible and agile manner. At the same time, the regulations would remain subject to parliamentary scrutiny and disallowance.

4 Offences of strict liability and reversal of evidential burden of proof

4.1 The Minister notes that the Committee has drawn its scrutiny concerns to the attention of Senators and leaves to the Senate as a whole to determine the appropriateness of:

(1) the imposition of strict liability on offences with higher than 60 penalty units; and

(2) the use of offence-specific excuses which reverse the evidential burden of proof.

4.2 The following information is provided by the Minister to assist the Senate with its consideration of these matters.

5 Offences of strict liability

5.1 The Minister acknowledges that the proposal of a 200 penalty unit maximum penalty for offences of strict liability relating to the importation, manufacture, supply, commercial possession and advertisement of vapes by unlawful actors is higher than the recommended maximum penalty for strict liability offences in the *Guide to Framing Commonwealth Offences* (**the Guide**).

5.2 However, departure from the recommendation is considered necessary and appropriate in the circumstances to:

(1) achieve effective deterrence in a market that demonstrates brazen disregard to existing regulatory controls;

(2) uphold the integrity of the new regulatory regime.; and

(3) in one case, maintain relative consistency with the existing penalties for equivalent conduct in the TG Act.

5.3 Higher maximum penalties for offences of strict liability are considered necessary and appropriate to act as a sufficient deterrent in circumstances where there are legitimate grounds for penalising persons lacking 'fault' in relation to the importation, manufacture, supply, commercial possession or advertisement of vaping goods.[1] These activities pose a serious and immediate threat to public

[1] The Guide on page 23 provides that '[t]he punishment of offences not involving fault is likely to significantly enhance the effectiveness of the enforcement regime in deterring certain conduct'.

health and undermine the significant progress Australian has made in relation to tobacco control.[2]

5.4 The proposed higher penalty for offences of strict liability will also ensure that infringement notices are quick and effective regulatory tools that act as appropriate deterrence on their own, noting an infringement is an alternative to criminal prosecution or the commencement of civil penalty proceedings.[3]

5.5 This is because an infringement notice given with respect to a single allegation of an offence of strict liability will be 12 penalty units,[4] as opposed to a maximum penalty of 200 penalty units if the matter was to proceed to criminal prosecution (or higher if the person is charged with a fault-based offence).

5.6 Maximum penalties for criminal offences signify the seriousness with which the Government regards the relevant offence in question. The Minister considers a maximum penalty of 200 penalty units is appropriate because of the scale of the illicit vaping problem and the serious effects of vaping on population health.

5.7 The Minister brings to the Committee's attention that the TG Act contains 82 offences of strict liability and 74 of these have maximum penalties higher than 60 penalty units (or equivalent). A summary of all offences of strict liability in the TG Act is included at **Attachment A**.

5.8 A summary table of similar provisions between the therapeutic goods framework, and the proposed new vaping goods chapter is provided below for reference, and by way of illustration.

Existing therapeutic goods prohibition	**Maximum penalty for strict liability offence**	**Proposed new vaping prohibition**	**Maximum penalty for strict liability offence**
Prohibitions on importation, manufacture and supply			
19B(4A)(a)(i) – offence of strict liability relating to the importation of unlawful therapeutic goods[5]	100 penalty units	41Q(2) – offence of strict liability relating to the importation of vaping goods without authority	200 penalty units
19B(4A)(a)(iii) – offence of strict liability relating to the manufacture of	100 penalty units	41QA(2) – offence of strict liability relating to the manufacture of	200 penalty units

[2] The significant public health risks are explained at pages 3 to 5 of the explanatory memorandum to the Bill and are not reproduced in this advice.
[3] It is noted that the infringement notice regime in the TG Act, in Part 5A-2, includes detailed prescription of the form of a notice and all of the safeguards to which it is subject.
[4] See 42YKA(2) of the TG Act.
[5] See 41MI(5)(a)(i) of the TG Act for the corresponding offence of strict liability relating to the import of an unlawful medical device by a sponsor.

Existing therapeutic goods prohibition	Maximum penalty for strict liability offence	Proposed new vaping prohibition	Maximum penalty for strict liability offence
unlawful therapeutic goods[6]		vaping goods without authority	
19B(4A)(a)(iv) – offence of strict liability relating to the supply of unlawful therapeutic goods[7]	100 penalty units	41QB(2) – offence of strict liability relating to the supply of vaping goods without authority	200 penalty units
Prohibitions on advertising			
42DL(3) – offence of strict liability relating to the advertisement of unlawful therapeutic goods	100 penalty units	42DZD(2) - offence of strict liability relating the advertisement of unlawful vaping goods	200 penalty units

5.9 The historical justification for increasing the maximum penalty for the offences of strict liability relating to therapeutic goods from 60 penalty units to 100 penalty units in Chapter 3 was not expressly explained in the relevant explanatory materials.[8]

5.10 However, the increase was likely considered by Parliament to be appropriate for the protection of the individual patients who would be exposed to therapeutic goods that were not appropriately regulated for safety.[9]

5.11 This justification for departing from the Guide similarly applies to vaping goods and otherwise reflects the need for more serious penalties to be set as a deterrent to an industry that is predominantly unperturbed by the level of existing penalties. The existing offences in the TG Act apply to all nicotine vapes. Despite these controls, Australia has witnessed extensive illicit trade in nicotine vapes in recent years.

5.12 The proposed offences of strict liability for breaching a condition of a consent in relation to vaping goods is analogous to similar provisions with respect to therapeutic goods. The objective seriousness of breaching a condition of a consent is similarly analogous. It is therefore necessary and appropriate that the maximum

[6] See 41MI(5)(a)(iv) for the corresponding offence of strict liability relating to the manufacture of an unlawful medical device by a sponsor.
[7] See 41MI(5)(a)(iii) for the corresponding offence of strict liability relating to the supply of an unlawful medical device by a sponsor.
[8] See the explanatory memorandum, supplementary explanatory memorandum, and revised explanatory memorandum for the Therapeutic Goods Amendment Act (No. 1) 2006.
[9] See explanation for the offence of strict liability for subsection 29A(11).

penalty for the offences of strict liability between these two prohibitions is consistent.

