

The Senate

Standing
Committee on
Regulations and
Ordinances

Delegated Legislation Monitor

Monitor 14 of 2018

28 November 2018

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ISSN 2201-8689 (print)

ISSN 1447-2147 (online)

This document was prepared by the Senate Standing Committee on Regulations and Ordinances and printed by the Senate Printing Unit, Department of the Senate, Parliament House, Canberra.

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Introduction

Terms of reference

The Senate Standing Committee on Regulations and Ordinances (the committee) was established in 1932. The role of the committee is to examine the technical qualities of all disallowable instruments of delegated legislation and decide whether they comply with the committee's non-partisan scrutiny principles, which focus on statutory requirements, the protection of individual rights and liberties, and ensuring appropriate parliamentary oversight.

Senate Standing Order 23(3) requires the committee to scrutinise each instrument referred to it to ensure:

- (a) that it is in accordance with the statute;
- (b) that it does not trespass unduly on personal rights and liberties;
- (c) that it does not unduly make the rights and liberties of citizens dependent upon administrative decisions which are not subject to review of their merits by a judicial or other independent tribunal; and
- (d) that it does not contain matter more appropriate for parliamentary enactment.

Nature of the committee's scrutiny

The committee's scrutiny principles capture a wide variety of issues but relate primarily to technical legislative scrutiny. The committee therefore does not generally examine or consider the policy merits of delegated legislation. In cases where an instrument is considered not to comply with the committee's scrutiny principles, the committee's usual approach is to correspond with the responsible minister seeking further explanation or clarification of the matter at issue, or seeking an undertaking for specific action to address the committee's concern.

The committee's work is supported by processes for the registration, tabling and disallowance of legislative instruments under the *Legislation Act 2003*.¹

Publications

The committee's usual practice is to table a report, the *Delegated Legislation Monitor* (the monitor), each sitting week of the Senate. The monitor provides an overview of the committee's scrutiny of disallowable instruments of delegated legislation for the preceding period. Disallowable instruments of delegated

1 For further information on the disallowance process and the work of the committee see *Odgers' Australian Senate Practice*, 14th Edition (2016), Chapter 15.

legislation detailed in the monitor are also listed in the 'Index of instruments' on the committee's website.²

Ministerial correspondence

Correspondence relating to matters raised by the committee is published on the committee's website.³

Guidelines

Guidelines referred to by the committee are published on the committee's website.⁴

General information

The Federal Register of Legislation should be consulted for the text of instruments, explanatory statements, and associated information.⁵

The Senate Disallowable Instruments List provides an informal listing of tabled instruments for which disallowance motions may be moved in the Senate.⁶

The Disallowance Alert records all notices of motion for the disallowance of instruments, and their progress and eventual outcome.⁷

2 Regulations and Ordinances Committee, *Index of instruments*, http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Regulations_and_Ordinances/Index.

3 See www.aph.gov.au/regords_monitor.

4 See http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Regulations_and_Ordinances/Guidelines.

5 See Australian Government, Federal Register of Legislation, www.legislation.gov.au.

6 Parliament of Australia, *Senate Disallowable Instruments List*, http://www.aph.gov.au/Parliamentary_Business/Bills_Legislation/leginstruments/Senate_Disallowable_Instruments_List.

7 Regulations and Ordinances Committee, *Disallowance Alert 2018*, http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Regulations_and_Ordinances/Alerts.

Chapter 1

New and continuing matters

1.1 This chapter details concerns in relation to disallowable instruments of delegated legislation registered on the Federal Register of Legislation between 26 October 2018 and 8 November 2018 (new matters); and matters previously raised in relation to which the committee seeks further information (continuing matters).

1.2 Guidelines referred to by the committee are published on the committee's website.¹

Response required

1.3 The committee requests an explanation or information from relevant ministers with respect to the following concerns.

Instrument	Australian Meat and Live-stock Industry (Export of Sheep by Sea to Middle East—Northern Winter) Order 2018 [F2018L01529]
Purpose	Imposes additional conditions on holders of export licences who export sheep by sea to the Middle East between November and April
Authorising legislation	<i>Australian Meat and Live-stock Industry Act 1997</i>
Portfolio	Agriculture and Water Resources
Disallowance	15 sitting days after tabling (tabled Senate 12 November 2018). Notice of motion to disallow must be given by the third sitting day of 2019 ²

1 See http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Regulations_and_Ordinances/Guidelines.

2 In the event of any change to the Senate's sitting days, the last day for the notice would change accordingly.

Merits review³

1.4 Scrutiny principle 23(3)(c) of the committee's terms of reference requires the committee to ensure that instruments do not unduly make the rights and liberties of citizens dependent upon administrative decisions which are not subject to review of their merits by a judicial or other independent tribunal.

1.5 Part 3 of the instrument provides a framework for the secretary to exempt licensees from provisions of the instrument in certain circumstances. Subsection 12(1) allows the holder of a sheep export licence to apply to the secretary for an exemption from one or more provisions of the instrument in relation to a consignment of sheep to which the instrument applies. Subsection 13(1) provides that, on receiving an application made under section 13, the secretary may decide to grant the exemption or not to grant the exemption. Under subsection 13(3), the secretary may grant the exemption 'if the Secretary is satisfied, having regard to any matter that the Secretary considers relevant, that it is appropriate to grant the exemption'.

1.6 It appears that the secretary's decision to grant or refuse to grant an exemption from the requirements in the instrument involves a high level of discretion. The grant or refusal of an exemption also has the potential to affect the interests of individuals seeking to export sheep to the Middle East during the prescribed period. Consequently, it appears to the committee that such decisions may generally be suitable for independent merits review.

1.7 However, the explanatory statement to the instrument states that decisions under subsection 13(1) will not be reviewable, because:

Decisions regarding exemptions from this instrument are based on whether animal health and welfare can be protected if an exemption is granted. The impact of such a decision is not limited to one applicant, and may affect the interests of the entire sheep export sector. As such, a decision to provide an exemption must be solely at the discretion of the Secretary in circumstances the Secretary considers appropriate.⁴

1.8 The committee acknowledges that exemption decisions are based on matters of animal health and welfare, and that such decisions have the potential to affect the sheep export sector as a whole. However, it is not clear to the committee that the reasons given in the explanatory statement reflect established grounds for

3 Scrutiny principle: Senate Standing Order 23(3)(c).

4 Explanatory statement, p. 8.

the exclusion of merits review.⁵ Further, in the committee's view, the fact that an exemption decision may affect the interests of the entire sheep export industry, rather than one applicant, may support the provision of independent merits review, to ensure decisions of the secretary are made appropriately. Accordingly, the committee considers that the explanatory statement does not provide sufficient information to establish that decisions relating to the grant of exemptions from requirements in the instrument possess characteristics that would justify their exclusion from independent merits review.

