**Legislation (Exemptions and Other Matters) Amendment   
(2018 Measures No. 2) Regulations 2018**

**EXPLANATORY STATEMENT**

Issued under the Authority of the Attorney‑General

**OUTLINE**

The *Legislation Act 2003* (the Legislation Act) establishes a comprehensive regime for the publication of Commonwealth Acts and instruments. It also provides for the registration, tabling, parliamentary scrutiny and sunsetting (automatic repeal) of Commonwealth legislative instruments, and establishes an authoritative, complete and accessible register of those instruments, including compilations and explanatory statements.

Section 62 of the Legislation Actprovides the Governor-General with the power to make regulations prescribing matters required or permitted by that Act to be prescribed, or necessary or convenient to be prescribed, for carrying out or giving effect to that Act.

Subsections 44(2) and 54(2) of the Legislation Act provide that instruments prescribed by regulation for the purposes of paragraphs 44(2)(b) and 54(2)(b) are not subject to disallowance and sunsetting respectively. Paragraph 8(6)(b) of the Legislation Act provides that instruments prescribed by regulation for the purposes of that paragraph are not legislative instruments.

The *Legislation (Exemptions and Other Matters) Regulation 2015* (the Principal Regulation), made under section 62 of the Legislation Act, sets out exemptions from legislative instrument status, disallowance by the Parliament and sunsetting for instrument classes and particular instruments.

Schedule 1 to these Regulations amends the Principal Regulation to provide for, and clarify, exemptions from sunsetting for particular instruments. These instruments are the *Retirement Savings Accounts Regulations 1997*, the *Superannuation Industry (Supervision) Regulations 1994*, the *Therapeutic Goods Regulations 1990*, the *Therapeutic Goods (Medical Devices) Regulations 2002*, and particularinstruments made under the *Torres* *Strait Fisheries Act 1984.*

The Legislation Act does not specify any conditions that must be fulfilled before the power to make these Regulations may be exercised.

However, it is well-established practice that an assessment of whether it is appropriate to exempt an instrument from sunsetting is conducted on the basis of the following five criteria:

* the rule-maker has been given a statutory role independent of the Government, or is operating in competition with the private sector;
* the instrument is designed to be enduring and not subject to regular review;
* commercial certainty would be undermined by sunsetting;
* the instrument is part of an intergovernmental scheme; or
* the instrument is subject to a more rigorous statutory review process.

Additionally, the 2017 *Report on the Operation of the Sunsetting Provisions in the Legislation Act 2003* recommended that the policy criteria justifying the granting of exemptions from sunsetting should be expanded to include circumstances where all the following criteria apply:

* the instrument is sufficiently large and complex that the administrative burden associated with remaking the instrument would outweigh any regulatory benefit,
* the instrument is subject to regular review, and
* the instrument is subject to regular amendment.

This is consistent with the purpose of sunsetting, which is to ensure that legislative instruments are kept up to date and continue to be fit-for-purpose.

Each sunsetting exemption made by these Regulations was analysed against the above criteria and found to be not suitable for regular review under Part 4 of Chapter 3 of the Legislation Act.

Further information is provided at Attachment A.

**PROCESSES FOR REVIEW OF THESE REGULATIONS**

These Regulations are subject to tabling and disallowance under Part 2 of Chapter 3 of the Legislation Act, and will cease as if repealed on the day after the last of its provisions commence.

**Regulatory impact analysis**

Before the Principal Regulation was made, its expected impact was assessed using the Preliminary Assessment tool approved by the Office of Best Practice Regulation (OBPR). That assessment indicated that it will have no or low impact on business, individuals and the economy. This assessment has been confirmed by the OBPR and granted a standing exemption from Regulatory impact analysis requirements (OBPR reference 17635).

**Statement of compatibility with human rights obligations**

Before these Regulations were made, their impact on human rights was assessed using tools and guidance published by the Attorney‑General’s Department. These Regulations will make technical amendments to the Principal Regulation which will have no impact on the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. These Regulations are compatible with human rights as they do not raise any human rights issues.

**Consultation before making**

Before these Regulations were made, the Attorney-General considered the general obligation to consult imposed by section 17 of the Legislation Act. The Attorney-General was satisfied that consultation was appropriate and reasonably practicable to be undertaken*.* The exemptions were requested by the Minister for Revenue and Financial Services, the Minister for Health, and the Assistant Minister for Agriculture and Water Resources. Each of the Ministers provided information to the Attorney-General to enable analysis of their request.