5.13 A summary table is provided below between the therapeutic good framework, and the proposed vaping good chapter is provided below for reference, and by way of illustration.

Existing therapeutic goods prohibition	Maximum penalty for strict liability offence	Proposed new vaping prohibition	Maximum penalty for strict liability offence
21(10) – supply of therapeutic goods not in accordance with an authority, or a condition of the authority	100 penalty units	41RD(3) – act or omission breaches a condition of a consent	100 penalty units

6 Reversal of the evidential burden of proof

6.1 The Committee's view is that, in most of these cases, it is not apparent that the matters in the proposed defences are matters peculiarly within the defendant's knowledge, or that it would be significantly more difficult or costly for the prosecution to establish the matters than for the defendant to establish them.

6.2 The Minister advises that careful consideration has been given to balancing the need for the effective enforcement of the proposed offences in the Bill with the presumption of innocence. In short, the Minister considers the reversal of the onus of proof is justified to support the effectiveness of the overarching regulatory framework and achieve the objectives of the Bill having regard to the collaborative manner in which the new national scheme for the regulation of vapes is intended to be monitored and enforced.

6.3 The Minister understands that a matter should generally only be included in an offence-specific defence (as opposed to being specified as an element of the offence) where:

(1) it is peculiarly within the knowledge of the defendant; or

(2) it would be significantly more difficult and costly for the prosecution to disprove than for the defendant to establish the matter.

6.4 The Guide notes that a reverse onus of proof is more readily justified where the conduct proscribed by the offence poses a grave danger to public health or safety.

6.5 The relevant burden of proof that is proposed to be reversed is an evidential burden, not a legal burden. An evidential burden is very easily discharged and only requires a reasonable possibility of the matters existing to apply. Reversing the burden of proof is justified in the circumstances because of the public interest in the efficient regulation of vaping goods and the grave danger of the associated public health harms and for the reasons outlined below.

6.6 The supply of pharmaceutical medicines and medical devices in Australia is appropriately governed by a highly regulated framework of Commonwealth, state and territory legislation, regulations and instruments.

6.7 As a result, the circumstances in which a person will be permitted or otherwise authorised to import, manufacture, supply and/or possess vaping goods under the TG Act or a law of a state or territory are multifaceted and complex. For ease, these circumstances will be referenced in the following paragraphs as lawful pathways.

6.8 There is an expectation that legitimate importers, manufacturers, and suppliers, who form part of the pharmaceutical supply chain in both wholesale and retail contexts, will obtain the relevant licence, approval, authority, permission and/or consent to lawfully deal with vaping goods in Australia, as those persons or entities currently do in relation to prescription medicines.

6.9 The relevant licences, approvals, authorities, permissions and/or consents are administered and monitored by different Commonwealth, state and territory agencies, with responsibility for health and law enforcement. Depending on the nature of the conduct, the agencies are likely to include officers of the Office of Drug Control, the Australian Border Force, the Australian Federal Police, and state and territory police.

6.10 The lawful pathways are reflected in the exceptions set out in the Bill, which make clear when a person will be permitted to deal with vaping goods under the TG Act, a state or territory law, or a combination of both, including any applicable regulations. These exemptions are numerous to reflect the different lawful circumstances in which vaping goods may be lawfully imported, manufactured, supplied, possessed, or advertised.

6.11 Broadly speaking, the circumstances in which a vaping good may be lawfully supplied in Australia will depend on:

(1) the nature of the vaping good;

(2) the identification of the person who supplied the vaping good; and

(3) the identification of the person to whom the vaping good was supplied.

6.12 As the Committee is aware, the enforcement of these prohibitions is to be undertaken by both states and territories, as well as the Commonwealth.

Accordingly, the characterisation of the vaping goods or the authority under which vaping goods may be dealt with by a person, will not necessarily be readily apparent to the agency responsible for the enforcement action.

6.13 It would cost significant time and resources if the relevant enforcement authority was required to consider and disprove the possibility of **each** lawful pathway under multiple Commonwealth, state and territory legislative regimes as an element of the offence for the purposes of undertaking any compliance and enforcement action, including the issue of infringement notice or enforceable directions. In the context of issuing infringement notices or enforceable directions a prosecution, this would involve:

(1) determining the government department(s) in possession of the relevant evidence, which is very likely to be spread across multiple agencies at both Commonwealth and state and territory levels;

(2) making numerous and exhaustive enquiries with every relevant government department or agency to obtain admissible evidence to prove the unavailability of each lawful pathway in every jurisdiction to the requisite standard, noting that a lawful pathway may exist in one jurisdiction but not others; and

(3) dealing with any multi-jurisdictional (i.e. interstate) aspects relevant to the enforcement of the prohibitions, such as supply across borders and the applicability of co-existing licensing frameworks.

6.14 Obviously the same enquires would need to be undertaken for the purposes of referring a matter for criminal prosecution with the prosecution needing to obtain witness statements on these matters from multiple jurisdictions.

6.15 By contrast, defendants would only need to point to or adduce evidence that suggests a reasonable possibility that an exception applies, namely that the vaping goods are imported, manufactured, supplied or possessed pursuant to lawful authority. In practice, this would occur during the investigative phase rather than the production of evidence in court. Such evidence would be highly relevant to any decision to prosecute and the associated charges.

6.16 Equally, it would be an inefficient use of the court's time and resources if the prosecution was required to disprove each lawful pathway in a contested summary hearing or trial. This may potentially involve calling multiple witnesses to give evidence to disprove the availability of each lawful pathway in every relevant jurisdiction beyond reasonable doubt.

6.17 As illustrated at paragraphs 6.25 - 6.37 below, there will be matters that are peculiarly, and in some circumstances only, within the knowledge of the defendant, depending on the prohibited conduct, the nature of the goods, the identity of the defendant, the jurisdictions involved and agency responsibility for undertaking enforcement action.

