The Senate

Standing Committee for the Scrutiny of Delegated Legislation

Delegated Legislation Monitor

Monitor 10 of 2024

11 September 2024

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ISSN: 2652-4139 (print) ISSN: 2652-4147 (online)

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This report can be cited as: Senate Standing Committee for the Scrutiny of Delegated Legislation, *Delegated Legislation Monitor 10 of 2024*; AUSStaCSDLM 93.

This document was prepared by the Senate Standing Committee for the Scrutiny of Delegated Legislation and printed by the Senate Printing Unit, Department of the Senate, Parliament House, Canberra.

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Introduction

The Senate Standing Committee for the Scrutiny of Delegated Legislation, formerly the Senate Standing Committee on Regulations and Ordinances, was established in 1932. The role of the committee is to examine the technical qualities of all legislative instruments, and to decide whether they comply with the committee's non-partisan scrutiny principles or otherwise give rise to matters of interest to the Senate.

The *Delegated Legislation Monitor* (the Monitor) details the committee's views in relation to its technical scrutiny of legislative instruments registered on the Federal Register of Legislation. Part I of the Monitor details the committee's scrutiny concerns arising under the technical scrutiny principles set out in Senate standing order 23(3), extracted below. Part II of the Monitor details matters which the committee has resolved to draw to the attention of the Senate under standing order 23(4).

Committee information

Terms of reference

The committee's technical scrutiny principles are set out in Senate standing order 23(3), which requires the committee to scrutinise each instrument as to whether:

- (a) it is in accordance with its enabling Act and otherwise complies with all legislative requirements;
- (b) it appears to be supported by a constitutional head of legislative power and is otherwise constitutionally valid;
- (c) it makes rights, liberties, obligations or interests unduly dependent on insufficiently defined administrative powers;
- (d) those likely to be affected by the instrument were adequately consulted in relation to it;
- (e) its drafting is defective or unclear;
- (f) it, and any document it incorporates, may be freely accessed and used;
- (g) the accompanying explanatory material provides sufficient information to gain a clear understanding of the instrument;
- (h) it trespasses unduly on personal rights and liberties;
- (i) it unduly excludes, limits or fails to provide for independent review of decisions affecting rights, liberties, obligations or interests;
- (j) it contains matters more appropriate for parliamentary enactment;
- (k) in the case of an instrument exempt from sunsetting, it is appropriate for the instrument to be exempt from sunsetting;

- (I) in the case of an instrument that amends or modifies the operation of primary legislation, or exempts persons or entities from the operation of primary legislation, the instrument is in force only for as long as is strictly necessary; and
- (m) it complies with any other ground relating to the technical scrutiny of delegated legislation that the committee considers appropriate.

Additionally, Senate standing order 23(4) requires the committee to scrutinise each instrument to determine whether the attention of the Senate should be drawn to the instrument on the ground that it raises significant issues, or otherwise gives rise to issues that are likely to be of interest to the Senate.

Senate standing order 23(4A) further provides that the committee may, for the purpose of reporting on its terms of reference, consider instruments made under the authority of Acts of the Parliament that are not subject to disallowance. The committee may also consider whether it is appropriate for such instruments to be exempt from disallowance.

Nature of the committee's scrutiny

Technical legislative scrutiny

The committee operates on a non-partisan basis to scrutinise delegated legislation made by the executive branch of government against its technical scrutiny principles.

Resolving minor technical scrutiny concerns

After scrutinising a legislative instrument, the committee may initially engage in informal correspondence with agencies via its secretariat to gather information or seek clarification to identify and resolve minor technical scrutiny concerns. This engagement with agencies assists the committee in deciding whether it is necessary to seek further advice from the relevant minister about those concerns. Agency correspondence is not published; however, the relevant instruments are listed on the committee's website and in Chapter 3 of the Monitor.

Resolving significant technical scrutiny concerns

Where the committee considers that an instrument raises significant technical scrutiny concerns, it details its concerns in Part I of the Monitor for the benefit of the Senate in its oversight of delegated law-making powers. The committee generally seeks a formal response from the relevant minister in relation to concerns set out in this Part; however, in some circumstances the committee may report its scrutiny concerns to the Senate without seeking further information from the minister.

Undertakings

As a result of raising its scrutiny concerns with the relevant minister or agency, the committee may seek an undertaking for specific action to address its scrutiny concerns. The committee summarises outstanding and implemented undertakings in

Chapter 4 of the Monitor. The committee will record relevant undertakings on the

Matters of interest to the Senate

Index of Undertakings on its website.

The committee does not scrutinise the policy merits of delegated legislation. If the committee determines that an instrument raises significant issues, or otherwise gives rise to issues likely to be of interest to the Senate under standing order 23(4), it may draw these instruments to the attention of the Senate in Part II of the Monitor.

Disallowance process¹

The disallowance process is one of the key mechanisms by which Parliament exercises control over delegated legislation. The conditions for the disallowance process are set out in the *Legislation Act 2003* and are reflected in Senate standing order 78.

The committee will give a 'protective' notice of motion to disallow an instrument where it is unable to conclude its consideration of an instrument before the original disallowance period expires. In addition, the committee may give such a notice where the committee requires an undertaking to be implemented before it can conclude its consideration of the instrument. The committee will usually withdraw a 'protective' notice when it receives a satisfactory response to its scrutiny concerns or confirmation that any outstanding undertakings have been implemented.

The committee may also give a notice of motion to disallow an instrument where it considers that the instrument raises significant and unresolved scrutiny concerns, and the committee has therefore resolved to recommend to the Senate that the instrument be disallowed. In these circumstances, the committee will detail its significant scrutiny concerns in Chapter 1 of the Monitor.

Publications

Delegated Legislation Monitor

The committee's usual practice is to table its <u>Delegated Legislation Monitor</u> each Senate sitting week. Legislative instruments detailed in the Monitor are also listed in the <u>Index of Instruments</u> on the committee's website.

Scrutiny News

<u>Scrutiny News</u> is a brief newsletter summarising significant matters arising in the Monitor, as well as in the reports of the Senate Standing Committee for the Scrutiny of Bills. Past editions, and information about subscribing to the mailing list, are available on the Scrutiny of Bills Committee's website.

¹ For further information on the disallowance process see <u>Odgers' Australian Senate Practice</u> and <u>Guide to Senate Procedure No. 19 - Disallowance</u>.

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<u>Guidelines</u> relating to the committee's scrutiny principles are published on the committee's website.

Other resources

Ministerial responses to the committee's concerns can be accessed on the committee's website through either the <u>Delegated Legislation Monitors</u> webpage or the <u>Index of Instruments</u>.

The <u>*Federal Register of Legislation*</u> should be consulted for the text of instruments, explanatory statements, and associated information.

The <u>Senate Disallowable Instruments List</u> provides a listing of tabled instruments for which disallowance motions may be moved in the Senate.

The <u>*Disallowance Alert</u> records all notices of motion for the disallowance of instruments, and their progress and eventual outcome.</u>*

Report snapshot²

Scrutiny period	
Legislative instruments registered on the Federal Register of Legislation between	122
28 June and 22 July 2024	
Instruments in this period exempt from disallowance	20
Chapter 1: New and ongoing matters	
New legislative instruments commented on in report	3
Ongoing legislative instruments commented on in report	0
Chapter 2: Concluded matters	
Legislative instruments of which the committee has concluded its examination	0
following receipt of ministerial response	
Chapter 3: Agency engagement	
New legislative instruments where the committee engaged with the relevant	18
agency via its secretariat	
Legislative instruments of which the committee has concluded its examination	10
following receipt of agency response	
Chapter 4: Undertakings	
New undertakings made by ministers or agencies to address the committee's	11
scrutiny concerns	
Undertakings which the committee was made aware had been implemented	12
during this period	
Outstanding undertakings	24
Chapter 5: Scrutiny of Commonwealth expenditure	
Advance to the Finance Minister determinations	0
Instruments specifying Commonwealth expenditure under the Financial	3
Framework (Supplementary Powers) Act 1997 and the Industry Research and	
Development Act 1986	
Levying of taxation in delegated legislation	4
Chapter 6: Exemptions from disallowance and sunsetting	
Instruments that do not meet the committee's expectations regarding exemptions	12
from disallowance under standing order 23(4A)	
Instruments that do not meet the committee's expectations regarding exemptions	10
from sunsetting under standing order 23(3)(k)	

This entry can be cited as: Senate Standing Committee for the Scrutiny of Delegated Legislation, Report snapshot, *Delegated Legislation Monitor 10 of 2024*; [2024] AUSStaCSDLM 94.

Part I—Technical legislative scrutiny

1.1 This Chapter details the committee's significant new and ongoing scrutiny concerns in legislative instruments relating to the committee's technical legislative scrutiny principles in Senate standing order 23(3).

New matters

1.2 The committee has identified significant technical scrutiny concerns in relation to the instrument listed below.

Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024¹

FRL No.	<u>F2024L00839</u>
Purpose	The purpose of this instrument is to amend the Therapeutic Goods Regulations 1990 and Therapeutic Goods (Medical Devices) Regulations 2002 to support the national vaping reforms set out in the <i>Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024</i> (the Amendment Act).
Authorising legislation	Therapeutic Goods Act 1989
Portfolio	Health and Aged Care
Disallowance	15 sitting days after tabling (tabled in the Senate on 3 July 2024).
	Notice of motion to disallow must be given by 17 September 2024.

Overview

1.3 The Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024 (the instrument) supports the national vaping reforms set out in the *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024* (the Amendment Act) which restricts the importation, domestic manufacture, supply, commercial possession and advertisement of vaping goods.