The following agencies were consulted on the Regulations: the Treasury, the Australian Taxation Office, the Department of Health (including the Therapeutic Goods Administration), the Department of Agriculture and Water Resources and the Australian Fisheries Management Authority.

**OTHER ISSUES**

**Matter incorporated by reference**

These Regulations do not apply, adopt or incorporate other matters by reference.

**More information**

An explanation of the provisions of, and the Schedule to, these Regulations is provided in Attachment A.

**ATTACHMENT A**

**NOTES ON PROVISIONS AND SCHEDULES**

**Section 1 Name**

This section provides that the title of these Regulations is the *Legislation (Exemptions and Other Matters) Amendment (2018 Measures No. 2) Regulations 2018*.

**Section 2 Commencement**

This section provides for the whole of the Regulations to commence on the day after it is registered on the Federal Register of Legislation.

**Section 3 Authority**

This section provides that the Regulations are made under the *Legislation* *Act 2003*.

**Section 4 Schedules**

This section provides that each instrument that is specified in a Schedule to the Regulations is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to the Regulations has effect according to its terms.

**Schedule 1 Amendments**

Schedule 1 to the Regulations amends section 12 of the *Legislation (Exemptions and Other Matters) Regulation 2015* (the Principal Regulation) to insert new exemptions from sunsetting. Section 12 provides for particular instruments that are not subject to sunsetting.

**Items 1 and 2** insert new items 56B and 59A into the table under section 12 of the Principal Regulation.

New item 56B provides an exemption from sunsetting for the *Retirement Savings Accounts Regulations 1997* (the RSA Regulations). The RSA Regulations are made under section 200 of the *Retirement Savings Accounts Act 1997* (the RSA Act). The RSA Act provides for retirement savings accounts to be offered by certain financial institutions, the approval process for entities that can offer such accounts and the supervision of these entities*.* The RSA Regulations prescribe the operation of a number of the fundamental building blocks essential to the effective operation of the retirement savings accounts superannuation structure.

New item 59A provides an exemption from sunsetting for the *Superannuation Industry (Supervision) Regulations 1994* (the SIS Regulations). The SIS Regulations are made under section 353 of the *Superannuation Industry (Supervision) Act 1993* (the SIS Act). The SIS Act provides for the prudent management of certain superannuation funds, approved deposit funds and pooled superannuation trusts, and for their supervision by the Australian Prudential Regulation Authority (APRA), the Australian Securities and Investment Commission (ASIC) and the Commissioner of Taxation*.* The SIS Regulations prescribe the operation of the fundamental building blocks essential to the effective operation of the superannuation system.

The RSA Regulations and the SIS Regulations are substantial, at 143 pages and 398 pages respectively, as of June 2018. They are also complex, with both instruments having considerable interactions with numerous other legislative instruments, including instruments directly regulating the superannuation industry and instruments in areas such as social security and family law. The RSA Regulations are referenced in four primary Acts and eight Regulations. The SIS Regulations are referenced in eight primary Acts and 81 Regulations.

The process of remaking the RSA Regulations and the SIS Regulations would impose a considerable demand on the resources of the Treasury and the Office of Parliamentary Counsel over an extended period. To identify and amend all the consequential interactions and cross-references would add significantly to the complexity of such a project. Such a volume of work would have to be split into multiple parts and occur over the course of a number of years, and would necessitate extensive stakeholder input and consultation. The administrative burden associated with such a project would outweigh any regulatory benefit.

Further, the regulation of superannuation is already subject to ongoing review and amendment. The need to balance a stable framework of superannuation regulation and the need to update the RSA Regulations and the SIS Regulations has been struck by reforming discrete sections of the regulations on a thematic basis. These amendments have been supported by extensive consultation and often have followed a public review. This approach ensures that there is strong stakeholder engagement in the process and enables stakeholders to more easily adapt to the change as the reforms are limited to a particular set of issues each time.

The various reviews undertaken and new initiatives in superannuation have resulted in numerous amendments to the RSA Regulations and the SIS Regulations since their commencement. The RSA Regulations have been amended all but one year since 1997 by 62 amending instruments. The SIS Regulations have been amended every year since 1994 by 133 amending instruments. These amendments have been subject to parliamentary scrutiny.