6.18 Whilst the Minister cannot provide an assurance that each matter set out in the exceptions will be peculiarly within the defendant's knowledge in any given case, the multiple variables that may apply collectively in any given case means that the reversal of the evidential burden is central to the effective and timely national administration and enforcement of the regulatory regime.

6.19 In this regard, consideration has been given to the need to adopt a simplified and accessible drafting approach such that the matters for which there is a reverse evidential burden are peculiar to the knowledge of the defendant and significantly more difficult and costly for the prosecution to disprove than for the defendant to adduce or point to evidence that suggests a reasonable possibility that a matter, which is the subject of an exception, exists..

6.20 As a matter of practicality, the circumstances in which the conduct articulated in the offences may be otherwise lawful will be readily apparent to the defendant in any given case. That is because a defendant will only be required to point to or adduce evidence, which suggests that a lawful pathway exists. Such evidence will ordinarily comprise a single document issued by a Commonwealth, state or territory agency.

6.21 If that evidence is not accepted by an enforcement officer and the matter progresses to criminal prosecution, the prosecution would bear the legal burden to disprove the availability of that lawful pathway beyond reasonable doubt. Consistent with the regulatory framework for therapeutic goods, a lawful pathway set out in the exceptions will be readily available to, and cheaply and quickly established by, the defendant.

6.22 In contrast, criminal actors without lawful authority for importing, manufacturing, supplying, possessing or advertising vaping goods are unlikely to be able to readily point to or adduce evidence that suggests a reasonable possibility of the authority existing.

6.23 Critically, there would be significant delays to any enforcement action if an enforcement officer was required to disprove each lawful pathway set out in the exceptions in the Bill before taking enforcement action. This would be unacceptable in situations involving the commercial possession and supply of vaping goods in convenience stores located near schools, which would ordinarily warrant seizure.

6.24 In this situation, there is unlikely to be any lawful authority for the possession and supply of vaping goods. Any delay to the expedient seizure and forfeiture of unlawful vaping goods would therefore compromise the safety of school children. Fundamentally, such delay would undermine and frustrate the overarching policy objectives of the Bill, which is to reduce the risk of criminal actors preying on the vulnerability of particularly members of society, in particular young people.

Clause 41Q – importation

6.25 It is an exception to an offence or civil penalty provision under clause 41QD if the importation of the vaping goods is not prohibited under the *Customs Act 1901* (Cth).

6.26 The Minister advises that the importation of vaping goods under the *Customs Act 1901* is not prohibited in certain circumstances, including where the defendant has a licence or permit issued by the Office of Drug Control or where a traveller's exemption applies. The application of a traveller's exemption will depend on whether the vaping goods are for the treatment of a traveller or someone under their care, which is information peculiarly within the knowledge of the traveller.

6.27 The Australian Border Force will ordinarily enforce controls relating to vaping goods at the border, relying on its own legislation but sometimes in conjunction with the Therapeutic Goods Administration and potentially the Australian Federal Police. Consequently, several different enforcement officers may need to rely on information provided by an importer to determine whether an exception to the offence under the TG Act applies.

6.28 A legitimate importer of a consignment of therapeutic vaping goods will be able to readily provide a licence or permit demonstrating their authority to import. In contrast, depending on the enforcement officer in question, information issued by the Office of Drug Control may not be on hand or capable of being identified in a timely manner, thereby creating delays in enforcement and expense to the relevant enforcement agency.

Clause 41QA – manufacture

6.29 It is an exception to an offence or civil penalty provision under clause 41QA if the vaping goods are therapeutic goods and a person has been provided a relevant authority, such as a licence, conformity assessment document or consent by the Secretary, to manufacture vaping goods.

6.30 The Minister advises that the following aspects of the exception to offences and civil penalty provisions relating to manufacture under clause 41QA would be difficult for the prosecution to readily establish where the agency responsible for the enforcement action is a state or territory health department or Commonwealth, state or territory police:

(1) whether the person was in possession of a Part 3-3 licence under the TG Act or was the holder of a conformity assessment document that applies to vaping goods in accordance with subparagraphs 41QA(5)(b)(i) and (ii).

6.31 This is because these documents would most readily, and peculiarly, be within the knowledge and possible immediate possession of the defendant and could be difficult and costly to establish by the enforcement agency. In the context of conformity assessment documents, manufacturers can use conformity assessment documents issued by comparable overseas regulators as a lawful means to manufacture medical devices in Australia. No Australian authority, including the

TGA, will necessarily have a central record of all these documents unless the vaping goods are included in the Australian Register of Therapeutic Goods.

Clause 41QB – supply

6.32 The Minister advises that the following aspects of the exception to offences and civil penalty provisions relating to supply under clause 41QB would be difficult for the prosecution to readily establish where the agency responsible for the enforcement action is a state or territory health department or Commonwealth, state or territory police:

(1) whether the vaping goods are exempt goods for the purposes of paragraph 41QB(6)(b) of the wholesale supply exception or paragraph 41QB(9)(b) of the retail supply exception;

(2) whether the person was in possession of a licence and permission under section 50 of the *Customs Act 1901* or is otherwise approved under the corresponding regulations to import vaping goods in accordance with paragraph 41QB(7)(a) of the wholesale supply exception;

(3) whether the person was in possession of a Part 3-3 licence under the TG Act or was the holder of a conformity assessment document that applies to the vaping goods (paragraphs 41QB(7)(b) and (c) of the wholesale supply exception refer); and/or

(4) whether the recipient to whom the vaping goods are supplied was the holder of a licence in force under Part 3-3 of TG Act (paragraph 41QB(8)(a) of the wholesale supply exception refers).