1.4 In particular, the instrument amends the Therapeutic Goods Regulations 1990 (the TG Regulations) and Therapeutic Goods (Medical Devices) Regulations 2002 (the MD Regulations) to specify commercial quantities and units of vaping goods for the purposes of new offences and civil penalty provisions introduced

¹ This entry can be cited as: Senate Standing Committee for the Scrutiny of Delegated Legislation, Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024, *Delegated Legislation Monitor 10 of 2024*; [2024] AUSStaCSDLM 95.

by the Amendment Act for possessing vaping goods. The instrument also provides transitional arrangements under which certain therapeutic vaping goods that would otherwise be unlawful upon commencement of the Amendment Act can be dealt with and allows for the supply or export of compliant vaping goods that were imported or manufactured prior to 1 March 2024, as part of transitional arrangements to assist sponsors to comply with the reforms.

1.5 The committee has identified several technical scrutiny concerns in the instrument, outlined below.

Scrutiny concerns

Broad discretionary powers;² conferral of coercive powers;³ availability of independent merits review⁴

1.6 Senate Standing Order 23(3)(c) requires the committee to scrutinise each instrument as to whether it makes rights, liberties, obligations or interests unduly dependent on insufficiently defined administrative powers. This includes provisions that broadly delegate administrative powers or functions, as well as those that confer coercive powers. Senate Standing Order 23(3)(h) also requires the committee to scrutinise each instrument as to whether it trespasses unduly on personal rights and liberties. Under this principle, the committee is also concerned with provisions in instruments that contain coercive powers. Further, Senate Standing Order 23(3)(i) requires the committee to consider whether an instrument unduly excludes, limits or fails to provide for the independent review of decisions affecting rights, obligations or interests.

1.7 Items 4 and 28 in Part 1 of Schedule 1 to the instrument contain broad discretionary powers, which also appear to be coercive in nature, as they appear to require the production of documents and samples, and to allow entry and access to premises. These provisions introduce conditions to the exemptions contained in the MD Regulations and TG Regulations which allow for the lawful importation, manufacture and supply of unregistered therapeutic vaping devices and therapeutic vaping goods.⁵ The conditions introduced by the instrument require that sponsors of therapeutic vaping devices or therapeutic vaping goods must:

² Senate standing order 23(3)(c).

³ Senate standing order 23(3)(h).

⁴ Senate standing order 23(3)(i).

⁵ Item 4 amends Part 2 of Schedule 4 (table item 2.17) of the Therapeutic Goods (Medical Devices) Regulations 2002, and item 28 amends Schedule 5A (table item 15) of the Therapeutic Goods Regulations 1990.

- if requested by the Secretary, give the Secretary a 'reasonable number' of samples of the device or goods, within the period requested by the Secretary (at least five working days);⁶
- allow—or, if they are not the manufacturer, have procedures in place to ensure that the manufacturer allows—an authorised officer to enter 'at any reasonable time', 'any premises', including premises outside Australia, at which the sponsor or any other person 'deals with' the devices or goods;⁷
- allow—or, if they are not the manufacturer, have procedures in place to ensure that the manufacturer allows—an authorised officer, while on those premises to inspect the premises and device or goods and examine, take measurements of, conduct or require testing on them or on 'any thing' on those premises that 'relates to' the device or goods, as well as make any image or recording of those premises or 'any thing' on those premises;⁸ and
- if requested by the authorised officer, produce—or, if they are not the manufacturer, have procedures in place to ensure that the manufacturer produces—such documents 'relating to' the device or goods as the officer requires and allow them to copy the documents.⁹

1.8 The committee considers that instruments that confer broad discretionary powers on a person should set out the factors which the person must consider in exercising the discretion. The explanatory statement should also address the purpose and scope of the discretion and why it is necessary, and explain who will exercise the discretion, including whether they possess the appropriate qualifications and necessary skills. The committee also expects the explanatory statement to outline the nature and source of any relevant limitations on the exercise of the powers, including whether independent merits review is available of decisions made in connection with exercise of the powers. This is because such broad discretionary and coercive powers have the potential to seriously trespass on individuals' rights and liberties.

1.9 For this reason, the committee considers that provisions which contain coercive powers should not ordinarily be included in delegated legislation. Where an instrument nevertheless contains such provisions, the committee expects the explanatory statement to justify why the provisions are necessary and appropriate (including how the public interest is served by their inclusion), who may exercise the powers and whether they are required to possess specified skills or qualifications, whether independent merits review is available of decisions made, and actions taken, in connection with the exercise of the powers, and whether the provisions comply with

⁶ Item 4, paragraph (fa); item 28, paragraph (fa).

⁷ Item 4, subparagraphs (fb)(i) and (fd)(i); item 28, subparagraphs (fb)(i) and (fd)(i).

⁸ Item 4, subparagraphs (fb)(ii), (fb)(iii), (fd)(ii) and fd(iii); item 28, subparagraphs (fb)(ii), (fb)(iii), (fd)(ii) and fd(iii).

⁹ Item 4, paragraphs (fc) and (fe); item 28, paragraphs (fc) and (fe).

Chapters 7 and 8 of the Attorney General's Department's <u>Guide to Framing</u> <u>Commonwealth Offences, Infringement Notices and Enforcement Powers</u>.¹⁰

1.10 In this regard, the committee is unclear from the instrument and its explanatory statement as to the scope of the discretionary provisions outlined above, including the factors the Secretary or an authorised officer would take into account in deciding whether to request the production of samples or documents, what is meant by terms such as 'deals with' and 'relates to', or in what circumstances they may enter premises outside of Australia.

1.11 The explanatory statement states broadly that the conditions inserted by the instrument are necessary to enable the obtaining of information to determine whether therapeutic vaping devices, accessories and therapeutic vaping goods that have been notified as complying with essential principles in the principal instrument, and with standards, do in fact comply.¹¹ However, this does not appear to be an adequate explanation as to why it is considered necessary and appropriate to provide for powers that are so broad and coercive in nature, including to provide for entry to premises outside of Australia. Nor does it explain who is defined as an 'authorised officer' and therefore who may exercise the powers to require the production of samples or enter premises and whether they possess appropriate skills and qualifications.

1.12 In light of the above, the committee requests the minister's advice as to:

- whether further detail can be provided about the nature and scope of the powers inserted by items 4 and 28 in Part 1 of Schedule 1 to the instrument, including how these powers have been, or are intended to be, exercised, any constraints on the grant and exercise of these powers, and what factors are likely to be taken into account in exercising the discretion under these provisions;
- whether further detail can be provided as to why the provisions are necessary and appropriate, including how the public interest is served by their inclusion in the instrument;
- who is an 'authorised officer' that exercises powers under these provisions – including authorised officers that may enter premises outside Australia – and whether they are required to possess specific skills or qualifications to exercise these powers;
- the legislative authority under which 'authorised officers' may enter premises outside of Australia and how these provisions operate in practice to enable officers to do so in different jurisdictions;

¹⁰ Attorney-General's Department, <u>A Guide to Framing Commonwealth Offences, Infringement</u> <u>Notices and Enforcement Powers</u> (24 May 2024).

¹¹ Explanatory statement, p. 7; p. 18.

- whether independent merits review is available of decisions made and actions taken in connection with exercise of the broad discretionary powers; and
- whether the Attorney General's Department's *Guide to Framing Commonwealth Offences* was considered in drafting these provisions.

Privacy¹²

1.13 Senate standing order 23(3)(h) requires the committee to scrutinise each legislative instrument as to whether it trespasses unduly on personal rights and liberties, including the right to privacy. The committee considers that provisions which enable the collection, use and disclosure of personal information may trespass on an individual's right to privacy, and should generally be included in primary, rather than delegated, legislation.

1.14 Where an instrument nevertheless contains such provisions, the explanatory statement should explain the nature and scope of the provisions (including the nature and extent of the information that may be disclosed and the persons and/or entities to whom disclosure is permitted). The explanatory statement should also address why the provisions are considered necessary and appropriate, what safeguards are in place to protect the personal information, and whether these are set out in law or in policy (including whether the *Privacy Act 1988* applies).

1.15 A number of the conditions inserted into the MD Regulations and TG Regulations by the instrument appear to provide for the production to, and copying of documents by, authorised officers. For example, paragraph (fc) of items 4 and 28 in Part 1 of Schedule 1 states that a sponsor must, if requested by an authorised officer, produce to them such documents relating to the device or goods as the officer requires and allow them to copy the documents. Paragraph (fe) of the same items also requires a sponsor that is not the manufacturer of the device or goods to have procedures in place to ensure that the manufacturer produces or allows the copying of such documents. Further, paragraphs (fb) and (fd) provide that a sponsor must allow—or if they are not the manufacturer have procedures in place to ensure that the manufacturer so the device or goods, and to make any still or moving image or any recording of the premises or any thing on the premises.

1.16 However, the explanatory statement does not explain the nature and scope of the information that may be collected, used and/or disclosed under the instrument, including whether it may contain personal information and how any such personal information may be used or collected. In particular, it is not clear whether any personal information may be produced or copied under paragraphs (fc) or (fe) of items 4 and

¹² Senate standing order 23(3)(h).

28, or whether any samples, moving or still images taken under paragraphs (fb) or (fd) may include personal information, noting these paragraphs refer to 'any thing' related to the device or goods, and 'any thing' on the premises. The explanatory statement also does not explain if, and to whom, any personal information may be disclosed or whether there are any safeguards in place to protect the use, collection and/or disclosure of any personal information.

1.17 In light of the above, the committee requests the minister's advice as to:

- the nature and scope of any documents or information that may be required to be produced to and collected, used or disclosed by, authorised officers under the instrument, with particular reference to items 4 and 28 in Part 1 of Schedule 1, and whether these are likely to include personal information; and, if so,
- whether any safeguards apply to protect any personal information collected, used or disclosed under the instrument, and whether these are set out in law or policy, including whether the *Privacy Act 1988* applies.

Retrospective effect¹³

1.18 Under Senate Standing Order 23(3)(h), the committee is required to scrutinise each instrument as to whether it trespasses unduly on personal rights and liberties. This includes whether an instrument has retrospective effect.