1.9 In this regard, the committee notes that it expressed the same concerns in relation to the Australian Meat and Live-stock Industry (Export of Sheep by Sea to Middle East) Order 2018 (previous instrument).⁶ In response to the committee's concerns, the minister advised that exemption decisions are not suitable for independent merits review because, due to the particular circumstances in which such decisions are made, there would be no appropriate remedy.⁷ The committee acknowledged that advice and stated that it would be appropriate for such information to be included in the explanatory statement.⁸ However, it does not appear that the explanatory statement to the previous instrument has been amended to include such information.

1.10 The committee requests the minister's advice as to whether the explanatory statement to the instrument will be amended to clarify that decisions made under section 14 of the instrument are not subject to merits review due to the lack of availability of an appropriate remedy.

1.11 The committee further requests that the explanatory statement to the Australian Meat and Live-stock Industry (Export of Sheep by Sea to Middle East) Order 2018 [F2018L01010] be amended to include the same information.

5 See Attorney-General's Department, Administrative Review Council, *What decisions should be subject to merit review?* (1999), <https://www.arc.ag.gov.au/Publications/Reports/Pages/Downloads/Whatdecisionsshouldbesubjecttomeritreview1999.aspx>.

6 [F2018L01010]. See Senate Standing Committee on Regulations and Ordinances, *Delegated Legislation Monitor 9 of 2018*, pp. 1-3.

7 Senate Standing Committee on Regulations and Ordinances, *Delegated Legislation Monitor 10 of 2018*, p. 42.

8 Senate Standing Committee on Regulations and Ordinances, *Delegated Legislation Monitor 10 of 2018*, p. 43.

Instrument	National Rental Affordability Scheme Amendment (Investor Protection) Regulations 2018 [F2018L01547]
Purpose	Enhances protections for investors in the National Rental Affordability Scheme
Authorising legislation	<i>National Rental Affordability Scheme Act 2008</i>
Portfolio	Social Services
Disallowance	15 sitting days after tabling (tabled Senate 12 November 2018). Notice of motion to disallow must be given by the third sitting day of 2019 ⁹

Privacy¹⁰

1.12 Scrutiny principle 23(3)(b) of the committee's terms of reference requires the committee to ensure that instruments of delegated legislation do not trespass unduly on personal rights and liberties, including the right to privacy.

1.13 Subsection 22D(2) of the National Rental Affordability Scheme Regulations 2008 (principal regulations) (inserted by item 14 of Schedule 1 to the instrument) provides that, in circumstances where a National Rental Affordability Scheme (NRAS) allocation is transferred from one approved participant to another, the first approved participant must give the second approved participant 'any information' that is 'requested by the Secretary' and 'relevant to the administration of the Scheme'.

1.14 Regarding the purpose of new section 22D, the explanatory statement explains that:

Following a transfer of an allocation, the gaining approved participant may have limited information about the allocation and the rental dwelling. Regulation 22D ensures that the gaining approved participant has all the relevant information required to meet their obligations under the Principal Regulations.¹¹

9 In the event of any change to the Senate's sitting days, the last day for the notice would change accordingly.

10 Scrutiny principle: Senate Standing Order 23(3)(b).

11 Explanatory statement, p. 9.

1.15 The statement of compatibility further explains that the disclosure of the information specified in new subsection 22D(2) of the instrument is necessary to enable the incoming approved participant 'to lodge a Statement of Compliance and claim the incentive for the rental property', if such an incentive is available under the principal regulations.¹²

1.16 The statement of compatibility also provides the following information regarding the potential impact of the disclosure requirements on privacy:

[T]his obligation does not adversely affect the right to privacy and reputation. The requirement to provide information does not expose the approved participant to a criminal offence or civil penalty if they fail to comply. The information that is required to be provided is information "relevant to the administration of the Scheme" and the type of information that would generally be provided to the Secretary every 12 months as part of the Statement of Compliance for the allocation.¹³

1.17 In this regard, the committee notes that the fact that a person is not subject to a criminal or civil penalty for failing to disclose information does not, of itself, address concerns about whether a particular measure will unduly trespass on a person's privacy.

1.18 Further, it remains unclear to the committee whether information 'relevant to the administration of the Scheme' could include personal information, and, if so, what safeguards are in place to protect the privacy of individuals who are required to disclose such information.

1.19 The committee requests the minister's advice as to whether information disclosed under new section 22D of the National Rental Affordability Scheme Regulations 2008 could include personal information; and, if so, what safeguards are in place to protect the personal privacy of individuals in relation to that information.

12 Statement of compatibility, p. 2.

13 Statement of compatibility, p. 2.

Instrument	<p>Vehicle Standard (Australian Design Rule 94/00 - Audible Warning) 2018 [F2018L01513]</p> <p>Vehicle Standard (Australian Design Rule 42/05 - General Safety Requirements) 2018 [F2018L01514]</p> <p>Vehicle Standard (Australian Design Rule 90/00 - Steering System) 2018 [F2018L01515]</p> <p>Vehicle Standard (Australian Design Rule 95/00 - Installation of Tyres) 2018 [F2018L01516]</p> <p>Vehicle Standard (Australian Design Rule 96/00 - Commercial Vehicle Tyres) 2018 [F2018L01517]</p> <p>Vehicle Standard (Australian Design Rule 23/03 - Passenger Car Tyres) 2018 [F2018L01518]</p> <p>Vehicle Standard (Australian Design Rule 91/00 - Rear Underrun Impact Protection) 2018 [F2018L01519]</p> <p>Vehicle Standard (Australian Design Rule 93/00 - Forward Field of View) 2018 [F2018L01521]</p>
Purpose	Set out standards for the design, construction and operation of vehicles supplied to the Australian market
Authorising legislation	<i>Motor Vehicle Standards Act 1989</i>
Portfolio	Infrastructure, Regional Development and Cities
Disallowance	15 sitting days after tabling (tabled Senate 12 November 2018). Notice of motion to disallow must be given by the third sitting day of 2019 ¹⁴

Incorporation¹⁵

1.20 The *Legislation Act 2003* (Legislation Act) provides that instruments may incorporate, by reference, part or all of Acts, legislative instruments and other documents as they exist at particular times. Paragraph 15J(2)(c) of the Legislation Act

14 In the event of any change to the Senate's sitting days, the last day for the notice would change accordingly.

15 Scrutiny principle: Senate Standing Order 23(3)(a).

requires the explanatory statement to a legislative instrument that incorporates a document to contain a description of that document and to indicate how it may be obtained.