6.33 The Minister advises that the following aspects of the exception to offences and civil penalty provisions relating to supply under clause 41QB would be difficult for the prosecution to readily establish where the agency responsible for enforcement action is the TGA:

(1) whether the person was in possession of a wholesaler licence, or is otherwise authorised, to supply one or more substances included in Schedule 4 to the current Poisons Standard under a law of the state or territory in which the supply occurred, and the supply occurred in accordance with the licence authority (paragraph 41QB(7)(d) of the wholesale supply exception refers);

(2) whether the person is medical practitioner or nurse practitioner who was in possession of a licence, or is otherwise authorised, to supply one or more substances included in Schedule 4 to the current Poisons Standard under a law of the state or territory in which the supply occurred (paragraph 41QB(10)(b) of the retail supply exception refers); and/or

(3) whether the recipient of the vaping goods is a wholesaler, pharmacist, medical practitioner or nurse practitioner who is the holder of a licence, or is otherwise authorised, to supply one or more substances included in Schedule 4 to the current Poisons Standard under a law of the state or

territory in which the recipient carries on a business, practises or is employed (paragraph 41QB(8)(b) of the wholesale supply exception refers).

Clause 41QC – commercial possession (commercial quantity)

6.34 The Minister advises that the following aspects of the exception to offences and civil penalty provisions relating to commercial possession under clause 41QC would be difficult for the prosecution to readily establish where the agency responsible for the enforcement action is a state or territory health department or Commonwealth, state or territory police:

(1) whether the vaping goods are exempt goods for the purposes of paragraph 41QC(13)(b);

(2) whether the person was in possession of a licence and permission under section 50 of *the Customs Act 1901* or is otherwise approved under the corresponding regulations to import vaping goods (paragraph 41QC(14)(a) refers); and/or

(3) whether the person was in possession of a Part 3-3 licence under the TG Act or was the holder of a conformity assessment document that applies to vaping goods (paragraphs 41QC(14)(b) and (c) refer).

6.35 The Minister advises that the following aspects of the exception to offences and civil penalty provisions relating to possession under clause 41QC would be difficult for the prosecution to establish where the agency responsible for enforcement action is the TGA:

(1) whether the person is a wholesaler, pharmacist, medical practitioner or nurse practitioner who is the holder of a licence, or is otherwise authorised, to supply one or more substances included in Schedule 4 to the current Poisons Standard under a law of the state or territory in which the person possesses the goods (paragraph 41QC(14)(d) refers).

Clause 41QD – commercial possession (less than commercial quantity)

6.36 The Minister advises that the following aspects of the exception to offences and civil penalty provisions relating to commercial possession under clause 41QD would be difficult for the prosecution to readily establish where the agency responsible for the enforcement action is a state or territory health department or Commonwealth, state or territory police:

(1) whether the vaping goods are exempt goods for the purpose of paragraph 41QD(7)(b);

(2) whether the person was in possession of a licence and permission under section 50 of *the Customs Act 1901* or is otherwise approved under the corresponding regulations to import vaping goods (paragraph 41QD(8)(a) refers);

(3) whether the person was a holder of a Part 3-3 licence under the TG Act or was the holder of a conformity assessment document that applies to vaping goods (paragraphs 41QD(8)(b) and (c) refer);

(4) whether the person was in possession of the vaping goods for the use by the person personally (paragraph 41QD(9)(a) refers); and/or

(5) whether the person was in possession of the vaping goods on behalf of another person for whom the vaping goods have been lawfully supplied (paragraph 41QD(9)(b) refers).

6.37 The Minister advises that the following aspects of the exception to offences and civil penalty provisions under clause 41QD would be extremely difficult for the prosecution to establish where the agency responsible for enforcement action is the TGA:

(1) whether the person is a wholesaler, pharmacist, medical practitioner or nurse practitioner who is the holder of a licence, or is otherwise authorised, to supply one or more substances included in Schedule 4 to the current Poisons Standard under a law of the state or territory in which the person possesses the goods (paragraph 41QD(d) refers);

(2) whether the person was in possession of the vaping goods for the use by the person personally (paragraph 41QD(9)(a) refers); and/or

(3) whether the person was in possession of the vaping goods on behalf of another person for whom the vaping goods have been lawfully supplied (paragraph 41QD(9)(b) refers).

7 Broad discretionary power in subclause 41RC(1)

7.1 The Minister acknowledges that the Committee expects that the inclusion of broad discretionary powers should be justified in the explanatory memorandum and has requested advice as to:

(1) why it is necessary and appropriate to provide the Secretary with a broad power to consent to the manufacture, supply or possession of vaping goods, or to refuse such an application, or grant it subject to conditions; and

(2) what criteria may be considered by the Secretary in making a decision under subclause 41RC(1).

Necessary and appropriate

7.2 A broad discretionary power is necessary and appropriate to ensure that all legitimate actors within the lawful supply chain are subject to regulatory supervision and oversight in accordance with the regulatory objectives of the Bill to mitigate risks associated with diversion and otherwise facilitate legitimate patient access in accordance with the TG Act.

7.3 A primary objective of the reforms is to ensure that therapeutic vapes are accessed through existing lawful pathways for the supply of pharmaceutical goods in Australia. The Bill identifies multiple situations where the persons involved in the importation, manufacture, supply and commercial possession of vaping goods will have clear lawful authority to do so. These are enumerated in the exceptions. The consent scheme proposed in clause 41RC is designed to cover other situations where potential legitimate actors in the pharmaceutical supply chain are not covered by a pre-existing licence, approval, authority or permit under the *Customs Act 1901*, TG Act or a state or territory law.

7.4 The broad discretionary power is necessary to deal with such gaps. Without a broad discretionary power, a cohort of potential legitimate actors may be inadvertently left without a mechanism to legitimise their relationship with the national vaping scheme involving the Commonwealth, state and territories. Without consent, such persons would not be able to participate in the lawful manufacture, supply or possession of vaping goods in Australia and otherwise expose themselves to regulatory action.