The complex and evolving nature of the financial services industry, combined with the size and significance of the superannuation industry, indicates that the RSA Regulations and the SIS Regulations will continue to be the subject of regular review and amendment into the future. This will ensure that the RSA Regulations and the SIS Regulations remain up to date and continue to be fit-for-purpose.

Accordingly, it is appropriate to exempt the RSA Regulations and the SIS Regulations from sunsetting as they are subject to regular review and amendment, and are sufficiently large and complex such that the administrative burden associated with remaking them would outweigh any regulatory benefit.

**Item 3** inserts new items 63AA and 63AB into the table under section 12 of the Principal Regulation.

Item 63AA

New items 63AA(a) and (b) provide exemptions from sunsetting for the *Therapeutic Goods Regulations 1990* (the Therapeutic Goods Regulations) and the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Medical Devices Regulations), respectively. The Therapeutic Goods Regulations and the Medical Devices Regulations are both made under section 63 of the *Therapeutic Goods Act 1989* (the Therapeutic Goods Act). The objects of the Therapeutic Goods Act are to:

* establish and maintain a national system of controls for the quality, safety, efficacy/performance and timely availability of therapeutic goods used in, or exported from, Australia, and
* provide a framework for the States and Territories to adapt a uniform approach to control the availability and accessibility, and ensure the safe handling, of poisons in Australia.

The Therapeutic Goods Regulations and the Medical Devices Regulations expand or qualify specific measures contained in the Therapeutic Goods Act and within the parameters set by that Act. This allows more flexibility and specificity in the regulatory scheme for therapeutic goods to ensure that the objects of the Act are practically achievable.

The Therapeutic Goods Act, the Therapeutic Goods Regulations and the Medical Devices Regulations are part of a uniform national regulatory scheme for therapeutic goods. This cooperative scheme was developed following agreement in 1991 by the Australian Health Ministers Advisory Council to develop a comprehensive national system to regulate therapeutic goods. This agreement was developed to address the regulatory gap with respect to sole traders engaged in intrastate trade and commerce.

The uniform national regulatory scheme is an applied law scheme in which the Commonwealth is the host jurisdiction. The Therapeutic Goods Act, the Therapeutic Goods Regulations and the Medical Devices Regulations are applied, as amended from time to time, in each State and Territory, with the exception of Western Australia and Queensland, as law of that jurisdiction. This occurs under the following provisions:

* sections 4 and 31 of the *Poisons and Therapeutic Goods Act 1966* (NSW)
* sections 3 and 6 of the *Therapeutic Goods (Victoria) Act 2010* (VIC)
* sections 4 and 11Aof the *Controlled Substances Act 1984* (SA)
* sections 3 and 6 of the *Therapeutic Goods Act 2001* (TAS)
* sections 156 and 157 of the *Medicines, Poisons and Therapeutic Goods Act 2008* (ACT), and
* sections 5, 228, 230 and 231 of the *Medicines, Poisons and Therapeutic Goods Act* (NT).

The scheme is designed such that each time the Therapeutic Goods Act, the Therapeutic Goods Regulations or the Medical Devices Regulations are amended, the amendments apply automatically in the participating States and Territories. This ensures that there is no regulatory gap in relation to non-constitutional corporations engaged in intrastate trade and commerce related to therapeutic goods and that there is uniformity of regulation among the participating States and Territories.

The Therapeutic Goods Administration, which is part of the Commonwealth Department of Health, engages as appropriate with State and Territory Health bodies in relation to proposed amendments to the Therapeutic Goods Act, the Therapeutic Goods Regulations and the Medical Devices Regulations. For example, this may include engaging with State and Territory Health Departments, State and Territory public hospitals, or State and Territory members of the Inter-Jurisdictional Committee of the Australian Commission on Safety and Quality in Health Care. Such collaboration enhances the effective operation of the uniform national regulatory scheme.

Accordingly, as the Therapeutic Goods Regulations and the Medical Devices Regulations are part of an intergovernmental scheme, under which it was agreed that the instruments would apply automatically in participating States and Territories to address a regulatory gap, it would be inappropriate for the Commonwealth to unilaterally sunset the instruments and an exemption from sunsetting is appropriate.

