

Health and Environment Committee

Report No. 16, 57th Parliament

Subordinate legislation tabled between 1 September 2021 and 12 October 2021

1 Aim of this report

This report summarises the findings of the Health and Environment Committee (committee) following its examination of the subordinate legislation within its portfolio areas tabled between 1 September 2021 and 12 October 2021. It reports on any issues identified by the committee relating to the policy to be given effect by the legislation, its consistency with fundamental legislative principles, its compatibility with human rights¹ and its lawfulness.² It also reports on the compliance of the explanatory notes with the *Legislative Standards Act 1992* (LSA)³ and the compliance of the human rights certificates with the Human Rights Act 2019 (HRA).⁴

2 Subordinate legislation examined

No.	Subordinate legislation	Date tabled	Disallowance date
140	Medicines and Poisons (Medicines) Regulation 2021	12 October 2021	24 February 2022
141	Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021	12 October 2021	24 February 2022
142	Medicines and Poisons (Pest Management Activities) Regulation 2021	12 October 2021	24 February 2022
143	Therapeutic Goods Regulation 2021	12 October 2021	24 February 2022
145	Nature Conservation and Other Legislation (COVID-19–Fee Waiver) Amendment Regulation 2021	12 October 2021	24 February 2022

¹ Section 8 of the Human Rights Act 2019 (HRA) provides that a statutory provision is compatible with human rights if it does not limit a human right, or limits a human right only to the extent that is reasonable and demonstrably justifiable in accordance with s 13 of the HRA. Section 13 of the HRA provides that a human right may be subject to reasonable limits that can be demonstrably justified in a free and democratic society based on human dignity, equality and freedom. Section 13 sets out a range of factors that may be relevant in determining whether a limit on a human right is reasonable and justifiable.

² *Parliament of Queensland Act 2001*, s 93.

³ *Legislative Standards Act 1992* (LSA), Part 4. Section 24 sets out the information that must be included in the explanatory notes for subordinate legislation which is required to be tabled in the Legislative Assembly with the subordinate legislation (LSA, s 22).

⁴ The human rights certificate, which must be tabled in the Legislative Assembly with the subordinate legislation, must state: a) whether, in the responsible Minister's opinion, the subordinate legislation is compatible with human rights, and if so, how it is compatible; and b) if, in the responsible Minister's opinion, a part of the subordinate legislation is not compatible with human rights, the nature and extent of the incompatibility (see HRA, s 41(1)-(3)).

148	Public Health (Further Extension of Declared Public Health Emergency—COVID-19) Regulation (No. 3) 2021	12 October 2021	24 February 2022
150	Nature Conservation (Protected Areas) Amendment Regulation (No. 3) 2021	12 October 2021	24 February 2022

*Disallowance dates are based on proposed sitting dates as advised by the Leader of the House. These dates are subject to change.

3 Committee consideration of the subordinate legislation

The committee identified no issues regarding the policy to be given effect by the subordinate legislation or its lawfulness.

The committee considered a number of fundamental legislative principle issues as part of its examination. In all cases the committee was satisfied that any potential breaches of fundamental legislative principle were appropriate and sufficiently justified.

All explanatory notes accompanying the subordinate legislation complied with requirements of section 24 of the LSA.

The committee considered a number of potential human rights limitations resulting from the subordinate legislation. In all cases, the committee was satisfied that the limitations were reasonable and demonstrably justified.

All human rights certificates provided with the subordinate legislation provided a sufficient level of information to facilitate understanding of the subordinate legislation's compatibility with human rights.

Each item of subordinate legislation considered is discussed in further detail below.

4 Medicines and Poisons (Medicines) Regulation 2021 - SL No. 140

The *Medicines and Poisons Act 2019* (Medicines and Poisons Act) commenced on 27 September 2021,⁵ introducing a new regulatory framework for medicines and poisons in Queensland. The purpose of the Medicines and Poisons Act is to repeal and replace the existing legislation with a new regulatory framework comprising the Act, the Medicines and Poisons (Medicines) Regulation 2021 (SL No. 140), the Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021 and the Medicines and Poisons (Pest Management Activities) Regulation 2021.⁶

The Medicines and Poisons Act outlines who can deal with medicines and what dealings they can undertake. SL No. 140 supports the Act by:

... setting the scope of lawful practice for dealings with medicines, as well as stipulating how dealings with medicine must be done, including compliance with departmental standards and substance management plans.⁷

According to the explanatory notes, the policy objectives of SL No. 140 are:

- supporting the objectives of the Act to ensure regulated substances are used safely and effectively and to reduce public harm;
- the use of modern electronic medication management systems (for example, electronic prescription management systems and electronic medicine registers) to better support public health outcomes;

⁵ SL No. 140, explanatory notes, p 2.