1.21 The committee is concerned to ensure that every person interested in or affected by the law is able to readily access its terms, without cost. The committee therefore expects the explanatory statement to an instrument that incorporates one or more documents to provide a description of each incorporated document and to indicate where it can be readily and freely accessed. The committee's expectations in this regard are set out in its *Guideline on incorporation of documents*.¹⁶

1.22 With reference to these matters, the committee notes that the instruments appear to incorporate a number of documents, including UN resolutions, guidelines and manuals, the laws of foreign jurisdictions, and Australian and international standards. The explanatory statements indicate the manner in which the documents are incorporated (that is, either in force at a particular time or in force from time to time).¹⁷ Each explanatory statement also provides web addresses to where some of the incorporated documents (for example, UN resolutions and foreign laws) may be accessed free of charge. However, the explanatory statements also indicate that the standards incorporated by the instrument, as well as some of the other incorporated documents (for example, certain manuals) are only available for purchase. In this regard, the explanatory statement to Vehicle Standard (Australian Design Rule 42/05 – General Safety Requirements 2018¹⁸ (ADR 42/05) explains that:

ISO 1185:2003 and ISO 4000-1:2015 are available for purchase only through the International Organisation for Standardisation (ISO) and various associated national standards bodies. Vehicle manufacturers, component suppliers and test facilities routinely access these standards as part of their professional library.

The tyre and rim standards manuals/year books in clause 19 of this standard are available for purchase only through each respective regional or national tyre association. Vehicle manufacturers, tyre manufacturers

16 Regulations and Ordinances Committee, *Guideline on incorporation of documents*, http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Regulations_and_Ordinances/Guidelines/Guideline_on_incorporation_of_documents.

17 In this regard, the committee notes that section 7A of the *Motor Vehicle Standards Act 1989* (MVS Act) permits the incorporation of certain standards as in force from time to time. However, the explanatory statements to the instruments indicate that the incorporated standards are incorporated as in force at the time the instruments commence, in order to comply with the Legislation Act.

18 [F2018L01514].

and test facilities access these standards manuals as part of their professional library.¹⁹

1.23 Similar explanations are included in the explanatory statements to the other instruments.

1.24 The committee appreciates that key users of the instruments (for example, vehicle manufacturers and test facilities) are likely to have access to the incorporated standards as part of their professional libraries. However, the committee is also interested in the broader issue of access for other parties who might be affected by, or interested in, the law.

1.25 The issue of access to material incorporated into the law by reference to external documents, such as Australian and international standards, has been one of ongoing concern to Australian parliamentary scrutiny committees. In 2016 the Joint Standing Committee on Delegated Legislation of the Western Australian Parliament published a detailed report on this issue, comprehensively outlining the significant scrutiny concerns associated with the incorporation of standards by reference, particularly where the incorporated material is not freely available.²⁰

1.26 The committee's expectation, at a minimum, is that consideration be given to any means by which the document is or may be made available to interested or affected persons. This may be, for example, by noting availability through specific public libraries, or by making the document available for viewing on request. Consideration of this principle and details of any means of access identified or established should be reflected in the explanatory statement to the instrument.

1.27 The committee requests the minister's advice as to where the documents incorporated by the instruments may be accessed free of charge; and requests that the explanatory statements be amended to include this information.

19 Explanatory statement to Vehicle Standard (Australian Design Rule 42/05 – General Safety Requirements) 2018 [F2018L01514], p. 4.

20 Parliament of Western Australia, Joint Standing Committee on Delegated Legislation, Thirty-Ninth Parliament, Report 84, *Access to Australian Standards Adopted in Delegated Legislation* (June 2016) <http://www.parliament.wa.gov.au/parliament/commit.nsf/all/6BCDA79F24A4225648257E3C001DB33F?opendocument&tab=tab3>.

Further response required

1.28 The committee requests further explanation or information from relevant ministers with respect to the following concerns.

1.29 Correspondence relating to these matters is published on the committee's website.²¹

Instrument	CASA EX111/18 — English Language Proficiency Assessments Exemption 2018 [F2018L01214]
Purpose	Extends exemptions relating to certain English language proficiency requirements to 30 September 2021
Authorising legislation	<i>Civil Aviation Safety Regulations 1998</i>
Portfolio	Infrastructure, Regional Development and Cities
Disallowance	The time to give a notice of motion to disallow expired on 15 November 2018. Notice given on 15 November 2018 ²² Motion must be resolved by the seventh sitting day of 2019.

Parliamentary oversight: continuing exemption²³

1.30 In [Delegated Legislation Monitor 12 of 2018](#),²⁴ the committee requested the minister's advice as to:

- whether amendments to the Civil Aviation Safety Regulations are being considered to resolve the difficulties associated with English language proficiency assessments; and

21 See www.aph.gov.au/regords_monitor.

22 See Parliament of Australia, *Disallowance Alert 2018*, http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Regulations_and_Ordinances/Alerts.

23 Scrutiny principle: Senate Standing Order 23(3)(d).

24 Senate Standing Committee on Regulations and Ordinances, *Delegated Legislation Monitor 12 of 2018*, pp. 10-12.

- if not, the justification for continuing the exemptions to the Civil Aviation Safety Regulations.

Minister's response

1.31 The Minister for Infrastructure and Transport advised:

CASA has advised that it will address the difficulties associated with ELP assessments as soon as practicable during 2019.

Committee's response

1.32 The committee thanks the minister for this response, and notes the minister's advice that the Civil Aviation Safety Authority (CASA) intends to address the difficulties associated with the English language proficiency assessments as soon as practicable during 2019.

1.33 The committee has concluded its examination of this issue.

Merits review²⁵

1.34 In [Delegated Legislation Monitor 12 of 2018](#),²⁶ the committee requested the minister's advice as to:

- whether decisions by CASA to approve, or refuse to approve, a person to conduct English language proficiency assessments are subject to merits review; and
- if not, what characteristics of those decisions would justify excluding merits review.