1.19 Together, items 3 and 33 of Schedule 1 of the instrument appear to have retrospective effect. Item 3 amends the sponsor notice requirements in table item 2.17 in the MD Regulations, so that these requirements apply to goods imported or manufactured before 1 March 2024. Item 33 is a transitional provision which amends Regulation 11.73 of the MD Regulations, so that amendments made by the instrument apply to therapeutic goods imported before, on or after 1 March 2024. The effect of these provisions together is to extend the exemption in table item 2.17 so that a sponsor notice must be provided in relation to goods imported or manufactured before 1 March 2024, before the device can be supplied to the consumer.

1.20 The explanatory statement states that these provisions do not have retrospective effect because the exemption requires the sponsor to prospectively meet the relevant requirements, including the giving of a sponsor notice, for the exemption to apply. However, the committee's view is that an instrument may have a retrospective effect where it attaches new conditions or requirements to processes which commenced under a previous legal framework, via the application of transitional provisions.¹⁴ While the above exemptions apply prospectively, they appear to apply new conditions in relation to goods that were imported or

¹³ Senate standing order 23(3)(h).

¹⁴ Senate Standing Committee for the Scrutiny of Delegated Legislation, <u>Guidelines (3rd Edition)</u> (July 2024), p.28.

manufactured before 1 March 2024 and therefore appear to apply retrospectively in line with the committee's understanding.

1.21 Where an instrument has retrospective effect, the committee expects the explanatory statement to explain the nature and scope of the provisions and why retrospectivity is considered necessary and appropriate. The explanatory statement should also set out whether any person has been, or may be, disadvantaged by the retrospective effect and, if so, what steps have been taken to avoid such disadvantage.

1.22 In light of the above, the committee requests the minister's advice as to:

- the nature and scope of items 3 and 33 of Schedule 1 to the instrument and whether they are intended to apply retrospectively as understood by the committee and reflected in principle (h) of its guidelines; and, if so,
- why the retrospective effect is considered necessary and appropriate; and
- whether any person has been or may be disadvantaged and, if so, what steps will be taken to avoid such disadvantage.

Immunity from liability¹⁵

1.23 Under Senate Standing Order 23(3)(h), the committee is required to scrutinise each instrument as to whether it trespasses unduly on personal rights and liberties, including whether it confers immunity from liability.

1.24 Item 22 in Part 1 of Schedule 1 to the instrument inserts a new regulation 46B into the TG Regulations to prescribe a person to whom powers or functions are delegated under subsection 57(1A) of the *Therapeutic Goods Act 1989* (the Act) for the purposes of paragraph (b) of the definition of 'protected person' in subsection 62(3).¹⁶ Subsection 57(1A) of the Act enables the Secretary to delegate certain powers relating to enforcement and forfeiture of things seized under search warrant to an officer of: a Department of State of a State; a Department or administrative unit of the Public Service of a Territory; or an authority of a State or a Territory; that has functions relating to therapeutic goods, health or law enforcement.

1.25 Where an instrument includes provisions providing for immunity from liability, the committee expects that its explanatory statement explains the nature and scope of the immunity, and why the breadth of the immunity is considered necessary and appropriate, including in relation to each specific class of person to whom it applies.

1.26 In this case, the explanatory statement provides that the effect of this amendment is to protect persons from criminal responsibility in circumstances relating to obtaining, possessing or conveying goods in connection with finding out whether there has been compliance with the Act or the TG Regulations. It also provides that

¹⁵ Senate standing order 23(3)(h).

¹⁶ See item 22 of Schedule 1, Part 1 of the instrument.

this amendment will ensure that state and territory officers can undertake compliance and enforcement activities without contravening the Act.¹⁷

1.27 However, the scope of this provision is unclear to the committee, particularly noting the broad range of persons to whom powers may be delegated under subsection 57(1A) of the Act. It is also unclear from the explanatory statement why this immunity is considered necessary and appropriate in relation to each class of delegate under subsection 57(1A)

1.28 In light of the above, the committee requests the minister's advice as to:

- the scope of the immunity from liability under new regulation 46B inserted by item 22 in Part 1 of Schedule 1 to the instrument, and those individuals who are likely to be included as 'protected persons' under subsection 57(1A) and paragraph 62(3)(b) of the *Therapeutic Goods Act 1989*; and
- whether further justification can be provided as to why this immunity from liability is considered to be necessary and appropriate, noting the potentially broad scope of individuals it may apply to.

Clarity of drafting¹⁸

1.29 Senate Standing Order 23(3)(e) requires the committee to scrutinise each instrument as to whether its drafting contains an error or is unclear. On this occasion, the instrument's explanatory statement describes the instrument as making amendments to support vaping reforms introduced by the 'Therapeutic Goods and Other Legislation (Vaping Reforms) Act 2024 (the Amendment Act)',¹⁹ and includes numerous subsequent references to the 'Amendment Act'. It appears that this is intended to refer to the *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024.* The explanatory statement also states under the heading to item [28] (page 17): 'Item 25 repeals paragraphs (g) and (h) of item 15 and inserts new paragraphs (fa), (fb), (fc), (fd), (fe), (g) and (h).' It appears that this was intended to refer to item 28.

1.30 The committee notes the importance of accurate drafting in delegated legislation and explanatory statements, to assist users of the law to navigate legislation and its explanatory materials and to understand their rights and obligations.

1.31 In light of the above, the committee requests the minister's advice as to whether the explanatory statement can be amended to correct the possible drafting errors identified above.

¹⁷ Explanatory statement, pp.15-16.

¹⁸ Senate standing order 23(3)(e).

¹⁹ Explanatory statement, pp. 1 and 25.

Therapeutic Goods (Vaping Goods—Possession and Supply) Determination 2024

Therapeutic Goods (Vaping Goods—Possession and Supply) Amendment Determination 2024²⁰

FRL No.	<u>F2024L00847; F2024L00890</u>
Purpose	F2024L00847: The purpose of the instrument is to determine specified vaping goods, or specified classes of vaping goods, that may be supplied or possessed in Australia, and specified persons, or specified classes of persons who may possess or supply those goods. The instrument also specifies the circumstances in which those persons may do so, and any applicable conditions that must be complied with.
	F2024L00890: The purpose of the instrument is to amend the Therapeutic Goods (Vaping Goods – Possession and Supply) Determination 2024 to extend the notification requirements, by one month, that apply to specified persons intending to surrender vaping goods to the Department of Health and Aged Care and to persons possessing a particular commercial quantity of vaping goods; to extend the expiration of the application of some items relating to possession and/or supply, and to make some minor amendments to defined terms and ensure consistency with the regulatory framework in the Act.
Authorising legislation	Therapeutic Goods Act 1989
Portfolio	Health and Aged Care
Disallowance	F2024L00847: 15 sitting days after tabling (tabled in the Senate on 3 July 2024). Notice of motion to disallow must be given by 17 September 2024. F2024L00890: 15 sitting days after tabling (tabled in the Senate
	on 12 August 2024). Notice of motion to disallow must be given by 19 September 2024.

Overview

1.32 Division 1 of Part 4A-2 of the *Therapeutic Goods Act 1989* (the Act) sets out offences and civil penalties for the importation, manufacture, supply and commercial

²⁰ This entry can be cited as: Senate Standing Committee for the Scrutiny of Delegated Legislation, Therapeutic Goods (Vaping Goods—Possession and Supply) Determination 2024, Delegated Legislation Monitor 10 of 2024; [2024] AUSStaCSDLM 96.

possession of vaping goods unless an exception applies. In addition to specific statutory authorisations and permissions, section 41R of the Act enables the minister to determine, by legislative instrument, that specified vaping goods or a specified class of vaping goods may be supplied or possessed in Australia by a specified person or class thereof; in the circumstances, and subject to any conditions specified in, the determination.

1.33 The Therapeutic Goods (Vaping Goods-Possession and Supply) Determination 2024 (the instrument) is made under section 41R of the Act to authorise specified persons to possess and supply specified vaping goods in certain circumstances, subject to specified conditions.

1.34 Some of the authorisations in the instrument are time limited to enable the disposal or depletion of existing stock of vaping goods where supply was previously lawful. The Therapeutic Goods (Vaping Goods – Possession and Supply) Amendment Determination 2024 (the amendment instrument) amends the instrument to:

- extend the notification requirements for specified persons intending to surrender vaping goods;
- extend the operation of some items relating to possession and/or supply from 30 September to 30 November 2024; and
- amend defined terms and ensure consistency with the regulatory framework in relation to the supply of medicinal cannabis vaping goods.

1.35 The committee has identified several technical scrutiny concerns in the instrument, as amended by the amendment instrument, detailed below.

Scrutiny concerns

Matters more appropriate for inclusion in primary legislation;²¹ exemptions from the operation of primary legislation;²² adequacy of explanatory materials²³

1.36 Senate standing order 23(3)(j) requires the committee to consider whether an instrument contains matters more appropriate for parliamentary enactment. This includes where an instrument sets out significant elements of a regulatory scheme. In addition, Senate standing order 23(3)(l) requires the committee to consider whether an instrument contains continuing exemptions from the operation of primary legislation. Finally, under Senate Standing Order 23(3)(g), the committee scrutinises instruments as to whether their explanatory statements provide sufficient information to gain a clear understanding of the instrument.

1.37 Division 1 of Part 4A-2 of the Act sets out a number of offences and civil penalty provisions relating to importation, manufacture, supply and possession of commercial

²¹ Senate standing order 23(3)(j).

²² Senate standing order 23(3)(I).

²³ Senate standing order 23(3)(g).

vaping goods, unless an exception authorises such activities. The Act sets out some exceptions to those offences, but further provides in paragraphs 41QB(9)(c) (supply of vaping goods), 41QC(14)(f) (possessing at least commercial quantity of vaping goods) and 41QD(8)(c) (possessing less than commercial quantity of vaping goods) that it is an exception where the minister has made a determination under section 41R of the Act.