7.5 It is anticipated that persons who may be granted consent could include:

(1) persons legitimately transporting vaping goods within a state or territory or from one state or territory to another;

(2) persons storing vaping goods for supply to a legitimate wholesaler or a pharmacist;

(3) pharmacists compounding or carrying out a step in the manufacture of different vaping goods in accordance with a prescription;

(4) persons unable to legally obtain a state or territory licence to wholesale prescription medicines because the vaping goods intended for supply are not captured by the state or territory licensing provisions. For example, zero nicotine vaping goods are not covered by the relevant entry in schedule 4 to the Poisons Standard (prescription only substances) and therefore will not be covered by a state or territory wholesale licence for prescription medicines; and

(5) persons not eligible to legally obtain a manufacturing licence under Part 3-3 of the TG Act, or a conformity assessment document because of the nature of the vaping goods.

7.6 Moreover, regulatory supervision provided by the proposed consent scheme in clause 41RC will also ensure that the risk of diversion of vaping goods to the illicit market is appropriately managed and mitigated. This is particularly the case for vaping goods that may be transported or stored over significant periods of time.

7.7 Conditions are also proposed to ensure the safety, quality and efficacy of the goods supplied and any restrictions on permitted activities allowed by the consent.

7.8 If a decision not to grant a person consent is made, or a person disagrees with conditions imposed, the following avenues of review are available:

(1) internal review under section 60 of the TG Act;

(2) external merits review by the Administrative Appeals Tribunal; and

(3) judicial review.

Criteria

7.9 The criteria for granting a consent are expected to be established in a policy document determined by the Minister to ensure that potential legitimate actors who propose to be involved in the manufacture, supply and possession of vaping goods can reasonably adhere to regulatory expectations for the proposed activity and the vaping goods. The criteria specified in the policy document would be consistent with the objects of the TG Act, and the purpose of the proposed new Chapter in which the consent power is housed.

7.10 Where the activities proposed are manufacture, storage and transport, it is anticipated that the applicants would need to be able to demonstrate relevant technical skills, appropriate facilities and resources to ensure that the proposed activity may be carried out in compliance with minimum safety and quality requirements under the TG Act, and other applicable laws.

7.11 Applicants would also be expected to attest to their fitness and propriety to deal with vaping goods, and state that there is no risk of diversion of the vaping goods to criminal elements, on account of their genuine connection with the pharmaceutical supply chain.

7.12 It is proposed that an approved form will be used to specify the information required in support of the request for a consent in accordance with the policy document. This information is likely to include the type of activity being proposed, the type or kind of vaping goods involved, the amount, number or quantity of vaping goods and the suitability of the person to hold the consent such as a declaration as to the person's fitness and propriety and the absence of any relevant convictions.

8 Enforceable directions – clause 42YT

8.1 The Committee has requested advice as to:

(1) the criteria that will be considered by the Secretary when determining whether the Secretary believes on reasonable grounds that a person is not complying with the TG Act or its instruments; and

(2) whether independent merits review is available for directions issued under subclause 42YT(2) of the Bill, and if not, why not.

8.2 The Committee has not requested advice on what criteria the Secretary will consider when determining whether it is necessary to exercise powers under the clause to protect the health and safety of humans.

Belief on reasonable grounds

8.3 As the Committee is aware, the term "reasonable grounds" appears in several legislative contexts and is frequently used in the context of administrative decision-making.

8.4 In the seminal decision of *McKinnon v Secretary, Dept of Treasury*[10] the High Court set a low bar for what constitutes "reasonable grounds", by holding that:

(1) "reasonable grounds" means grounds based on reason, as distinct from something irrational, absurd or ridiculous[11]; and

(2) reasonable grounds will exist if the mind of a person guided by reason could accept such grounds, even if there may be reasonable grounds the other way[12].

8.5 Further, as the Committee is aware, when a statute prescribes that there must be 'reasonable grounds' for a state of mind — including suspicion and belief — it requires the existence of facts which are sufficient to induce that state of mind in a reasonable person.[13]

Not complying with the TG Act or its instruments

8.6 A person does not comply with the TG Act or its instruments when engaged in conduct which is subject to a prohibition, such as an offence or civil penalty provision in the TG Act for the unlawful importation, manufacture, supply and possession of certain goods, and failures to comply with conditions.

8.7 There are also prohibitions which are directed to non-compliance with legislative instruments, including applicable standards made under section 10 of the TG Act and the prohibitions for non-compliance in section 14 and corresponding provisions for medical devices, pharmacovigilance record keeping and reporting requirements specified for the purposes of paragraphs 28(5)(ca) and (5)(e) of the TG Act.[14][15]

Criteria

8.8 In deciding whether to believe on reasonable grounds that a person is not complying with the TG Act or its instruments, a decision maker will need to point to facts (such as information or documents) which are sufficient to induce in the mind of a reasonable person that the person is in contravention of the elements of the relevant prohibition.

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[10] (2006) 228 CLR 423.
[11] At [68] (per Hayne J).
[12] At [131] (per Callinan and Heydon JJ).
[13] *George v Rockett* (1990) 170 CLR 104 at 112.
[14] TGA (August 2023) 'Pharmacovigilance responsibilities of medicine sponsors' TGA.
[15] *Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021.*

8.9 Having formed the requisite belief on reasonable grounds, the decision maker will then consider whether 'it is necessary to exercise powers under this section to protect the health and safety of humans' to satisfy the second limb in paragraph 42YT(1)(b). Such a provision ordinarily requires the decision maker to consider whether the relevant action imposes a greater degree of restraint than the reasonable protection of the public requires.[16] This imposes a requirement of proportionality and requires the decision maker to weigh up the alternative measures available to protect the health and safety of humans.

8.10 In this regard, the Secretary will take into consideration the need for direction to prevent serious human health and safety issues that need to be immediately addressed and the most appropriate direction to address the critical circumstance.

8.11 In weighing the facts, the decision maker would also take into consideration the need for further action that may be warranted in relation to the suspected non-compliance. This is a consideration, for example, in the comparable case of issuing an infringement notice under 42YK of the TG Act. This provision has no legislated criteria for the decision maker determining whether to believe on reasonable grounds that a person is not complying with the TG Act or its instruments.