Minister's response

1.35 The Minister for Infrastructure and Transport advised:

CASA also advised that it is unlikely that any decision to approve, or refuse to approve, a person to conduct ELP assessments under the exemption is reviewable by the Administrative Appeals Tribunal (AAT). The findings of "Seaview Lord Howe Pty Ltd and Another and Civil Aviation Authority (1995)", determined that decisions made under the Civil Aviation Order (CAO) had to be construed as decisions under the Civil Aviation Act 1988 (the Act), as the CAO was made under the Act. In light of this finding, the discretion to approve a person to conduct assessments of the

25 Scrutiny principle: Senate Standing Order 23(3)(c).

26 Senate Standing Committee on Regulations and Ordinances, *Delegated Legislation Monitor 12 of 2018*, pp. 10-12.

Aviation ELP or General ELP comprises a key aspect of the exemption, which itself is made under regulation 11.245 of the CASR, which is made under the Act. As the exemption is made under the regulations, but the decision about the approval is made under the exemption, it is therefore not reviewable.

The premise of the Committee's question assumes that by the making of the exemption, a decision to approve or to refuse to give an approval can be the subject of merits review. This is not the case, as stated in section 25(1) of the *Administrative Appeals Tribunal Act 1975*.

In the context of the aviation legislation, without an amendment to the Act or an instrument directly made under it, such as the CASR, the exemption cannot express that a decision made under it is reviewable by the AAT.

The exemption is beneficial to the aviation industry, as it expands the group of competent persons who are authorised to conduct the ELP assessment, in the context where there is a shortage. Without the exemption, the persons who can seek approval to conduct ELP, could not otherwise conduct ELP assessment. The absence of a formal merits review mechanism enables a person dissatisfied with CASA's approval decision to lodge a complaint with CASA's Industry Complaints Commissioner, who reports to CASA's Board.

Committee's response

1.36 The committee thanks the minister for this response, and notes the minister's advice that decisions by CASA to approve, or refuse to approve, a person to conduct English language proficiency assessments are unlikely to be reviewable by the Administrative Appeals Tribunal (AAT), because such decisions are made according to the instrument rather than the *Civil Aviation Act 1988* (CA Act).

1.37 The committee also notes the minister's advice that amendments to the CA Act or the instrument would be required for such decisions to be reviewable by the AAT, and the advice that persons dissatisfied with CASA's approval decision can make a complaint to CASA's Industry Complaints Commissioner (ICC).

1.38 The committee acknowledges that there is some uncertainty as to whether decisions to approve, or refuse to approve, a person to conduct English language proficiency assessments according to the exemption are subject to merits review. However, it appears to the committee that the AAT's decision in *Re Seaview Lord Howe Pty Ltd and Civil Aviation Authority* (1995) 38 ALD 422 (*Seaview*) (as referred to in the minister's response) supports merits review being available, rather than unavailable. In this respect, the committee notes that in *Seaview* Justice Mathews determined that decisions made under a Civil Aviation Order (CAO) should be treated as being made under the CA Act for the purposes of section 31(1)(a) of the CA Act,

because instruments made according to delegated powers are ultimately authorised by their empowering Act.²⁷ Consequently, it appears to the committee that the findings in *Seaview* suggest that a decision made according to the exemption would be subject to merits review by the AAT according to section 31 of the CA Act, because the decision is ultimately authorised by the CA Act.

1.39 It is also unclear to the committee why subsection 25(1) of the AAT Act would preclude merits review in relation to decisions made under the instrument. In this regard, the committee notes that subsection 25(1) of the AAT Act provides that:

An enactment may provide that applications may be made to the Tribunal:
(a) for review of decisions made in the exercise of powers conferred by that enactment.

1.40 Section 3 of the AAT Act relevantly defines 'enactment' to include 'an instrument (including rules, regulations or by-laws) made under an Act or under such an Ordinance'. Consequently, noting the AAT's findings in *Seaview*, it is not clear to the committee that the instrument could not include a provision that enables merits review of decisions to approve, or refuse to approve, a person to conduct English language proficiency assessments.

1.41 Where an instrument fails to provide for or excludes merits review, the committee expects the explanatory statement to expressly identify established grounds for excluding merits review, by reference to the Administrative Review Council's guidance document, *What decisions should be subject to merit review?*. The committee notes that no such grounds are identified in either the explanatory statement or the minister's response.

1.42 Finally, the committee notes that it does not consider complaint mechanisms such as the ICC to be an adequate substitute for independent merits review. In this respect, the committee notes that the ICC does not appear to be sufficiently independent of the primary decision-maker, as it reports to the CASA board. Moreover, unlike a tribunal conducting independent merits review, the ICC does not appear to have the power to set aside the decision under review and substitute a different decision.²⁸

1.43 In light of the discussion above, the committee requests the minister's further advice as to why decisions to approve, or refuse to approve, a person to conduct English language proficiency assessments should not be subject to independent merits review, by reference to the established grounds for excluding

27 (1995) 38 ALD 422, 425.

28 CASA, *CASA Industry Complaints Commissioner*, <https://www.casa.gov.au/about-us/standard-page/casa-industry-complaints-commissioner>.

review as set out in the Administrative Review Council's guidance document, *What decisions should be subject to merit review?*.

1.44 If no relevant ground for excluding independent merits review can be established, the committee requests the minister's advice as to the appropriateness of amending the instrument to explicitly provide for independent merits review.

Instrument	CASA 66/18 — Number of Cabin Attendants (Alliance Airlines) Direction 2018 [F2018L01244]
Purpose	Enables Alliance Airlines Pty Limited to continue operating designated aircraft with one cabin attendant for every 50 passenger seats or part of that number
Authorising legislation	<i>Civil Aviation Regulations 1988</i>
Portfolio	Infrastructure, Regional Development and Cities
Disallowance	The time to give a notice of motion to disallow expired on 15 November 2018. Notice given on 15 November 2018 ²⁹ Motion must be resolved by the seventh sitting day of 2019.

Merits review³⁰

1.45 In [Delegated Legislation Monitor 12 of 2018](#),³¹ the committee requested the minister's advice as to:

- whether decisions by the Civil Aviation Safety Authority to approve or refuse to approve revisions of Alliance Airlines' operations manual are subject to merits review; and
- if not, what characteristics of those decisions would justify excluding merits review.

29 See Parliament of Australia, *Disallowance Alert 2018*, http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Regulations_and_Ordinances/Alerts.