1.38 The instrument is made pursuant to section 41R of the Act and determines that specified vaping goods or a class of vaping goods may be supplied or possessed in Australia by specified persons, or a class thereof, in the circumstances and subject to the conditions specified. The instrument therefore has the effect of creating exemptions to offence provisions in the Act. A number of the exceptions in the instrument also provide a time-limited amnesty period enabling the disposal or depletion of existing stock where supply was previously lawful.²⁴

1.39 The committee's longstanding view is that provisions which amend or create exemptions to primary legislation, or which contain significant elements of a regulatory scheme should be included in primary, rather than delegated legislation. However, if such amendments or modifications are nonetheless included in delegated legislation, the committee's expectation is that the explanatory statement comprehensively justifies the nature and scope of the relevant exemptions, including whether it is appropriate to include them in delegated, rather than primary, legislation. The committee also expects that exemption provisions should be time-limited or at least subject to sunsetting, which applies in this case, as the instrument is subject to sunsetting.

1.40 While the instrument is subject to sunsetting and some items are time limited to enable disposal or depletion of existing stock where supply was previously lawful, neither the explanatory statement to the instrument nor the amending instrument adequately explains why it was considered necessary and appropriate to include the detail of these exemptions in delegated legislation. Rather, the explanatory statement to the instrument provides only that the 'exceptions to the offences and civil penalty provisions specify legitimate persons who may import, manufacture, supply and possess vaping goods, being persons who are generally authorised or permitted under Commonwealth or state and territory legislation to be lawfully involved in the therapeutic goods supply chain' and that some of the items in the instrument are 'time limited to enable the disposal or depletion of existing stock of vaping goods where supply was previously lawful under Commonwealth and state or territory laws.'²⁵ The

See Schedule 1, item 1 and Schedule 2, items 1 and 5 (as amended by Schedule 1, item 13 of the Therapeutic Goods (Vaping Goods – Possession and Supply) Amendment Determination 2024).

²⁵ Explanatory statement to the Therapeutic Goods (Vaping Goods—Possession and Supply) Determination 2024, pp. 1 and 15.

explanatory statement does not provide further justification as to why these were considered necessary and appropriate for inclusion in delegated legislation.

1.41 In light of the above, the committee requests the minister's advice as to why it is considered necessary and appropriate to include the exceptions to the offences in Division 1 of Part 4A-2 of the *Therapeutic Goods Act 1989* in delegated legislation, rather than primary legislation.

Broad discretionary powers;²⁶ coercive powers;²⁷ clarity of drafting;²⁸adequacy of explanatory materials;²⁹ availability of independent merits review³⁰

1.42 Senate Standing Order 23(3)(c) requires the committee to scrutinise each instrument as to whether it makes rights, liberties, obligations or interests unduly dependent on insufficiently defined administrative powers. This includes provisions that broadly delegate administrative powers or functions, as well as those that confer coercive powers. Senate Standing Order 23(3)(h) requires the committee to scrutinise each instrument as to whether it trespasses unduly on personal rights and liberties. Under this principle, the committee is concerned with provisions in instruments that contain coercive powers. Senate Standing Order 23(3)(i) also requires the committee to consider whether an instrument unduly excludes, limits or fails to provide for the independent review of decisions affecting rights, obligations or interests.

1.43 Additionally, Senate Standing Order 23(3)(e) requires the committee to scrutinise each instrument as to whether its drafting contains an error or is unclear. Under Senate Standing Order 23(3)(g), the committee also scrutinises instruments as to whether their explanatory statements provide sufficient information to gain a clear understanding of the instrument.

1.44 Schedules 1 and 2 of the instrument specify vaping goods, the persons who may possess or possess and supply such goods, the circumstances in which they may do so and any applicable conditions. This includes an authorisation for persons who obtained the vaping goods in the course of their exportation business, which is subject to conditions including transportation, record keeping and a requirement to notify police where they reasonably suspect that goods have been lost or stolen.

1.45 However, a number of these conditions (set out in table items 3-6 of Schedule 1 and items 4-11 and 13 of Schedule 2, as amended by items 18 and 21 of the amendment instrument) include broad discretionary powers, which also appear to be coercive in nature as they require or enable production, seizure and inspection of documents and information.

²⁶ Senate standing order 23(3)(c).

²⁷ Senate standing order 23(3)(h).

²⁸ Senate standing order 23(3)(e).

²⁹ Senate standing order 23(3)(g).

³⁰ Senate standing order 23(3)(i).

1.46 The committee considers that instruments conferring broad discretionary powers on a person should also set out the factors which the person must consider in exercising the discretion within the instrument. The explanatory statement should also address the purpose and scope of the discretion, why it is necessary, and explain who will exercise the discretion, including whether they possess the appropriate qualifications and necessary skills. The committee further expects the explanatory statement to outline any limitations on the exercise of the powers and whether independent merits review is available of decisions made in connection with exercise of these powers.

1.47 Additionally, as provisions which contain coercive powers have the potential to seriously trespass on personal rights and liberties, the committee considers that these provisions should not ordinarily be included in delegated legislation. Where an instrument nevertheless contains such provisions, the committee expects the explanatory statement to justify why these provisions are necessary and appropriate, including how the public interest is served by their inclusion. In addition, the explanatory statement should explain who may exercise the powers and whether they are required to possess specified skills or qualifications, as well as whether independent review is available of decisions made, and actions taken, in connection with the exercise of the powers, and whether the provisions comply with Chapters 7 and 8 of the Attorney General's Department's *Guide to Framing Commonwealth Offences, Infringement Notices and Enforcement Powers* (the AGD guide).³¹

1.48 In this regard, a number of the table items in Schedules 1 and 2 of the instrument impose conditions on possession or supply requiring that those subject to the conditions must, if requested by the department, provide any information that it requires about:

- the goods;
- the person's possession of the goods, and any other persons involved in such activities; and
- any other matter that the department determines is relevant.³²

³¹ Attorney-General's Department, <u>A Guide to Framing Commonwealth Offences, Infringement</u> <u>Notices and Enforcement Powers</u> (24 May 2024).

³² See Schedule 1: table items 3-6, and Schedule 2: table items 4-11 and 13 (as amended by the Therapeutic Goods (Vaping Goods—Possession and Supply) Amendment Determination 2024).

1.49 In addition, persons who have entered Australia on board a ship or plane and are responsible for medical treatment of groups visiting Australia³³ must carry a list of the quantity and nature of goods imported, keep a record of their use, and produce the list or record for inspection 'at the request of' a Customs officer, an authorised officer or authorised person, as defined under the Therapeutic Goods Regulations 1990 (the TG Regulations) or the Act (see Schedule 2, table item 3).

1.50 Neither the explanatory statement to the instrument or the amending instrument adequately explains why it is considered necessary and appropriate to provide for these broad discretionary and coercive powers, how the public interest is served by their inclusion in the instrument, whether there are any constraints or safeguards on their exercise, and/or whether independent merits review is available for decisions made in connection with exercise of these powers. The committee considers the availability of independent merits review to be important, noting that broad discretionary and coercive powers have the potential to seriously trespass on individuals' rights and liberties. It is also unclear from the explanatory statement whether the AGD guide was taken into consideration in drafting these provisions.

1.51 Further, it is unclear from the explanatory statement to the instrument how and in what circumstances, decision makers within the department would exercise the power to require information or the nature of the information they are likely to require, or when a Customs officer, an authorised officer or authorised person would request the production of information in relation to imported goods. It is also unclear what is meant by 'any other matters' that the department determines are relevant or 'any other person involved' and what factors may be taken into account in determining these matters. In this regard, the explanatory statement to the instrument appears to merely restate the terms of the relevant table item but does not otherwise justify the inclusion of coercive powers or how the broad discretion would be exercised.³⁴

1.52 It is also not apparent from the instrument or its explanatory statement (nor from the explanatory statement to the amending instrument) which officers within the department would exercise the power to request the provision of information, and whether they have the appropriate skills and qualifications to exercise such powers.

³³ Schedule 2, table item 3 of the Therapeutic Goods (Vaping Goods-Possession and Supply) Determination 2024. A 'visiting group' is defined in section 4 as a group of persons specified in an approval under sub-regulation 5A(5) of the Customs (Prohibited Imports) Regulations 1956. Sub-regulation 5A(5) of the Customs (Prohibited Imports) Regulations 1956 approves the importation of vaping goods by members responsible for medical treatment of groups of persons including members of military forces of another country who are visiting Australia for military training, groups of persons visiting Australia to participate in sporting events, groups of persons comprising the Head of State or Head of government of a foreign county and senior Government officials of that country who are visiting Australia on official business.

³⁴ See, for example, page 6 of the explanatory statement to the Therapeutic Goods (Vaping Goods—Possession and Supply) Determination 2024.

1.53 In light of the above, the committee requests the minister's advice as to:

- whether further detail can be provided about the nature and scope of the conditions in table items 3-6 of Schedule 1 and table items 4-11 and 13 of Schedule 2 of the instrument (as amended by items 18 and 21 of the amendment instrument), including how the powers to request information or the production of lists or records for inspection have been or are intended to be exercised, the scope of 'any information' and 'any other person', and any constraints on the grant and exercise of these powers;
- factors that are likely to be taken into account by officers of the department in determining what is 'any other matter' considered relevant and whether examples can be provided of such matters;
- whether further detail can be provided as to why the above provisions are necessary and appropriate, including how the public interest is served by their inclusion in the instrument, rather than in primary legislation;
- which officers of the department are authorised to request the production of 'any information' under table items 3-6 of Schedule 1 and table items 4-11 and 13 of Schedule 2 of the instrument and whether they are required to possess specific skills or qualifications to exercise these powers;
- whether independent merits review is available of decisions made and actions taken in connection with exercise of the broad discretionary and coercive powers under the above provisions; and
- whether the Attorney General's Department's *Guide to Framing Commonwealth Offences* was considered in drafting these provisions.

Privacy³⁵

1.54 Senate standing order 23(3)(h) requires the committee to scrutinise each legislative instrument as to whether it trespasses unduly on personal rights and liberties, including the right to privacy. The committee considers that provisions which enable the collection, use and disclosure of personal information may trespass on an individual's right to privacy, and should generally be included in primary, rather than delegated, legislation.