Availability of merits review

8.12 Independent merits review is not available for directions issued under subclause 42YT(2) of the Bill.

8.13 This approach is considered necessary and appropriate to ensure that effective and timely enforcement action is taken with respect to alleged unlawful goods, noting this action will only be taken if it is considered necessary to protect the health and safety of humans. Judicial review will still be available to a person affected by the decision.

8.14 This reflects a balanced compromise between the needs of effective law enforcement in protection of human health and safety, and a persons' right of review of administrative decisions. This approach strikes an appropriate balance which is reasonable, necessary, and proportionate in pursuit of the Bill's legitimate objectives, noting that this power applies to all goods regulated under the TG Act, not just vaping goods.

Procedural fairness

8.15 As the Committee is also aware, the Secretary will be required to comply with procedural fairness in relation to the exercise of the power. This will provide an opportunity for the person to:

(1) provide submissions as to why the power should not be exercised;

(2) comment on any adverse information proposed to be relied on;

[16] See *Thomas v Mowbray* [2007] HCA 33, [22] per Gleeson CJ.

(3) make submissions as to why the proposed action is not necessary to protect the health and safety of humans; and

(4) otherwise propose other measures which can be implemented to ameliorate the Secretary's concerns.

8.16 Such a process will provide a check on the arbitrary use of the power.

9 Seizure of assets – clause 52AAA

9.1 The Committee has requested advice as to whether it is intended that use and derivative use immunities apply to materials incidentally seized and retained under clause 52AAA of the Bill.

9.2 The Guide on page 97 provides that a 'use' immunity protects a person who is required to give self-incriminating evidence from that evidence being used against him or her in court. At page 98, the Guide defines 'derivative use' immunity as protecting a 'person who is required to give self-incriminating evidence from that evidence being used to gather other evidence against that person'. Page 99 provides an example, 'if Person A provides a document that would tend to indicate that [they] had committed a particular offence, that document cannot be used to gather further evidence against [them], but it may be used to investigate other persons'.

9.3 The Minister understands that use and derivative use immunity has no application in the context of clause 52AAA for the reasons set out below.

9.4 As the Committee indicated at paragraph 1.55, clause 52AAA is concerned with the forfeiture of things seized under a warrant issued pursuant to section 50 of the TG Act. Under section 47 of the TG Act, only evidential material can be seized under a section 50 warrant.

9.5 Evidential material is defined in section 45A of the TG Act as follows:

(1) in respect of an offence against this Act:

(a) any thing with respect to which the offence has been committed or is suspected, on reasonable grounds, to have been committed; or

(b) any thing as to which there are reasonable grounds for suspecting that it will afford evidence as to the commission of the offence; or

(c) any thing as to which there are reasonable grounds for suspecting that it is intended to be used for the purpose of committing the offence; and

(2) in respect of a contravention of a civil penalty provision:

(a) any thing with respect to which the civil penalty provision has been contravened or is suspected, on reasonable grounds, of having been contravened; or

(b) any thing as to which there are reasonable grounds for suspecting that it will afford evidence as to the contravention of the civil penalty provision; or

(c) any thing as to which there are reasonable grounds for suspecting that it is intended to be used for the purpose of contravening the civil penalty provision.

9.6 Materials, or things which are not evidential material within the meaning of the term, and otherwise authorised under the warrant will not be authorised for seizure, and subsequently will not be a thing seized under a warrant issued under section 50.

9.7 Paragraph 50(4)(e) of the TG Act provides that the warrant must 'state the purpose for which the warrant is issued'. The evidential material can only be seized and used for those purposes. There are existing legal principles and precedent which support this.

9.8 Moreover, unlike the *Crimes Act 1914* (Cth), the warrant provisions in the TG Act do not confer the power to seize material related to an offence other than that for which a warrant was issued. There is also nothing in the TG Act that permits seized materials to be used and shared to officers of other state and Commonwealth agencies other than for the purpose for which the warrant is issued.

9.9 Finally, it would be inconsistent with the intent of the provisions for use and derivative immunities to apply to evidential material obtained under a warrant and subsequently forfeited in accordance with clause 52AAA.

9.10 For these reasons, clause 52AAA is not intended to capture 'materials incidentally seized', rather only to apply to evidential material authorised by the section 50 warrant.

9.11 The Minister would be happy to provide further advice or clarifications.

10 Delegation of administrative powers and functions

10.1 The Committee requests the Minister's advice as to the intended formulation of the delegation in subclause 57(1A) of the TG Act. The Committee's preference is for the delegation to be limited to the head of the relevant departments and administrative units.

10.2 The intended formulation of the delegation in subclause 57(1A) is to officers of a department, unit or authority that have functions relating to therapeutic goods, health or law enforcement. It is not intended that the delegation be limited to the head of the relevant departments and administrative units. The explanatory materials will be updated to reflect this intention.

10.3 It is not practical, nor appropriate for enforcement related functions, such as entry, search and seizure powers to be only delegated to heads of relevant departments and administrative units. It is expected that significant enforcement

activities will be required by the Commonwealth, states and territories. By way of indication of the expected extent of enforcement activities, the TGA since 1 October 2021, has seized under warrant more than 340,000 nicotine vaping products, and over 19,500 voluntarily surrendered. Enforcement related functions will require a number of persons with varying technical skills due to the significant amount of seizures of illicit goods that will likely be executed. Such powers are appropriately delegated to experienced and skilled persons who undertake investigations and related regulatory functions. It is anticipated that there may be a number of persons with different technical skills, including forensic data analysts, health officials and police officers, who will have jurisdiction to exercise powers under the applied laws.

10.4 The approach to delegation of these powers is an extension of the current regulatory framework, which enables state and territory officers to exercise the powers of authorised officers under the TG Act. The enforcement of controls on therapeutic goods (and proposed under this Bill, vaping goods) is carried out under a national system of controls; essentially a federal cooperative scheme between the Commonwealth, states and territories. Consistent with the scheme, the Commonwealth will take responsibility for enforcing importation, manufacture, sponsor supply and advertisement. The states and territories will take responsibility for enforcing wholesale supply, retail supply and commercial possession.