30 Scrutiny principle: Senate Standing Order 23(3)(c).

31 Senate Standing Committee on Regulations and Ordinances, *Delegated Legislation Monitor 12 of 2018*, pp. 15-16.

Minister's response

1.46 The Minister for Infrastructure and Transport advised:

Under regulation 208 of the Civil Aviation Regulations 1988 (CAR), CASA may give directions as to the operating crew required to be carried on an aircraft having regard to the safety of air navigation. It is unlikely that a decision to approve, or refuse to approve, a change to the operations manual affecting emergency procedures for the relevant aircraft, including procedures relating to able-bodied passengers is reviewable by the AAT, as per the previously referred findings of "Seaview Lord Howe Pty Ltd and Another and Civil Aviation Authority (1995)".

The premise of the Committee's question assumes that by the making of the exemption, a decision to approve or to refuse to give an approval can be the subject of merits review. This is not the case, as Section 25(1) of the Administrative Appeals Tribunal Act 1975 states.

Similarly to the ELP assessments, the cabin crew direction cannot express that a decision made under it is reviewable by the AAT. In the context of the cabin crew direction, scrutiny principle 23(3)(c) can only apply to the CAR and not a direction made under it.

The cabin crew direction is beneficial to the airline, as it reduces the number of cabin crew it has to carry. A critical aspect of the direction is that it was made based on the airline's procedures at the time it was issued, providing the airline with flexibility. The airline has not raised this matter as an issue and CASA has to date not refused to approve any changes to an airline's manual in this context. A person dissatisfied with CASA's approval decision may lodge a complaint with CASA's Industry Complaints Commissioner, who reports to CASA's Board.

Committee's response

1.47 The committee thanks the minister for this response. The committee notes the minister's advice that decisions by the Civil Aviation Safety Authority (CASA) to approve, or refuse to approve, a revision to Alliance Airlines' (Alliance) operations manual are unlikely to be reviewable by the Administrative Appeals Tribunal (AAT), because such decisions are made according to the instrument rather than the *Civil Aviation Act 1988* (CA Act).

1.48 The committee also notes the minister's advice that amendments to the CA Act or the instrument would be required for such decisions to be reviewable by the AAT, and the advice that persons dissatisfied with CASA's approval decision can make a complaint to CASA's Industry Complaints Commissioner (ICC).

1.49 The committee acknowledges that there is some uncertainty as to whether decisions to approve, or refuse to approve, a revision to Alliance's operations manual are subject to merits review. However, as outlined at [1.38], in light of the findings in

Re Seaview Lord Howe Pty Ltd and Civil Aviation Authority (1995) 38 ALD 422 it appears to the committee that decisions made under the present instrument should similarly be subject to independent merits review. Additionally, for the reasons outlined at [1.39]-[1.40], it appears that the present instrument could include a provision enabling merits review by the AAT. The committee emphasises in this regard that scrutiny principle 23(3)(c) allows the committee to consider whether an administrative decision made under *any* disallowable legislative instrument is subject to independent merits review.

1.50 Further, for the reasons outlined at [1.42] above, the committee does not consider the review by the ICC to be an adequate substitute for merits review.

1.51 Where an instrument fails to provide for or excludes merits review, the committee expects the explanatory statement to expressly identify established grounds for excluding merits review, by reference to the Administrative Review Council's guidance document, *What decisions should be subject to merit review?*. The committee notes that no such grounds are identified in either the explanatory statement or in the minister's response.

1.52 In light of the discussion above, the committee requests the minister's further advice as to why decisions to approve, or refuse to approve, a revision to Alliance Airlines' operations manual should not be subject to independent merits review, by reference to the established grounds for excluding review as set out in the Administrative Review Council's guidance document, *What decisions should be subject to merit review?*.

1.53 If no relevant ground for excluding independent merits review can be established, the committee requests the minister's advice as to the appropriateness of amending the instrument to explicitly provide for independent merits review.

Advice only

1.54 The committee draws the following matters to the attention of relevant ministers and instrument-makers on an advice only basis.

Instrument	Customs (Trans-Pacific Partnership Rules of Origin) Regulations 2018 [F2018L01468]
Purpose	Prescribes matters relating to rules of origin for the purpose of the the <i>Customs Act 1901</i>
Authorising legislation	<i>Customs Act 1901</i>
Portfolio	Home Affairs
Disallowance	15 sitting days after tabling (tabled Senate 12 November 2018) Notice of motion to disallow must be given by the third sitting day of 2019 ³²

Incorporation³³

1.55 The *Legislation Act 2003* (Legislation Act) provides that instruments may incorporate, by reference, part or all of Acts, legislative instruments and other documents as they exist at particular times. Paragraph 15J(2)(c) of the Legislation Act requires the explanatory statement to a legislative instrument that incorporates a document to contain a description of that document and to indicate how it may be obtained.

1.56 The committee is concerned to ensure that every person interested in or affected by the law is able to readily access its terms, without cost. The committee therefore expects the explanatory statement to an instrument that incorporates one or more documents to provide a description of each incorporated document and to

32 In the event of any change to the Senate's sitting days, the last day for the notice would change accordingly.

33 Scrutiny principle: Senate Standing Order 23(3)(a).

indicate where it can be readily and freely accessed. The committee's expectations in this regard are set out in its *Guideline on incorporation of documents*.³⁴

1.57 With reference to these matters, the committee notes that the instrument appears to incorporate the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (TPP-11).³⁵ The explanatory statement indicates that the TPP-11 is incorporated as in force from time to time.³⁶ However, neither the instrument nor its explanatory statement indicates where the TPP-11 may be accessed free of charge.

1.58 The committee notes that section 4 of the instrument states that 'Agreement' has the meaning given by section 153ZKU of the *Customs Act 1901*. That section provides a definition of 'Agreement', and indicates where the TPP-11 may be accessed free of charge.³⁷ Nevertheless, in the interests of promoting clarity and intelligibility for persons interested in or affected by the law, the committee considers that the explanatory statement to the instrument should expressly indicate where the TPP-11 may be accessed free of charge.

1.59 The committee draws to the minister's attention the lack of information in the explanatory statement regarding free access to the Comprehensive and Progressive Agreement for Trans-Pacific Partnership, which appears to be incorporated by the instrument.

34 Regulations and Ordinances Committee, *Guideline on incorporation of documents*, http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Regulations_and_Ordinances/Guidelines/Guideline_on_incorporation_of_documents.

35 In this regard, see paragraph 6(1)(a), subsections 9(1) and 10(2), and subparagraphs 13(b)(i) and 14(b)(l) of the instrument. The instrument refers to the TPP-11 as the 'Agreement'.