1.55 Where an instrument nevertheless contains such provisions, the explanatory statement should explain the nature and scope of the provisions (including the nature and extent of the information that may be disclosed and the persons and/or entities to whom disclosure is permitted). The explanatory statement should also address why the provisions are considered necessary and appropriate, what safeguards are in place

³⁵ Senate standing order 23(3)(h).

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to protect the personal information, and whether these are set out in law or in policy (including whether the *Privacy Act 1988* (the Privacy Act) applies).

1.56 It appears to the committee that many of the conditions in the instrument enable or require the disclosure and collection of information which may contain personal information. However, it is unclear from the explanatory statement whether this is the case.

1.57 In this regard, persons who acquire vaping goods in the course of their export business, must:

- retain a copy of the receipt provided by the person who delivered the goods for at least 12 months after the goods are delivered;³⁶
- retain a record of the export date, amount or quantity and description of the goods exported, the method of export, and the name and signature of the person recording the information for at least 12 months after the goods are exported;³⁷
- if the person 'reasonably suspects' that any of the goods have been lost or stolen—notify police in the State or Territory where they suspect the goods were lost or stolen;³⁸ and
- if requested by the department—provide 'any information' that the department requires about the goods, the person's possession of the

³⁶ Schedule 1, table item 3, column 5, paragraph (d). See also Schedule 1, table item 5, column 5, paragraph (e) and Schedule 2:table item 6, column 5, paragraph (h); table item 7, column 5, paragraph (i) (as repealed and replaced by the Therapeutic Goods (Vaping Goods—Possession and Supply) Amendment Determination 2024); table item10, column 5, paragraph (h); and table item 11, column 5, paragraph (g).

³⁷ Schedule 1, table item 3, column 5, paragraph (f). See also Schedule 1: table item 4, column 5, paragraphs (a) and (c); table item 5, column 5, paragraph (g); and table item 6, column 5, paragraph (e) (relating to destruction or disposal of goods).

³⁸ Schedule 1, table item 3, column 5, paragraph (g). See also Schedule 1: table item 4, column 5, paragraph (d); table item 5, column 5, paragraph (h); table item-6, column 5, paragraph (f) (as amended by the Therapeutic Goods (Vaping Goods—Possession and Supply) Amendment Determination 2024); and Schedule 2: table item 4, column 5, paragraph (f); table item 5, column 5, paragraph (f); table item 6, column 5, paragraph (i); table item 7, column 5, paragraph (h) (as repealed and replaced by the Therapeutic Goods (Vaping Goods—Possession and Supply) Amendment Determination 2024); table item 10, column 5, paragraph (i); and table item 11, column 5, paragraph (h).

goods and any other person involved in such activities, as well as 'any other matter' determined relevant.³⁹

1.58 Further, the effect of the table item 3 in Schedule 2 of the instrument is that a person who has entered Australia on board a ship or plane and is responsible for medical treatment of certain groups visiting Australia (a 'visiting group')⁴⁰ may possess and supply vaping goods to members of those groups. Such persons are subject to conditions that require them to:

- keep records of the quantity, nature and use of the goods while the 'visiting group' is in Australia; and
- produce those records at the request of a Customs officer, an 'authorised officer' (under Part 5 of the TG Regulations) or an 'authorised person' (under section 41FN of the Act).⁴¹

1.59 It appears to the committee that such records may contain individuals' sensitive health information. However, the explanatory statement to the instrument does not address whether these records are likely to contain personal information and if so, what safeguards apply.

1.60 The statement of compatibility with human rights, attached to the explanatory statement, states: 'The majority of information required to be provided to the Department, or provided as part of a record, as part of complying with the Determination will be business related information rather than personal information...However, in a small number of instances, persons may be engaged in unlawful dealings with vaping goods or dealing with vaping goods as part of the lawful

³⁹ Schedule 1, table item 3, column 5, paragraph (h). See also Schedule 1: table item 4, column 5, paragraph (f); table item 5, column 5, paragraph (i); table item 6, column 5, paragraph (g); and Schedule 2: table item 4, column 5, paragraph (a); table item 5, column 5, paragraph (g); table item 6, column 5, paragraph (a); table item 7, column 5, paragraph (i) (as repealed and replaced by the Therapeutic Goods (Vaping Goods—Possession and Supply) Amendment Determination 2024); table item 8, column 5, paragraph (c); table item 9, column 5, paragraph (b) (as repealed and replaced by the Therapeutic Goods (Vaping Goods—Possession and Supply) Amendment Determination 2024); table item 10, column 5, paragraph (j); table item 11, column 5, paragraph (i); and table item 13, column 5, paragraph (d).

⁴⁰ A 'visiting group' is defined in section 4 of the instrument as a group of persons specified in an approval under sub-regulation 5A(5) of the Customs (Prohibited Imports) Regulations 1956. Sub-regulation 5A(5) of the Customs (Prohibited Imports) Regulations 1956 approves the importation of vaping goods by members responsible for medical treatment of groups of persons including members of military forces of another country who are visiting Australia for military training, groups of persons visiting Australia to participate in sporting events, groups of persons comprising the Head of State or Head of government of a foreign county and senior Government officials of that country who are visiting Australia on official business.

⁴¹ Schedule 2, table item 3 to the Therapeutic Goods (Vaping Goods-Possession and Supply) Determination 2024.

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supply chain...as a small business, meaning that their business records may necessarily involve disclosing personal information such as their name.'

1.61 However, it would be more instructive for users of the law and in line with the committee's expectations if the explanatory statement included information about the scope of personal information that may be required to be retained, used, collected and/or disclosed, with reference to each specific relevant provision of the instrument. In particular, it is unclear what is envisaged in 'any other information' that may be required to be provided to the department. It is also unclear as to the extent to which any personal information retained or provided may be used or further disclosed and whether any safeguards apply, such as application of the Privacy Act or any destruction requirements where records are no longer retained.

1.62 In light of the above, the committee requests the minister's advice as to:

- the nature and scope of any documents or information that may be required to be produced and collected, used or disclosed under the instrument and whether these are likely to include personal information; and, if so,
- whether any safeguards apply to protect any personal information collected, used or disclosed under the instrument, and whether these are set out in law or policy, including whether the *Privacy Act 1988* applies.

Clarity of drafting⁴²

1.63 Senate Standing Order 23(3)(e) requires the committee to scrutinise each instrument as to whether its drafting contains an error or is unclear.

1.64 In this regard, table item 6 in Schedule 2 to the instrument (as amended by the amendment instrument) authorises the possession and supply of vaping goods to persons in the legitimate supply chain where importation, manufacture, possession and supply was previously lawful. The condition in subparagraph (h)(iii) in column 5 of this table item requires such persons to retain for at least 12 months after supply of vaping goods, 'the written agreement or a copy of the written agreement referred to in paragraph (f) of Column 5'. It appears that this may be intended to instead refer to the written agreement in paragraph (f) of Column 4.

1.65 The committee notes the importance of accurate drafting in delegated legislation to assist users of the law to navigate legislation and its explanatory materials and to understand their rights and obligations.

1.66 In light of the above, the committee requests the minister's advice as to whether the instrument can be amended to correct the possible drafting error identified above.

⁴² Senate standing order 23(3)(e).

Chapter 2 Concluded matters

2.1 This Chapter details the committee's concluding comments on significant technical scrutiny issues in legislative instruments relating to the committee's principles in Senate standing order 23(3).

2.2 The committee has resolved not to conclude its examination of any instruments raising significant technical scrutiny concerns in this Monitor.

Chapter 3 Agency engagement¹

3.1 As part of its technical scrutiny of legislative instruments, the committee may engage with relevant agencies via its secretariat to gather information or seek clarification to resolve minor technical scrutiny concerns. While this correspondence is confidential, the committee lists the relevant instruments on its website and provides a statistical overview of the relevant scrutiny issues raised in its Annual Reports. The committee reports on matters which cannot be satisfactorily resolved via engagement with the relevant agency in Chapter 1 of the Monitor.

3.2 Some instruments may be listed as both 'new' and 'concluded', where the committee via its secretariat has both raised and resolved concerns with the relevant agency in the period covered by the Monitor.

New matters

3.3 The committee commenced engaging with the relevant agency via its secretariat about the following instruments.² Engagement on instruments marked with an asterisk was on an advice only basis.

Instrument

Australian Prudential Regulation Authority Supervisory Levies Determination 2024 [F2024L00813]

Defence Trade Legislation Amendment Regulations 2024 [F2024L00904]

Family Assistance (Immunisation Principles and Vaccination Schedules) (DSS) Amendment Determination 2024 [F2024L00819]

Financial Framework (Supplementary Powers) Amendment (Finance Measures No. 2) Regulations 2024 [F2024L00859]

Food Standards (Application A1257 – Australian native bee honey – Consequential Amendments) Variation [F2024L00894]*

Industry Research and Development (Space Literacy and Workforce Program) Instrument 2024 [F2024L00863]

List of Threatened Species Amendment (382) Instrument 2024 [F2024L00880]

List of Threatened Species Amendment (383) Instrument 2024 [F2024L00876]

List of Threatened Species Amendment (398) Instrument 2024 [F2024L00878]

¹ This entry can be cited as: Senate Standing Committee for the Scrutiny of Delegated Legislation, Agency engagement, *Delegated Legislation Monitor 10 of 2024*; [2024] AUSStaCSDLM 97.

² For further details, see the <u>Index of Instruments</u> page on the committee's website.