Item 63AB

Item 63AB provides exemptions from sunsetting for particular instruments made under the *Torres Strait Fisheries Act 1984* (the Torres Strait Act). The exemptions are justified on the basis that the instruments are part of intergovernmental schemes, being either the Protected Zone Joint Authority established under the Torres Strait Act, or the *Treaty between Australia and the Independent State of Papua New Guinea concerning sovereignty and maritime boundaries in the area between the two countries, including the area known as the Torres Strait, and related matters* (the Torres Strait Treaty), which is given effect under Australian domestic law by way of the Torres Strait Act. Further detail in relation to each exemption is provided below.

Paragraph 63AB(a)

New paragraph 63AB(a) provides an exemption from sunsetting for declarations made under subsection 3(3) of the Torres Strait Act. There are currently two declarations made under this provision:

* *Declaration of adjacent coastal area of Papua New Guinea*, and
* *Declaration of adjacent coastal area of Australia*.

Declarations made by the Minister under paragraphs 3(3)(a) and (b) of the Torres Strait Act provide, for the purposes of that Act, a consistent interpretation of the phrase ‘traditional inhabitants’ as used in the Torres Strait Treaty. Article 1.1(m) of the Torres Strait Treaty defines ‘traditional inhabitant’ in relation to Australia as ‘persons who… live in the Protected Zone or the adjacent coastal area of Australia’. The article further defines ‘traditional inhabitant’ in relation to Papua New Guinea as ‘persons who… live in the Protected Zone or the adjacent coastal area of Papua New Guinea’. Section 3 of the Torres Strait Act provides that ‘traditional inhabitant’ in that Act means ‘a person covered by the definition of ***traditional inhabitants*** in Article 1 of the Torres Strait Treaty’ (emphasis original). Declarations made by the Minister under paragraphs 3(3)(a) and (b) of the Torres Strait Act declare a particular area to be the ‘adjacent coastal area’ of Papua New Guinea or Australia, respectively, for the purpose of defining ‘traditional inhabitant’ in the Torres Strait Act.

The Torres Strait Treaty was developed by Papua New Guinea and Australia to provide a framework for the management of the border area between the two countries. It obliges Papua New Guinea and Australia to permit traditional inhabitants of the other country ‘free movement and the performance of lawful traditional activities in, and in the vicinity of, the Protected Zone’. Declarations made under paragraphs 3(3)(a) and (b) of the Torres Strait Act give effect to Australia’s obligations under the Torres Strait Treaty.

As such, instruments made under this power are part of the intergovernmental scheme between Australia and Papua New Guinea, as established by the Torres Strait Treaty, and it would be inappropriate for the Commonwealth to unilaterally sunset the instruments. Accordingly, it is appropriate for the instruments to be exempt sunsetting.

Paragraph 63AB(b)

New paragraph 63AB(b) provides an exemption from sunsetting for proclamations made under section 15 of the Torres Strait Act. There are currently two proclamations made under this provision:

* *Torres Strait Fisheries Act 1984 – Proclamation (07/02/1985)*, and
* *Torres Strait Fisheries Act 1984 – Proclamation (17/03/1999)*.

Proclamations made under subsection 15(1) declare an area of water to be ‘an area outside but near the Protected Zone’ for the purposes of the performance of particular activities in the course of commercial fishing. Proclamations made under subsection 15(2) declare an area to be ‘in the vicinity of the Protected Zone’. Under paragraph 28(2)(c) of the Torres Strait Act, proclamations made under subsections 15(1) and (2) define the ‘waters adjacent to Queensland’ for the purposes of the Protected Zone Joint Authority (the PZJA). In effect, proclamations made under section 15 facilitate the establishment of the PZJA as it defines the area of water that the PZJA has the power to regulate. For example, the Commonwealth’s power to make an arrangement with Queensland under subsection 31(1) of the Torres Strait Act may be exercised in respect of the ‘waters adjacent to Queensland’.

Additionally, the *Torres Strait Fisheries Act 1984 (Qld),* which establishes the powers of Queensland to make an arrangement with the Commonwealth in relation to a particular fishery and the powers of the Queensland Minister in relation to the PZJA, relies on proclamations made under section 15 of the Torres Strait Act to define the Act’s areas of application under paragraph 4(1)(b) of the Queensland Act.