36 Explanatory statement, p. 5. The committee notes that section 153ZKU(5) appears to provide authority to incorporate the TPP-11 in this manner.

37 Section 153ZKU of the *Customs Act 1901* provides that the TPP-11 could in 2018 be viewed in the Australian Treaties Library (ATL), at <http://www.austlii.edu.au>. The committee notes that the ATL is accessible free of charge.

Instrument	Financial Sector (Collection of Data) (reporting standard) determination No. 42 of 2018 [F2018L01496]
Purpose	Determines Reporting Standard LRS 750.0 Claims and Disputes
Authorising legislation	<i>Financial Sector (Collection of Data) Act 2001</i>
Portfolio	Treasury
Disallowance	15 sitting days after tabling (tabled Senate 12 November 2018). Notice of motion to disallow must be given by the third sitting day of 2019 ³⁸

Merits review³⁹

1.60 Scrutiny principle 23(3)(c) of the committee's terms of reference requires the committee to ensure that instruments do not unduly make the rights and liberties of citizens dependent on administrative decisions which are not subject to review of their merits by a judicial or other independent tribunal.

1.61 Section 13 of the instrument provides that the Australian Prudential Regulation Authority (APRA) may, by notice in writing, change the reporting periods or specify a reporting period for a company carrying on life insurance business in Australia ('life companies'), having regard to the particular circumstances of that company.

1.62 APRA's decision to change the reporting periods or specify a reporting period for a life company appears to involve at least an element of discretion, and may affect the interests of the life company. Consequently, it appears to the committee that such decisions under section 13 of the instrument may be suitable for independent merits review. However, neither the instrument nor the explanatory statement indicates whether decisions under this section are reviewable.

1.63 The committee notes that Part 3A of the *Financial Sector (Collection of Data) Act 2001* provides for independent merits review of 'reviewable decisions'. Section 31 of that Act defines 'reviewable decisions' to include decisions to determine a reporting standard for a particular financial sector entity. Consequently,

38 In the event of any change to the Senate's sitting days, the last day for the notice would change accordingly.

39 Scrutiny principle: Senate Standing Order 23(3)(c).

it appears to the committee that decisions under section 13 of the instrument may be reviewable.

1.64 However, the committee considers that, as a matter of best practice, an instrument or the explanatory statement to the instrument should state whether decisions are subject to independent merits review, and, if so, which provisions provide for review.

1.65 The committee draws to the attention of the minister the lack of information in the instrument and explanatory statement about the availability of independent merits review of decisions made under section 13 of the instrument.

Instrument	Health Insurance Legislation Amendment (2018 Measures No. 3) Regulations 2018 [F2018L01481]
Purpose	Implements the government's response to recommendations from the Medical Services Advisory Committee and the clinician-led Medicare Benefits Schedule Review Taskforce
Authorising legislation	<i>Health Insurance Act 1973</i>
Portfolio	Health
Disallowance	15 sitting days after tabling (tabled Senate 12 November 2018). Notice of motion to disallow must be given by the third sitting day of 2019 ⁴⁰

Incorporation⁴¹

1.66 The *Legislation Act 2003* (Legislation Act) provides that instruments may incorporate, by reference, part or all of Acts, legislative instruments and other documents as they exist at particular times. Paragraph 15J(2)(c) of the Legislation Act requires the explanatory statement to a legislative instrument that incorporates a document to contain a description of that document and to indicate how it may be obtained.

1.67 The committee is concerned to ensure that every person interested in or affected by the law is able to readily access its terms, without cost. The committee therefore expects the explanatory statement to an instrument that incorporates one

40 In the event of any change to the Senate's sitting days, the last day for the notice would change accordingly.

41 Scrutiny principle: Senate Standing Order 23(3)(a).

or more documents to provide a description of each incorporated document and to indicate where it can be readily and freely accessed. The committee's expectations in this regard are set out in its *Guideline on incorporation of documents*.⁴²

1.68 With reference to these matters, the committee notes that the instrument appears to incorporate the following documents:

- the *Berlin Questionnaire*,⁴³ and
- the *OSA50 screening questionnaire*.⁴⁴

1.69 The instrument indicates that the documents are incorporated as existing on 1 November 2018. However, neither the instrument nor its explanatory statement indicates where the documents may be accessed free of charge.

1.70 The committee secretariat's research indicates that each of the documents appears to be freely available online.⁴⁵ The committee also notes that, where other documents are incorporated by the instrument, the instrument or the explanatory statement indicates both the manner in which the document is incorporated and where it may be accessed free of charge. This suggests that the failure to include information as to where the *Berlin Questionnaire* and the *OSA50 screening questionnaire* may be accessed may have been due to an administrative oversight.

1.71 Nevertheless, the Legislation Act requires the explanatory statement to an instrument to contain a description of any incorporated document and to indicate how it may be obtained. The committee would therefore expect the explanatory statement to indicate how the *Berlin Questionnaire* and the *OSA50 screening questionnaire* may be obtained free of charge.

1.72 The committee draws the minister's attention to the absence of information in the explanatory statement regarding free access to the *Berlin Questionnaire* and the *OSA50 screening questionnaire*, which appear to be incorporated by the instrument.

42 Regulations and Ordinances Committee, *Guideline on incorporation of documents*, http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Regulations_and_Ordinances/Guidelines/Guideline_on_incorporation_of_documents.

43 Item 22, section 2.35.2A.

44 Item 22, section 2.25.2C.

45 For the *Berlin Questionnaire*, see <https://www.sleepapnea.org/wp-content/uploads/2017/02/berlin-questionnaire.pdf>. For the *OSA50 screening questionnaire*, see <http://www.climsleep.com/wp-content/uploads/2018/11/OSA-50-Screening-Questionnaire.pdf>.

Instrument	National Health (Immunisation Program – Designated Vaccines) Variation Determination (No. 4) 2018 [F2018L01530]
Purpose	Revises the circumstances in which two listed vaccines can be provided under the National Immunisation Program (NIP)
Authorising legislation	<i>National Health Act 1953</i>
Portfolio	Health
Disallowance	15 sitting days after tabling (tabled Senate 12 November 2018). Notice of motion to disallow must be given by the third sitting day of 2019 ⁴⁶

Consultation⁴⁷

1.73 Section 17 of the *Legislation Act 2003* (Legislation Act) provides that, before a legislative instrument is made, the rule-maker must be satisfied that there has been undertaken any consultation in relation to the instrument that is considered by the rule-maker to be appropriate, and reasonably practicable to undertake.