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Instrument

List of Threatened Species Amendment (399) Instrument 2024 [F2024L00882]

List of Threatened Species Amendment (400) Instrument 2024 [F2024L00885]

List of Threatened Species Amendment (401) Instrument 2024 [F2024L00887]

List of Threatened Species Amendment (402) Instrument 2024 [F2024L00883]

List of Threatened Species Amendment (403) Instrument 2024 [F2024L00879]

Tax Agent Services (Code of Professional Conduct) Determination 2024 [F2024L00849]

Tax Agent Services Amendment (Register Information) Regulations 2024 [F2024L00856]

Telecommunications (Emergency Management Persons and Emergency Laws) Instrument 2024 [F2024L00896]*

Therapeutic Goods (Excluded Goods) Amendment (Vaping) Determination 2024 [F2024L00843]

Concluded matters

3.4 The committee has concluded its consideration of the following instruments after engagement with relevant agencies via its secretariat.³

Instrument

Aged Care (Subsidy, Fees and Payments) Amendment (Multi-Purpose Services Subsidy Increase No. 2) Determination 2024 [F2024L00709]

Family Assistance (Immunisation Principles and Vaccination Schedules) (DSS) Amendment Determination 2024 [F2024L00819]

Food Standards (Application A1254 – Rosemary Extract as a Food Additive – extension of use) Variation [F2024L00577]

Food Standards (Application A1273 – Steviol glycosides as a food additive in Food for special medical purposes) Variation [F2024L00578]

Food Standards (Application A1275 – Transglutaminase from GM Bacillus licheniformis as a processing aid) Variation [F2024L00579]

Food Standards (Application A1276 – Food derived from herbicide-tolerant soybean line MON94313) Variation [F2024L00586]

Food Standards (Application A1277 – 2'-FL from GM Escherichia coli K-12 (gene donor: Helicobacter enhydrae) in infant formula products) Variation [F2024L00587]

³ For further details, see the <u>Index of Instruments</u> page on the committee's website.

Instrument

Health Insurance (Section 3C Pathology Services – Respiratory Pathogen Testing) Determination 2024 [F2024L00557]

Offshore Electricity Infrastructure (Declared Area OEI-02-2024) Declaration 2024 [F2024L00685]

Ozone Protection and Synthetic Greenhouse Gas Management Amendment (2024 Measures No. 1) Regulations 2024 [F2024L00730]

Chapter 4 Undertakings¹

4.1 This Chapter identifies the new undertakings that have been made in relation to instruments considered in this report and those that the committee is aware have been implemented as at 5 September 2024.

4.2 The committee expects undertakings to be implemented in a timely manner and to be kept informed on their progress until implemented. This Chapter lists undertakings that are outstanding for more than 90 days as at 5 September 2024.

4.3 A full list of undertakings is published on the *Index of Undertakings* on the committee's website.² Further information about the scrutiny concerns leading to these undertakings can be found through the links published on the *Index of Instruments* available on the committee's website.³

New undertakings

4.4 During this period, the following undertakings were made to address the committee's scrutiny concerns.

Instrument	Undertaking	Date made
Aged Care (Subsidy, Fees and Payments) Amendment (Multi-Purpose Services Subsidy Increase No. 2) Determination 2024 [F2024L00709]	The department undertook to progress a supplementary explanatory statement in response to the committee's scrutiny concerns regarding principle (d).	22 August 2024
Australian Passports (Application Fees) Amendment Determination 2024 [F2024L00618]	The department undertook to progress amendments to the explanatory statement in response to the committee's scrutiny concerns regarding principle (d).	5 September 2024
Australian Passports (Fees) Amendment Determination 2024 [F2024L00619]	The department undertook to progress amendments to the explanatory statement in response to the committee's scrutiny concerns regarding principle (d).	5 September 2024
Food Standards (Application A1254 – Rosemary Extract as a Food Additive – extension of use) Variation [F2024L00577]	The department undertook to progress amendments to the explanatory statement in response to the committee's scrutiny concerns regarding principle (d).	5 August 2024

¹ This entry can be cited as: Senate Standing Committee for the Scrutiny of Delegated Legislation, Undertakings, *Delegated Legislation Monitor 10 of 2024*; [2024] AUSStaCSDLM 98.

² See the <u>Index of Undertakings</u> page on the committee's website.

³ See the <u>Index of Instruments</u> page on the committee's website.

Food Standards (Application A1273 – Steviol glycosides as a food additive in Food for special medical purposes) Variation [F2024L00578]	The department undertook to progress amendments to the explanatory statement in response to the committee's scrutiny concerns regarding principle (d).	5 August 2024
Food Standards (Application A1275 – Transglutaminase from GM Bacillus licheniformis as a processing aid) Variation [F2024L00579]	The department undertook to progress amendments to the explanatory statement in response to the committee's scrutiny concerns regarding principle (d).	5 August 2024
Food Standards (Application A1276 – Food derived from herbicide-tolerant soybean line MON94313) Variation [F2024L00586]	The department undertook to progress amendments to the explanatory statement in response to the committee's scrutiny concerns regarding principle (d).	5 August 2024
Food Standards (Application A1277 – 2′ -FL from GM Escherichia coli K-12 (gene donor: Helicobacter enhydrae) in infant formula products) Variation [F2024L00587]	The department undertook to progress amendments to the explanatory statement in response to the committee's scrutiny concerns regarding principle (d).	5 August 2024
Health Insurance (Section 3C Pathology Services – Respiratory Pathogen Testing) Determination 2024 [F2024L00557]	The department undertook to progress a supplementary explanatory statement in response to the committee's concerns regarding principle (d).	20 August 2024
Offshore Electricity Infrastructure (Declared Area OEI-02-2024) Declaration 2024 [F2024L00685]	The department undertook to progress amendments to the explanatory statement in response to the committee's scrutiny concerns regarding principle (f).	19 August 2024
Ozone Protection and Synthetic Greenhouse Gas Management Amendment (2024 Measures No. 1) Regulations 2024 [F2024L00730]	The department undertook to progress amendments to the explanatory statement in response to the committee's scrutiny concerns regarding principles (c) and (k).	23 August 2024

Implemented undertakings

4.5 During this period, the following undertakings have been implemented.

Instrument	Undertaking	Date implemented
Australian National University (Governance) Statute 2023 [F2023L00867]	The Minister for Education advised that the Australian National University undertook to amend the explanatory statement in response to the committee's concerns.	20 June 2024

Defence (Non-foreign work restricted individual) Determination 2024 [F2024L00519]	The department undertook to progress amendments to the explanatory statement in response to the committee's scrutiny concerns.	23 August 2024
Defence (Non-relevant foreign country) Determination 2024 [F2024L00518]	The department undertook to progress amendments to the explanatory statement in response to the committee's scrutiny concerns.	23 August 2024
Financial Stability Standards for Securities Settlement Facilities Determination 2024 [F2024L00683]	The agency undertook to progress a replacement explanatory statement to address the committee's scrutiny concerns regarding principle (k).	27 August 2024
Financial Stability Standards for Securities Settlement Facilities Revocation 2024 [F2024L00682]	The agency undertook to progress a replacement explanatory statement to address the committee's scrutiny concerns regarding principle (k).	27 August 2024
Fuel Quality Standards (Ethanol E85) Determination 2024 [F2024L00477]	The department undertook to progress amendments to the explanatory statement to the instruments in response to the committee's scrutiny concerns.	28 August 2024
Fuel Quality Standards (Petrol) Determination 2024 [F2024L00475]	The department undertook to progress amendments to the explanatory statement to the instruments in response to the committee's scrutiny concerns.	28 August 2024
Great Barrier Reef Marine Park Amendment (No-Anchoring Areas) Regulations 2021 [F2021L00843]	The Minister for the Environment undertook to amend the principal instrument in response to the committee's scrutiny concerns.	30 August 2024
National Health (Pharmaceutical Benefits) Amendment (2024 Measures No. 1) Regulations 2024 [F2024L00380]	The department undertook to progress a supplementary explanatory statement to the instrument in response to the committee's concerns.	2 September 2024
Offshore Petroleum and Greenhouse Gas Storage (Greenhouse Gas Injection and Storage) Regulations 2023 [F2023L01551]	The minister made a further undertaking to amend the explanatory statement to the instrument in response to the committee's concerns.	23 August 2024
Safety, Rehabilitation and Compensation (Defence-related Claims)—Guide to the Assessment of the Degree of Permanent Impairment 2023 [F2023L00364]	The department undertook to progress amendments to the explanatory statement in response to the committee's scrutiny concerns.	5 July 2024
Vehicle Standard (Australian Design Rule 106/00 – Side Underrun Protection) 2023 [F2023L01317]	The department undertook to progress amendments to the explanatory statement in response to the committee's scrutiny concerns.	19 June 2024

Outstanding undertakings

4.6 The following undertakings remain outstanding more than 90 days after they were made.

Instrument	Undertaking	Date made
Anti-Money Laundering and Counter- Terrorism Financing Rules Amendment (Chapter 21 Amendments) Instrument 2024 [F2024L00088]	The Attorney-General undertook to codify in the Anti-Money Laundering and Counter- Terrorism Financing Act 2006 relevant exemptions intended to be enduring and to time limit those retained in delegated legislation.	20 March 2024
Bankruptcy Amendment (Service of Documents) Regulations 2022 [F2022L00528]	The Attorney-General undertook to amend the principal regulations in response to the committee's scrutiny concerns.	18 October 2022
Bankruptcy Regulations 2021 [F2021L00261]	The Assistant Minister to the Attorney- General undertook to advise the committee of the outcome of the government's targeted review of the appropriateness of modifying provisions currently prescribed in the instrument.	26 July 2021
Bankruptcy Regulations 2021 [F2021L00261]	The Assistant Minister to the Attorney- General undertook to amend the instrument in response to the committee's scrutiny concerns.	17 August 2021
Corporations Amendment (Design and Distribution Obligations—Income Management Regimes) Regulations 2023 [F2023L00193]	The Assistant Treasurer undertook to amend the instrument in response to the committee's scrutiny concerns.	31 July 2023
Funding) Regulations 2022 the ins	The Assistant Treasurer undertook to amend the instrument in response to the committee's scrutiny concerns.	31 July 2023
Environment Protection and Biodiversity Conservation (National Recovery Plan for Leadbeater's Possum (Gymnobelideus leadbeateri)) Instrument 2024 [F2024L00270]	The department undertook to progress amendments to the explanatory statement to the instrument in response to the committee's scrutiny concerns.	3 May 2024
Environment Protection and Biodiversity Conservation (National Recovery Plan for the Swift Parrot (Lathamus discolor)) Instrument 2024 [F2024L00482]	The department undertook to progress amendments to the explanatory statement to the instrument in response to the committee's scrutiny concerns.	2 May 2024