10.5 The national approach to the regulation of vaping goods is a centrepiece of the vaping reforms and will be critical to the success of the measures to achieve the public health objectives. By extending the power to delegate the powers and functions of the Secretary to state and territory officers, the Bill would complement existing arrangements in relation to authorised officers and therefore further enhance the compliance and enforcement effort in Australia.

10.6 Finally, it is intended that the delegation of these powers and functions would be subject to a binding direction that officers must adhere to standard operating procedures created by the Secretary to ensure consistency for the carrying out of enforcement powers.

Attachment – Existing offences of strict liability

	Existing offences of strict liability in the Therapeutic Goods Act	Maximum penalty
	Therapeutic goods	
1.	8(2) – failure to comply with a notice given to the person under section 8	60 penalty units
2.	9G(5) – false and misleading statement in requests for variation of entries in Australian Register of Therapeutic Goods	100 penalty units
3.	14(4A) – import of therapeutic goods that do not comply with standards	100 penalty units
4.	14(9AA) – supply of therapeutic goods that do not comply with standards	100 penalty units
5.	14(13AA) – export of therapeutic goods that do not comply with standards	100 penalty units
6.	15(6) – act or omission which breaches a condition of a consent	100 penalty units
7.	19(7F) – the person omits to do an act which breaches a requirement (notify the supply of therapeutic goods to the Secretary within 28 days after the supply)	10 penalty units
8.	19B(4A) – import, export, manufacture, supply of unlawful therapeutic goods by a sponsor	100 penalty units
9.	20(1BA) – import, export, manufacture, supply of therapeutic goods which have not been properly notified	100 penalty units
10.	20(2C) – import of exempt therapeutic goods under section 18A and the importation breaches a condition of the exemption	60 penalty units
11.	21A(4A) – false or misleading statement in connection with a certification of any matter under subsection 26A(2) or 26AB(2)	100 penalty units
12.	21A(8B) – act or omission which breaches a condition of the registration or listing of therapeutic goods	100 penalty units
13.	21A(11) – supply of therapeutic goods not in accordance with an authority under subsection 19(5), conditions or regulations	100 penalty units

	Existing offences of strict liability in the Therapeutic Goods Act	Maximum penalty
14.	21A(11E) – supply by a health practitioner of therapeutic goods not in accordance with rules specified in subsection 19(7A)	100 penalty units
15.	21A(13) – use of therapeutic goods in certain circumstances and the goods are not used in accordance with an approval or authority under section 19, or conditions	100 penalty units
16.	22(5) – advertising of a therapeutic good for an indication not accepted in relation to the goods inclusion in the Australian Register of Therapeutic Goods	100 penalty units
17.	22A(5) – false or misleading statement in an application for registration of therapeutic goods	100 penalty units
18.	30EC(5) – non compliance with requirements imposed under section 30EA	100 penalty units
19.	30F(6) – failure to comply with a requirement in a notice made under subsections 30F(2) and (3)	100 penalty units
20.	30H(3) – act or omission resulting in a breach of a condition of an exemption under section 18A relating to record keeping	60 penalty units
21.	31(4B) – failure to comply with a notice under section 31	100 penalty units
22.	31(7) – false or misleading information in compliance with a notice under section 31	100 penalty units
23.	31C(2) – failure to comply with a notice given under section 31A, 31AA, 31B or 31BA	100 penalty units
24.	31D(1A) – false or misleading information in compliance with a notice given under section 31A, 31AA, 31B or 31BA	100 penalty units
25.	31E(IB) – false or misleading document in compliance with a notice given under section 31A, 31AA, 31B or 31BA	100 penalty units
	Biologicals	
26.	32BA(4A) – import of an unlawful biological by a sponsor	100 penalty units
27.	32BB(4A) – export of an unlawful biological by a sponsor	100 penalty units
28.	32BC(4A) – manufacture of an unlawful biological by a sponsor	100 penalty units

	Existing offences of strict liability in the Therapeutic Goods Act	Maximum penalty
29.	32BD(4B) – supply of an unlawful biological by a sponsor	100 penalty units
30.	32BG(1A) – import, export, manufacture, supply of a biological by the sponsor and the person has not properly notified the Secretary of certain matters	100 penalty units
31.	32BI(5) – use of a biological in certain circumstances in the treatment of another person or for experimental purposes in humans	100 penalty units
32.	32BJ(3) – advertising of a biological for an indication not accepted in relation to the biologicals' inclusion in the Australian Register of Therapeutic	100 penalty units
33.	32CH(5) – act or omission in relation to a biological resulting in a breach of a condition of an exemption under section 32CB	60 penalty units
34.	32CJ(9) – failure to comply with a requirement in a notice given to the person under subsection 32CJ(2)	100 penalty units
35.	32CM(7F) - the person omits to do an act which breaches a requirement (notify the supply of biologicals to the Secretary within 28 days after the supply)	10 penalty units
36.	32CN(4A) – supply of a biological not in accordance with an authority under subsection 32CM(1), conditions or regulations	100 penalty units
37.	32CN(9) – supply by a health practitioner of a biological not in accordance with rules specified in subsection 32CM(7A), circumstances or conditions	100 penalty units
38.	32DO(5) – false statement made in, or in connection with, an application for inclusion of a biological in the Australian Register of Therapeutic Goods	100 penalty units
39.	32EF(5) – act or omission resulting in breach of a condition of the inclusion of the biological in the Australian Register of Therapeutic Goods	100 penalty units
40.	32HC(5) – act or omission resulting in breach of a requirement imposed on the person under section 32HA	100 penalty units
41.	32JB(1B) – failure to comply with a notice under section 32JA	100 penalty units