1.74 Under paragraphs 15J(2)(d) and (e) of the Legislation Act, the explanatory statement to an instrument must either contain a description of the nature of any consultation that has been carried out in accordance with section 17 or, if there has been no consultation, explain why no such consultation was undertaken. The committee's expectations in this regard are set out in its *Guideline on consultation*.⁴⁸

1.75 The explanatory statement to the instrument explains:

The Office of Best Practice Regulation has advised that regulatory amendments that update the listing of vaccines on the NIP and their associated price to be machinery in nature. Therefore it has been determined that further consultation is unnecessary.⁴⁹

46 In the event of any change to the Senate's sitting days, the last day for the notice would change accordingly.

47 Scrutiny principle: Senate Standing Order 23(3)(a).

48 Regulations and Ordinances Committee, *Guideline on consultation*, http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Regulations_and_Ordinances/Guidelines/consultation.

49 Explanatory statement, p. 2.

1.76 In this regard, the committee notes that the Office of Best Practice Regulation's requirements are separate to the requirements of the Legislation Act in relation to consultation. As set out in the committee's *Guideline on consultation*:

[A]lthough a RIS [regulatory impact statement] may not be required in relation to a certain instrument, the requirements of the Act regarding a description of the nature of consultation undertaken, or an explanation of why consultation has not occurred, must still be met.

1.77 The committee draws to the attention of the minister the apparent conflation of the requirements prescribed by the *Legislation Act 2003* and the Office of Best Practice Regulation regarding consultation in the explanatory statement.

Chapter 2

Concluded matters

2.1 This chapter sets out matters which have been concluded following the receipt of additional information from ministers.

2.2 Correspondence relating to these matters is available on the committee's website.¹

Instrument	Australian National Maritime Museum Regulations 2018 [F2018L01294]
Purpose	Provides for a range of matters relating to the Australian National Maritime Museum, including financial limits for the disposal of material, security arrangements and offences to protect the museum, and rules for the service of liquor
Authorising legislation	<i>Australian National Maritime Museum Act 1990</i>
Portfolio	Communications and the Arts
Disallowance	15 sitting days after tabling (tabled Senate 19 September 2018). Notice of motion to disallow must be given by 4 December 2018 ²

Merits review³

2.3 In [Delegated Legislation Monitor 13 of 2018](#),⁴ the committee sought the minister's advice as to the appropriateness of amending the instrument as soon as possible to provide for independent merits review of decisions made under section 14 of the instrument, and sought the minister's advice in relation to this matter.

1 See www.aph.gov.au/regords_monitor.

2 In the event of any change to the Senate's sitting days, the last day for the notice would change accordingly.

3 Scrutiny principle: Senate Standing Order 23(3)(c).

4 Senate Standing Committee on Regulations and Ordinances, *Delegated Legislation Monitor 13 of 2018*, pp. 39-46.

Minister's response

2.4 The Minister for Communications and the Arts advised:

I note in the committee's response that it considers it appropriate for decisions under section 14 of the instrument to be subject to an independent merits review because it remains possible that a person may be repeatedly prohibited from entering the premises by decisions made under this section. I will undertake, in 2019, to amend the instrument to include a provision that will subject decisions made under section 14 to an independent merits review by the Administrative Appeals Tribunal. I have instructed my Department to commence the process of amending the instrument at the earliest possible opportunity.

The Australian National Maritime Museum (the Museum) has advised that in the meantime, should any written complaints be received regarding decisions made under section 14 they will be considered by the Museum Director, and appropriate action taken.

Committee's response

2.5 The committee thanks the minister for this response and welcomes the minister's advice that he has instructed the department to commence the process of amending the instrument at the earliest possible opportunity to provide for independent merits review in relation to decisions made under section 14 of the instrument, in response to the committee's concerns.

2.6 The committee has concluded its examination of the instrument.

Instrument	CASA EX122/18 — Flight in Class D Airspace near Sunshine Coast Aerodrome (Sunshine Coast Sports Aviators) Instrument 2018 [F2018L01278]
Purpose	Permits members of Sunshine Coast Sports Aviators Inc. to operate hang-gliders and paragliders from sites near Port Cartwright, Queensland
Authorising legislation	<i>Civil Aviation Safety Regulations 1998</i>
Portfolio	Infrastructure, Regional Development and Cities
Disallowance	15 sitting days after tabling (tabled Senate 13 September 2018). Notice of motion to disallow must be given by 28 November 2018 ⁵

5 In the event of any change to the Senate's sitting days, the last day for the notice would change accordingly.

Incorporation⁶

2.7 In [Delegated Legislation Monitor 12 of 2018](#),⁷ the committee requested the minister's advice as to the manner in which the Letter of Agreement (LoA) between Airservices Australia and Sunshine Coast Aviators is incorporated; and requests that the explanatory statement be amended to include this information.

Minister's response

2.8 The Minister for Infrastructure and Transport advised:

CASA has advised that the instrument in Section 3 defines the LoA in general terms and includes a note pointing to the current LoA that does not purport to describe the manner of incorporation. However, paragraph 5(c) imposes a condition for a pilot to comply with the LoA that is in effect at the time of the relevant operation, which creates a 'from time to time' manner of incorporation, which is articulated in the Explanatory Statement.

Further to this, the power for the instrument to incorporate a document that does not yet exist, such as a future LoA, is expressly contemplated in Section 98(5D) of the Act. On this basis, CASA proposes to leave the Explanatory Statement unamended.

Committee's response

2.9 The committee thanks the minister for this response, and notes the minister's advice that the LoA is incorporated as in force from time to time. The committee notes the advice that this is evidenced by paragraph 5(c) of the instrument, which requires a pilot to comply with the LoA that is in effect at the time of the relevant operation.

2.10 The committee further notes the minister's advice that a power to incorporate documents as in force from time to time, including documents that do not yet exist, appears in subsection 98(5D) of the *Civil Aviation Act 1988*.

2.11 Finally, the committee notes the minister's advice that the Civil Aviation Safety Authority (CASA) proposes to leave the explanatory statement unamended. While noting this advice, the committee remains concerned that the manner in which the LoA is incorporated may not be immediately clear in view of the fact that the note to section 3 of the instrument refers to a particular version of the LoA (that is, version 2, dated 26 February 2015), which may suggest that the LoA is incorporated as in force at a particular date.