The PZJA is established under section 30 of the Torres Strait Act, and is an intergovernmental scheme with the Queensland Government providing for the management of fisheries in the Australian area of the Torres Strait Protected Zone and in adjacent coastal waters. Pursuant to subsection 30(2) of the Torres Strait Act, the PZJA consists of the Commonwealth Minister, the Queensland Minister and the Chairperson of the Torres Strait Regional Authority. The PZJA exercises powers and performs functions by way of meetings that follow procedures prescribed in section 40 of the Torres Strait Act. Such procedures include:

* the quorum of a meeting is two members, one of which is the Commonwealth Minister or her or his deputy, and
* decisions of the PZJA are subject to requests from the Queensland Minister and the Minister for the Torres Strait Regional Authority to delay the making of the decision to permit consultations to take place.

As the PZJA is an intergovernmental body, the unilateral sunsetting by the Commonwealth of proclamations made under section 15 of the Torres Strait Act would be inappropriate. Accordingly, it is appropriate to exempt the instruments from sunsetting.

While it is likely that proclamations made under section 15 of the Torres Strait Act are exempt from sunsetting under subsection 54(1) of the Legislation Act, it is appropriate to provide a specific exemption in the Principal Regulation to put the exemption beyond doubt.

Paragraph 63AB(c)

New paragraph 63AB(c) provides an exemption from sunsetting for arrangements made under section 31 of the Torres Strait Act. There is currently one arrangement made under this provision, the *Arrangement between the Commonwealth and State of Queensland under section 31 of the Torres Strait Fisheries Act 1984*.

Section 31 provides the Commonwealth with the power to make an arrangement with Queensland that the PZJA is to have the management of a particular fishery in waters adjacent to Queensland. Under subsection 28(1) of the Torres Strait Act, particular fisheries described in arrangements made under section 31 become ‘Protected Zone Joint Authority fisheries’ and the PZJA is given powers to manage such fisheries under subsection 36(1). Additionally, where a particular fishery becomes a ‘Protected Zone Joint Authority fishery’ various instruments made by the Commonwealth Minister cease to apply and permits granted by the Commonwealth Minister under section 12 have no application under subsection 35(2) of the Torres Strait Act. In effect, an arrangement made under section 31 facilitates the establishment of the PZJA as an intergovernmental scheme by defining the fisheries that the PZJA has power to regulate.

Moreover, under section 32 of the Torres Strait Act an arrangement made under section 31 may be terminated by instrument in writing by the Governor-General and the Governor of Queensland. This is consistent with the PZJA being an intergovernmental scheme. As such, it would be inappropriate for the Commonwealth to unilaterally sunset arrangements made under section 31 of the Torres Strait Act, and it is appropriate to exempt the instruments from sunsetting.

While it is likely that arrangements made under section 31 of the Torres Strait Act are exempt from sunsetting under subsection 54(1) of the Legislation Act, it is appropriate to provide a specific exemption in the Principal Regulation to put the exemption beyond doubt.

Paragraph 63AB(d)

New paragraph 63AB(d) provides an exemption from sunsetting for instruments made by or on behalf of the PZJA in the exercise of a power under subsection 35(1) of the Torres Strait Act. Paragraph 35(1)(a) provides that, for a PZJA fishery, specific powers of the Commonwealth Minister are exercisable by the PZJA. Instruments made under this power currently include:

*Torres Strait Prawn Fishery Management Plan 2009*

*Community Fishing Notice No.1 – Community fishing in the Torres Strait - prohibition on taking fish without a licence*

*Torres Strait Fisheries Management Notice No. 50*, and

* *Torres Strait Fisheries Management Notice No. 82*.

The PZJA exercises powers and performs functions by way of meetings that follow the procedures prescribed in section 40 of the Torres Strait Act, as described above. Pursuant to subsection 38(1) of the Torres Strait Act, the PZJA cannot delegate any of the powers that it may exercise by way of subsection 35(1) of the Torres Strait Act. Further, subsection 35(2) provides that where a fishery becomes a PZJA fishery, instruments made by the Minister under the powers that are exercisable by the PZJA under subsection 35(1), cease to apply to that fishery.

As such, instruments made by or on behalf of the PZJA in the exercise of a power under subsection 35(1) of the Torres Strait Act are part of the intergovernmental scheme between the Commonwealth and Queensland, and it would be inappropriate for the Commonwealth to unilaterally sunset the instruments. Accordingly, it is appropriate for these instruments to be exempt from sunsetting.

While it is likely that instruments made by or on behalf of the PZJA in an exercise of a power under subsection 35(1) of the Torres Strait Act are exempt from sunsetting under subsection 54(1) of the Legislation Act, it is appropriate to provide a specific exemption in the Principal Regulation to put the exemption beyond doubt.