	Existing offences of strict liability in the Therapeutic Goods Act	Maximum penalty
42.	32JB(6) – false or misleading document in compliance with the notice under section 32JA	100 penalty units
43.	32JI(1A) – failure to comply with a notice given under section 32JE, 32JF, 32JG or 32JH	100 penalty units
44.	32JI(3) – false or misleading information or document in compliance with notice given under section 32JE, 32JF, 32JG or 32JH	100 penalty units
	Manufacture of therapeutic goods	
45.	35(4A) – manufacture of therapeutic goods in certain circumstances	100 penalty units
46.	35(10) – manufacture of exempt goods under section 18A or 32CB and the person is not a holder of a licence	100 penalty units
47.	35B(6) – act or omission resulting in breach of a condition of a manufacturing licence	100 penalty units
	Medical devices	
48.	41EI(5) – false or misleading statement in, or connection with an application for a conformity assessment certificate	100 penalty units
49.	41EWD(4) – failure by an Australian corporation to keep records referred to in subsection 41EWD(1) for 15 years after they cease to be an Australian conformity assessment body	300 penalty units[17]
50.	41FE(5) – false or misleading statement in, or in connection with an application for including a medical device in the Register or a certification or purported certification under section 41FD	100 penalty units
51.	41HC(6E) – act or omission which breaches a requirement under subsection 41HC(6B) to notify the Secretary within 28 days after the supply	10 penalty units
52.	41JB(3B) – failure to comply with a notice given under section 41JA	100 penalty units
53.	41JB(8) – false or misleading information given in compliance with section 41JA notice	100 penalty units

[17] This is the equivalent of 60 penalty units when reference is had to the corporate multiplier in subsection 4B(3) of the *Crimes Act 1914*.

	Existing offences of strict liability in the Therapeutic Goods Act	Maximum penalty
54.	41JG(2) – failure to comply with a notice given under section 41JCA, 41JD, 41JE, 41JF or 41JFA	100 penalty units
55.	41JH(3) – false or misleading information given in compliance with a notice given under section 41JCA, 41JD, 41JE, 41JF or 41JFA	100 penalty units
56.	41JI(1A) – false or misleading document in compliance with a notice given under section 41JCA, 41JD, 41JE, 41JF or 41JFA	100 penalty units
57.	41KC(5) – act or omission which breaches a requirement imposed on the person under section 41KA	100 penalty units
58.	41MA(4A) – importation of a medical device which does not comply with the essential principles relating to matters other than the labelling of the device, without consent and coverage by an exemption under section 41GS	100 penalty units
59.	41MA(8B) – supply of a medical device which does not comply with the essential principles relating to matters other than the labelling of the device, without consent and coverage by an exemption under section 41GS	100 penalty units
60.	41MA(13) – export of a medical device which does not comply with the essential principles relating to matters other than the labelling of the device, without consent and coverage by an exemption under section 41GS	100 penalty units
61.	41MC(6) – act or omission which breaches a condition of a consent under section 41MA or 41MAA	100 penalty units
62.	41ME(4A) – manufacture and supply of a medical device in Australia and conformity assessment procedures have not been applied to the device, and without coverage by an exemption under section 41GS	100 penalty units
63.	41ME(9) – manufacture and export of a medical device from Australia and conformity assessment procedures have not been applied to the device, and without coverage by an exemption under section 41GS	100 penalty units
64.	41MI(5) – import, export, supply, manufacture of an unlawful medical device by a sponsor	100 penalty units
65.	41ML(3) – advertising of a medical device as being for a purpose not accepted in relation to the inclusion of the device in the Australian Register of Therapeutic Goods	100 penalty units

	Existing offences of strict liability in the Therapeutic Goods Act	Maximum penalty
66.	41MN(4A) – act or omission which breaches a condition of the inclusion of the kind of device in the Australian Register of Therapeutic Goods	100 penalty units
67.	41MN(8B) – act or omission which breaches a condition of a conformity assessment certificate issued in respect of the person	100 penalty units
68.	41MN(12) – act or omission which breaches a condition referred to in subsection 41EWA(5) by an Australian corporation	500 penalty units[18]
69.	41MNB(5) – act or omission in relation to a medical device which results in a breach of a condition of an exemption in force under section 41GS	60 penalty units
70.	41MO(4AA) – supply of a medical device otherwise in accordance with an authority granted under subsection 41HC(1), or a condition(s) or regulation(s)	100 penalty units
71.	41MO(4D) – supply of a medical device by a health practitioner not in accordance with rules, circumstances or conditions specified in rules in subsection 41HC(6)	100 penalty units
72.	41MO(9) – use of a medical device in the treatment of another person, or solely for experimental purposes in humans otherwise in accordance with the approval granted under section 41HB	100 penalty units
	Advertising	
73.	42DL(3) – advertising of unlawful therapeutic goods	100 penalty units
74.	42DLA(3) – act or omission which contravenes a notice given under section 42DKB	100 penalty units
75.	42DM(3) – advertising of therapeutic goods which does not comply with the Therapeutic Goods Advertising Code	100 penalty units
76.	42DP(2) – dissemination of generic information about therapeutic goods which does not comply with prescribed provisions of the Therapeutic Goods Advertising Code	100 penalty units
77.	42DS(2) – failure to comply with a notice given under section 42DR	100 penalty units

[18] This is the equivalent of 100 penalty units when reference is had to the corporate multiplier in subsection 4B(3) of the *Crimes Act 1914*.

	Existing offences of strict liability in the Therapeutic Goods Act	Maximum penalty
78.	42DS(5) – false or misleading information given in compliance with a notice given under section 42DR	100 penalty units
79.	42DW(3) – act or omission which contravenes a direction given under subsection 42DV(1) or (2) or a condition of the direction	100 penalty units
80.	42DV(6D) – failure to comply with a (recall) requirement under subsection (1) relating to a supply of therapeutic goods	100 penalty units
81.	45AC(2) – failure to comply with a notice given under section 45AB	100 penalty units
82.	45AD(2) – false or misleading information given in compliance with a notice given under section 45AB	100 penalty units

NOTE: section 52 of the TG Act has not been included in this table as it concerns the return of an authorised persons' identity card and is not relevant to this analysis.