Environment Protection and Biodiversity Conservation (Recovery Plan for the Spiny Rice-flower (Pimelea spinescens subsp. spinescens)) Instrument 2024 [F2024L00346]	The department undertook to progress amendments to the explanatory statement to the instrument in response to the committee's scrutiny concerns.	3 May 2024
Financial Framework (Supplementary Powers) Amendment (Health Measures No. 9) Regulations 2021 [F2021L01823]	The department undertook to progress amendments to the explanatory statement to disclose the funding information.	19 October 2022
Financial Sector Reform (Hayne Royal Commission Response) (Hawking of Financial Products) Regulations 2021 [F2021L01080]	The Assistant Treasurer undertook to amend the instrument in response to the committee's scrutiny concerns.	29 November 2022
Health Insurance (prudential standard) determination No. 2 of 2023 [F2023L00719]	The Department of the Treasury undertook to progress amendments to the explanatory statement to the instrument in response to the committee's scrutiny concerns.	27 July 2023
Health Insurance (prudential standard) determination No. 4 of 2023 [F2023L00733]	The Department of the Treasury undertook to progress amendments to the explanatory statement to the instrument in response to the committee's scrutiny concerns.	27 July 2023
Health Insurance (prudential standard) determination No. 5 of 2023 [F2023L00734]	The Department of the Treasury undertook to progress amendments to the explanatory statement to the instrument in response to the committee's scrutiny concerns.	27 July 2023
Health Insurance (prudential standard) determination No. 6 of 2023 [F2023L00738]	The Department of the Treasury undertook to progress amendments to the explanatory statement to the instrument in response to the committee's scrutiny concerns.	27 July 2023
Health Insurance (prudential standard) determination No. 7 of 2023 [F2023L00689]	The Department of the Treasury undertook to progress amendments to the explanatory statement to the instrument in response to the committee's scrutiny concerns.	27 July 2023
Health Insurance (prudential standard) determination No. 8 of 2023 [F2023L00691]	The Department of the Treasury undertook to progress amendments to the explanatory statement to the instrument in response to the committee's scrutiny concerns.	27 July 2023
Health Insurance (prudential standard) determination No. 9 of 2023 [F2023L00695]	The Department of the Treasury undertook to progress amendments to the explanatory statement to the instrument in response to the committee's scrutiny concerns.	27 July 2023

Higher Education Standards Framework (Threshold Standards) 2021 [F2021L00488]	The Department of Education, Skills and Employment undertook to amend the explanatory statement to the instrument in response to the committee's scrutiny concerns.	9 August 2021
National Anti-Corruption Commission Regulations 2023 [F2023L00759]	The Attorney-General undertook to amend the explanatory statement in response to the committee's scrutiny concerns	16 October 2023
Standards for Registered Training Organisations Amendment (Fit and Proper Person) Instrument 2023 [F2023L01182]	The Department of Employment and Workplace Relations undertook to progress amendments to the explanatory statement to the instrument in response to the committee's scrutiny concerns.	31 October 2023
Telecommunications (Interception and Access) (Communications Access Co- ordinator) Instrument 2022 (No. 2) [F2022L01321]	The Attorney-General undertook to amend the instrument in response to the committee's scrutiny concerns.	13 December 2022
Treasury Laws Amendment (Rationalising ASIC Instruments) Regulations 2022 [F2022L01629]	The Assistant Treasurer undertook to amend the instrument in response to the committee's scrutiny concerns.	31 July 2023
Veterans' Affairs (Treatment Principles – Extend Support Provided Under the Psychiatric Assistance Dog Program) Amendment Determination 2022 [F2022L00921]	The Department of Veterans' Affairs undertook to consider the committee's scrutiny concerns as part of a review of the Act.	7 September 2022

Part II—Matters of interest to the Senate

Chapter 5

Expenditure and taxation in delegated legislation¹

5.1 This Chapter identifies the instruments which the committee has resolved to draw to the attention of the Senate under standing order 23(4) in the interest of promoting appropriate parliamentary scrutiny of Commonwealth expenditure in delegated legislation.² This includes expenditure-related instruments and instruments that levy taxation.

Commonwealth expenditure

Instruments specifying expenditure under the Financial Framework (Supplementary Powers) Act 1997 and Industry Research and Development Act 1986

5.2 Instruments made under the *Financial Framework (Supplementary Powers) Act 1997* (the FF(SP) Act) and the *Industry Research and Development Act 1986* (the IRD Act) authorise the Commonwealth to spend public money on grants and programs specified. The committee has resolved to draw these instruments to the Senate's attention under Senate standing order 23(4).³

5.3 The table below lists the expenditure specified in legislative instruments made under the FF(SP) Act and IRD Act registered in the relevant period.

Instrument	Amount	Grant/Program
Financial Framework (Supplementary Powers) Amendment (Finance Measures No. 2) Regulations 2024 [F2024L00859]	\$2.8 million over three years from 2023-24	Voter Information Security Enhancement
Financial Framework (Supplementary Powers) Amendment (Home Affairs Measures No. 2) Regulations 2024 [F2024L00721]	\$477.7 million in 2023-24 for the Independent Management Arrangement ⁴	Assistance to Papua New Guinea regarding former Regional Resettlement Arrangement caseload

¹ This entry can be cited as: Senate Standing Committee for the Scrutiny of Delegated Legislation, Expenditure and taxation in delegated legislation, *Delegated Legislation Monitor 10 of 2024*; [2024] AUSStaCSDLM 99.

² Details of all instruments which the committee has resolved to draw to the attention of the Senate under standing order 23(4) are published on the <u>committee's website</u>.

³ Details of all instruments which authorise Commonwealth expenditure are published on the <u>committee's website</u>.

⁴ This amount is the overall expenditure for the Independent Management Arrangement, which comprises expenditure to assist Papua New Guinea in managing the former Regional Resettlement Arrangement caseload.

Page 36		Monitor 10 of 2024
	\$6.1 million in 2024-25	Specialised Domestic and Family Violence Visa Support Service
Industry Research and Development (Space Literacy and Workforce Program) Instrument 2024 [F2024L00863]	\$3.4 million in 2024-25	Space Literacy and Workforce Program

Levying of taxation in delegated legislation

5.4 The committee considers that one of the most fundamental functions of the Parliament is to levy taxation. The committee's longstanding view is that it is for the Parliament, rather than makers of delegated legislation, to set a rate of tax (in accordance with Senate standing order 23(3)(j)). Where a tax is imposed in delegated legislation, the committee's concerns are heightened if it is not limited by a cap in the relevant enabling Act.

5.5 As the levying of taxation in delegated legislation is a systemic technical scrutiny matter, the committee has resolved to draw the following instruments to the attention of the Senate under standing order 23(4).

Instrument	Limit on the taxation amount in primary legislation?
Australian Prudential Regulation Authority Supervisory Levies Determination 2024 [F2024L00813]	Yes
Industrial Chemicals Charges (Customs) Amendment Regulations 2024 [F2024L00912]	No
Industrial Chemicals Charges (Excise) Amendment Regulations 2024 [F2024L00913]	No
Industrial Chemicals Charges (General) Amendment Regulations 2024 [F2024L00911]	No

Chapter 6

Exemptions from disallowance and sunsetting¹

6.1 This Chapter lists the instruments which the committee has resolved to draw to the attention of the Senate under standing order 23(4) because they are exempt from disallowance and sunsetting and do not satisfy the committee's expectations in relation to the source and appropriateness of the exemptions following the committee's scrutiny under standing orders 23(4A) and 23(3)(k).

Exemptions from disallowance

6.2 On 16 June 2021, the Senate resolved that delegated legislation should be subject to disallowance to permit appropriate parliamentary scrutiny and oversight unless there are exceptional circumstances and any claim that circumstances justify exemption from disallowance will be subjected to rigorous scrutiny with the expectation that the claim will only be justified in rare cases.²

6.3 Senate standing order 23(4A) provides that the committee may consider instruments that are not subject to disallowance, including whether it is appropriate for these instruments to be exempt from disallowance. Noting the Senate's concern about the exemption of delegated legislation from disallowance, this section identifies the instruments which do not satisfy the committee's expectations regarding the circumstances of their exemption from disallowance.

6.4 Subject to exceptional circumstances, the committee's expectations will not be met where the instrument:

 is exempt from disallowance under one of the broad classes of exemptions in section 9 of the Legislation (Exemptions and Other Matters) Regulation 2015;³

¹ This entry can be cited as: Senate Standing Committee for the Scrutiny of Delegated Legislation, Exemptions from disallowance and sunsetting, *Delegated Legislation Monitor 10 of 2024*; [2024] AUSStaCSDLM 100.

² For further information on the resolutions adopted by the Senate on 16 June 2021, see the committee's website, *<u>Resolutions relating to oversight of delegated legislation</u>.*

³ Items 1 to 4 of section 9 of the Legislation (Exemptions and Other Matters) Regulation 2015 exempt the following classes of instruments from disallowance: instruments requiring the approval of either or both Houses of Parliament; instruments that are directions by a minister to any person or body; instruments (other than a regulation) relating to superannuation; and instruments made under annual Appropriation Acts.

- is exempt from disallowance under the blanket exemption for instruments facilitating the establishment or operation of an intergovernmental body or scheme in section 44(1) of the *Legislation Act 2003*;⁴
- overrides or modifies primary legislation;
- triggers, or is a precondition to, the imposition of custodial penalties or significant pecuniary penalties;
- restricts personal rights and liberties;
- facilitates the expenditure of public money, including Advance to the Finance Minister determinations; or
- otherwise contains a matter requiring parliamentary oversight.