2.12 Consequently, the committee considers that it would be appropriate for the explanatory statement to be amended to fully clarify the manner in which the LoA is

6 Scrutiny principle: Senate Standing Order 23(3)(a).

7 Senate Standing Committee on Regulations and Ordinances, *Delegated Legislation Monitor 12 of 2018*, pp. 13-14.

incorporated, so as to ensure clarity and intelligibility for persons interested in or affected by the law.

2.13 The committee has concluded its examination of the instrument.

Instrument	<p>Marine Navigation Levy Regulations 2018 [F2018L01298]</p> <p>Marine Navigation Levy Collection Regulations 2018 [F2018L01300]</p> <p>Marine Navigation (Regulatory Functions) Levy Regulations 2018 [F2018L01301]</p> <p>Marine Navigation (Regulatory Functions) Levy Collection Regulations 2018 [F2018L01302]</p>
Purpose	Set amounts of maritime industry levies, and prescribe how those levies are to be collected
Authorising legislation	<p>[F2018L01298]: <i>Marine Navigation Levy Act 1989</i></p> <p>[F2018L01300]: <i>Marine Navigation Levy Collection Act 1989</i></p> <p>[F2018L01301]: <i>Marine Navigation (Regulatory Functions) Levy Act 1991</i></p> <p>[F2018L01302]: <i>Marine Navigation (Regulatory Functions) Levy Collection Act 1991</i></p>
Portfolio	Infrastructure, Regional Development and Cities
Disallowance	15 sitting days after tabling (tabled Senate 20 September 2018). Notice of motion to disallow must be given by 5 December 2018 ⁸

No explanatory statement⁹

2.14 In [Delegated Legislation Monitor 12 of 2018](#),¹⁰ the committee requested the minister's advice as to why the explanatory statements to these instruments had not been registered on the Federal Register of Legislation, and requested that the explanatory statements be registered in accordance with paragraph 15G(4)(a) of the *Legislation Act 2003*.

8 In the event of any change to the Senate's sitting days, the last day for the notice would change accordingly.

9 Scrutiny principle: Senate Standing Order 23(3)(a).

10 Senate Standing Committee on Regulations and Ordinances, *Delegated Legislation Monitor 12 of 2018*, pp. 15-16.

Minister's response

The Minister for Infrastructure and Transport advised:

I can confirm that I approved Explanatory Statements for these instruments on 20 August 2018. These instruments were considered on 13 September 2018, by the Federal Executive Council, signed by the Governor General, His Excellency General the Honourable Sir Peter Cosgrove AK MC (Retd), and lodged on the Federal Register of Legislation by the Department. The Explanatory Statements to these instruments appear not [to] have been published successfully at this time due to an administrative or technical error or oversight.

As requested by the Committee and in accordance with paragraph 15G(4)(a) of the *Legislation Act 2003*, the Department has resubmitted Explanatory Statements for registration, which have now been published.

I will ensure a written statement explaining the lateness of lodgement is delivered to each House of the Parliament in accordance with subsection 39(3) of the *Legislation Act 2003*. The Department is currently preparing a statement for my consideration.

Committee's response

2.15 The committee thanks the minister for this response, and notes that the replacement explanatory statements have now been registered on the Federal Register of Legislation.

2.16 The committee further notes the minister's advice that the department is currently preparing a written statement explaining the lateness of the lodgement, and the minister will ensure that the statement is delivered to each House of the Parliament in accordance with subsection 39(3) of the *Legislation Act 2003*.

2.17 The committee has concluded its examination of the instrument.

Instrument	Therapeutic Goods Legislation Amendment (2018 Measure No. 3) Regulations 2018 [F2018L01434]
Purpose	Amends the Therapeutic Goods Regulations 1990 to reduce regulatory burden for hard surface disinfectants, and to lower the application fee for marketing approval applications for export only Class 1 medical devices
Authorising legislation	<i>Therapeutic Goods Act 1989</i>
Portfolio	Health
Disallowance	15 sitting days after tabling (tabled Senate 17 October 2018). Notice of motion to disallow must be given by the second sitting day of 2019 ¹¹

Unclear basis for determining fees¹²

2.18 In [Delegated Legislation Monitor 13 of 2018](#),¹³ the committee requested the minister's advice as to the basis on which the application fees in paragraphs (a) to (e), (g) and (h) in item 1 of Schedule 1 have been calculated.

Minister's response

2.19 The Minister for Health advised:

Those Australian fees relate to applications to include specified kinds of medical devices in the Australian Register of Therapeutic Goods (the Register), and were included in the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Medical Devices Regulations) before the making of the Amendment Regulations.

The purpose of item 1 of Schedule 1 to the Amendment Regulations was to introduce a new application fee for Class 1 medical devices intended by their manufacturer to be for export only. In doing so, the Amendment Regulations repealed and substituted the whole of item 1.5, including replicating the existing fees (with some minor renumbering, for greater clarity (see compilation No. 37 of the Medical Devices Regulations [F2018C00490] at <https://www.legislation.gov.au/Details/F2018C00490>).

11 In the event of any change to the Senate's sitting days, the last day for the notice would change accordingly.

12 Scrutiny principle: Senate Standing Order 23(3)(a).

13 Senate Standing Committee on Regulations and Ordinances, *Delegated Legislation Monitor 13 of 2018*, pp. 37-38.

The fees in paragraphs (a) – (e) and (h) of item 1 reflect the effort involved for staff of my Department's Medical Devices Branch in processing and verifying such applications. The fee in paragraph (g) of item 1 reflects both the cost of maintaining software used to process applications to include Class 1 medical devices (other than Class 1 devices intended by their manufacturer to be for export only or that are supplied in a sterile state or that have a measuring function) in the Register, and the efforts of staff of the Medical Devices Branch in verifying the information provided by applicants for such products.

Committee's response

2.20 The committee thanks the minister for this response, and notes the minister's advice that the fees in paragraphs (a) to (e) and (h) of item 1 of Schedule 1 to the instrument are intended to cover the costs of processing and verifying applications for medical devices to be included on the Australian Register of Therapeutic Goods (the Register).

2.21 The committee also notes the minister's advice that the fee in paragraph (g) of item 1 of Schedule 1 to the instrument reflects both the cost of maintaining the software used to process applications to include certain Class 1 medical devices on the Register, and the costs associated with the process of verifying information in such applications.

2.22 The committee considers that this information would have been useful in the explanatory statement.

2.23 The committee has concluded its examination of the instrument.

Senator John Williams (Chair)