6.5 To assess whether an instrument is appropriately exempt from disallowance, the committee expects that at a minimum, the explanatory statement will contain a statement that provides the source and the exceptional circumstances that justify the exemption from disallowance.

6.6 Further information about the committee's expectations regarding the exemption of delegated legislation from disallowance are contained in the committee's guidelines and the reports of its inquiry into the exemption of delegated legislation from parliamentary oversight.⁵

Instruments which do not meet the committee's expectations

6.7 The following instruments do not meet the committee's expectations under standing order 23(4A):

	Instrument	Source of exemption
	Agricultural and Veterinary Chemicals (MRL Standard for Residues of Chemical Products) Amendment Instrument (No. 2) 2024 [F2024L00860]	Subsection 44(1) of the <i>Legislation Act 2003</i>
_	Australia New Zealand Food Standards Code - Schedule 20 - Maximum residue limits Variation Instrument No. APVMA 2, 2024 [F2024L00861]	Subsection 44(1) of the <i>Legislation Act 2003</i>

⁴ Senate Standing Committee for the Scrutiny of Delegated Legislation, <u>Inquiry into the</u> <u>exemption of delegated legislation from parliamentary oversight: Final report</u> (March 2021) pp. 50–53 and 106–107.

Senate Standing Committee for the Scrutiny of Delegated Legislation, <u>Guidelines</u>, 3rd edition (July 2024) pp. 43-45, Senate Standing Committee for the Scrutiny of Delegated Legislation, <u>Inquiry into the exemption of delegated legislation from parliamentary oversight: Interim</u> <u>report</u> (December 2020) pp. 61–72; Senate Standing Committee for the Scrutiny of Delegated Legislation, <u>Inquiry into the exemption of delegated legislation from parliamentary oversight:</u> <u>Final report</u> (March 2021) pp. 99–123.

Instrument	Source of exemption
Australia New Zealand Food Standards Code – Standard 2.8.3 – Native bee honey [F2024L00893]	Subsection 44(1) of the <i>Legislation Act 2003</i>
Consumer Goods (Infant Products) Information Standard 2024 [F2024L00892]	Subsection 44(1) of the <i>Legislation Act 2003</i>
Consumer Goods (Infant Sleep Products) Safety Standard 2024 [F2024L00891]	Subsection 44(1) of the <i>Legislation Act 2003</i>
Federal Financial Relations (General Purpose Financial Assistance—2024-25 Payment No. 1) Determination 2024 [F2024L00898]	Subsection 9(5) of the <i>Federal Financial Relations Act 2009</i>
Federal Financial Relations (National Partnership Payments—2024-25 Payment No. 1) Determination 2024 [F2024L00858]	Subsection 16(5) of the <i>Federal Financial Relations</i> Act 2009
Food Standards (Application A1257 – Australian native bee honey – Consequential Amendments) Variation [F2024L00894]	Subsection 44(1) of the <i>Legislation Act 2003</i>
Food Standards (Application A1280 – Food derived from herbicide-tolerant and insect-protected corn line DAS1131) Variation [F2024L00895]	Subsection 44(1) of the <i>Legislation Act 2003</i>
Housing Australia Investment Mandate Amendment (2024 Measures No. 1) Direction 2024 [F2024L00866]	Section 9 of the Legislation (Exemptions and Other Matters) Regulation 2015
Local Government (Financial Assistance) (Final Factor for 2023-24 and Estimated Factor for 2024- 25) Determination 2024 [F2024L00812]	Subsection 44(1) of the <i>Legislation Act 2003</i>
National Disability Insurance Scheme (NDIS Worker Screening Law) Amendment Determination 2024 [F2024L00867]	Subsection 44(1) of the <i>Legislation Act 2003</i>

Exemptions from sunsetting

6.8 Senate standing order 23(3)(k) requires the committee to scrutinise instruments which are exempt from the sunsetting provisions of the *Legislation Act 2003* (the Legislation Act), including whether it is appropriate for these instruments to be exempt from sunsetting.

6.9 The sunsetting framework established under section 50 of the Legislation Act provides that all legislative instruments registered on the Federal Register of Legislation after 1 January 2005 are automatically repealed ten years after registration. Sunsetting provides the opportunity for Parliament (as well as ministers

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and agencies) to ensure that the content of delegated legislation remains appropriate, and for Parliament to maintain effective, regular oversight of delegated powers.

6.10 On 16 June 2021, the Senate resolved that delegated legislation should be subject to sunsetting to permit appropriate parliamentary scrutiny and oversight unless there are exceptional circumstances and any claim that circumstances justify exemption from sunsetting will be subjected to rigorous scrutiny with the expectation that the claim will only be justified in rare cases.⁶

6.11 Where an instrument is exempt from sunsetting, Senate standing order 23(3)(k) requires the committee to scrutinise each instrument as to whether the exemption is appropriate. Noting the Senate's concern about the exemption of delegated legislation from sunsetting, this section identifies instruments which do not satisfy the committee's expectations regarding the appropriateness of their exemption from sunsetting.

6.12 Subject to exceptional circumstances, the committee's expectations will not be met where the instrument:

- is exempt from sunsetting under one of the broad classes of exemptions in section 11 of the Legislation (Exemptions and Other Matters) Regulation 2015;⁷
- is exempt from sunsetting under the blanket exemption of instruments facilitating the establishment or operation of an intergovernmental body or scheme in section 54(1) of the *Legislation Act 2003;*⁸
- overrides or modifies primary legislation;
- triggers, or is a precondition to, the imposition of custodial penalties or significant pecuniary penalties;
- restricts personal rights and liberties;
- facilitates the expenditure of public money on an ongoing basis; or

⁶ For further information on the resolutions adopted by the Senate on 16 June 2021, see the committee's website, *<u>Resolutions relating to oversight of delegated legislation</u>.*

⁷ Items 1 to 7 of section 11 of the Legislation (Exemptions and Other Matters) Regulation 2015 exempt the following classes of instruments from sunsetting: instruments giving effect to international obligations of Australia; instruments that establish a body having power to enter into contracts; instruments that are directions by a minister to any person or body; instruments which confer power on a self-governing Territory; ordinances made under a power delegated in an Act providing for the government of a non-self-governing Territory; instruments (other than a regulation) relating to superannuation; and instruments made under annual Appropriation Acts.

⁸ Senate Standing Committee for the Scrutiny of Delegated Legislation, <u>Inquiry into the</u> <u>exemption of delegated legislation from parliamentary oversight: Final report</u> (March 2021) pp. 50–53 and 106–107.

• otherwise contains a matter requiring parliamentary oversight.

6.13 To assess whether an instrument is appropriately exempt from sunsetting, the committee expects that at a minimum, the explanatory statement will contain a statement that provides the source and the exceptional circumstances that justify the exemption from sunsetting.

6.14 Further information about the committee's expectations about the exemption of delegated legislation from sunsetting are contained in the committee's guidelines and the reports of its inquiry into the exemption of delegated legislation from parliamentary oversight.⁹

Instruments which do not meet the committee's expectations

6.15 Instruments listed below do not meet the committee's expectations under standing order 23(3)(k).

Instrument	Source of exemption
Agricultural and Veterinary Chemicals (MRL Standard for Residues of Chemical Products) Amendment Instrument (No. 2) 2024 [F2024L00860]	Subsection 54(1) of the <i>Legislation Act 2003</i>
Australia New Zealand Food Standards Code - Schedule 20 - Maximum residue limits Variation Instrument No. APVMA 2, 2024 [F2024L00861]	Subsection 54(1) of the <i>Legislation Act 2003</i>
Australia New Zealand Food Standards Code – Standard 2.8.3 – Native bee honey [F2024L00893]	Subsection 54(1) of the <i>Legislation Act 2003</i> Section 11 of the Legislation (Exemptions and Other Matters) Regulation 2015
Defence Trade Legislation Amendment Regulations 2024 [F2024L00904]	Section 11 of the Legislation (Exemptions and Other Matters) Regulation 2015
Federal Financial Relations (General Purpose Financial Assistance—2024-25 Payment No. 1) Determination 2024 [F2024L00898]	Subsection 54(1) of the <i>Legislation Act 2003</i>
Federal Financial Relations (National Partnership Payments—2024-25 Payment No. 1) Determination 2024 [F2024L00858]	Subsection 54(1) of the <i>Legislation Act 2003</i>

⁹ Senate Standing Committee for the Scrutiny of Delegated Legislation, <u>Guidelines</u>, 3rd edition (July 2024) pp. 37–38; Senate Standing Committee for the Scrutiny of Delegated Legislation, <u>Inquiry into the exemption of delegated legislation from parliamentary oversight: Interim</u> <u>report</u> (December 2020) pp. 89–90; Senate Standing Committee for the Scrutiny of Delegated Legislation, <u>Inquiry into the exemption of delegated legislation from parliamentary oversight:</u> <u>Final report</u> (March 2021) pp. 87–88 and 99–123.

Instrument	Source of exemption
Food Standards (Application A1257 – Australian native bee honey – Consequential Amendments) Variation [F2024L00894]	Subsection 54(1) of the <i>Legislation Act 2003</i> Section 11 of the Legislation (Exemptions and Other Matters) Regulation 2015
Food Standards (Application A1280 – Food derived from herbicide-tolerant and insect-protected corn line DAS1131) Variation [F2024L00895]	Subsection 54(1) of the <i>Legislation Act 2003</i> Section 11 of the Legislation (Exemptions and Other Matters) Regulation 2015
Housing Australia Investment Mandate Amendment (2024 Measures No. 1) Direction 2024 [F2024L00866]	Section 11 of the Legislation (Exemptions and Other Matters) Regulation 2015
Local Government (Financial Assistance) (Final Factor for 2023-24 and Estimated Factor for 2024- 25) Determination 2024 [F2024L00812]	Subsection 54(1) of the <i>Legislation Act 2003</i>

Senator Deborah O'Neill Chair