⁶ SL No. 140, human rights certificate, p 1.

⁷ SL No. 140, human rights certificate, p 1.

- improving terminology for medicines that are associated with increased risks of diversion or harm by providing access to real-time prescription information at the point of care, providing more clarity for restrictions of use and reporting obligations;
- improved clarity for authorised activities and approved persons, previously known as particular endorsements, to reduce reliance on approvals;
- more flexible requirements for authorised activities, such as storage and disposal, that are commensurate with the approved person’s qualifications and activities and the public health and safety risk of the medicines; and
- better facilitation of the prescribing, manufacturing, delivery and administration of medicated feed for use by primary producers.⁸

To achieve these policy objectives, SL No. 140:

- includes new terminology for categories of medicines⁹
- prescribes classes of approved persons to undertake regulated activities with regulated substances¹⁰
- provides a set of criteria the chief executive must consider when deciding to approve an Extended Practice Authority (EPA)¹¹
- refers to departmental standards as acceptable methods by which to achieve prescribed outcomes¹²
- sets out the places that must have a substance management plan and who is responsible for making the plan at that place¹³
- adopting part of the *Commonwealth Standard for the Uniform Scheduling of Medicines and Poisons* (Poisons Standard)¹⁴
- facilitates the real-time prescription monitoring system (‘the monitored medicines database’)¹⁵
- provides for some additional offences not covered by the Medicines and Poisons Act and prescribes that penalty infringement notices may be issued for particular offences¹⁶
- simplifies licensing requirements for medicines and poisons, and creates a new fee structure for licences under the framework¹⁷
- prescribes standard conditions for general approval holders¹⁸
- sets out provisions relating to: prescribing and prescriptions, destruction and disposal of medicines, the supply and storage of medicines, recording and reconciling of medicines, selling stock of medicines, procurement and purchasing of medicines, standing orders, compounding of medicines and medicated feed.¹⁹

⁸ SL No. 140, explanatory notes, p 3.

⁹ SL No. 140, explanatory notes, p 3.

¹⁰ SL No. 140, explanatory notes, p 4.

¹¹ SL No. 140, explanatory notes, pp 4-5.

¹² SL No. 140, explanatory notes, p 5.

¹³ SL No. 140, explanatory notes, p 6.

¹⁴ SL No. 140, explanatory notes, pp 6-7.

¹⁵ SL No. 140, explanatory notes, pp 7-9.

¹⁶ SL No. 140, explanatory notes, pp 9, 17.

¹⁷ SL No. 140, explanatory notes, pp 9-10; 10-12; 17.

¹⁸ SL No. 140, explanatory notes, p 10.

¹⁹ SL No. 140, explanatory notes, pp 12-17.

With respect to consultation on the new regulatory framework, the explanatory notes state:

Preliminary consultation has taken place since 2014 with stakeholders from a broad range of industries about the new legislative approach for medicines in Queensland. In late 2018, an indicative version of the Medicines Regulation was included in stakeholder consultation on the draft Medicines and Poisons Bill. The feedback received was used to further refine the framework to meet current industry practices.²⁰

4.1 Consistency with fundamental legislative principles

4.1.1 Rights and liberties of individuals – Penalties

Whether legislation has sufficient regard to rights and liberties of individuals depends on whether, for example, penalties and other consequences imposed by legislation are proportionate and relevant. Legislation should provide a higher penalty for an offence of greater seriousness than for a lesser offence. Penalties within legislation should be consistent with each other.²¹

SL No. 140 includes offence provisions for non-compliance with the following:

- use of electronic prescription management systems²²
- establishing stores and safes for S8 medicines (controlled medicines), and management of S8 stores and safes²³
- maintenance of medicines register²⁴
- recording and keeping of information²⁵
- tracking and delivery of certain medicines²⁶
- restrictions on used containers²⁷
- unlawful advertising of medicines
- installation of medicine vending machines.²⁸

The maximum penalties for the offence provisions are between 20 penalty units (\$2,757) and 80 penalty units (\$11,028).²⁹

According to the explanatory notes, the offences and penalty amounts in SL No. 140 are generally consistent with similar offence and penalty provisions in the previous Health (Drugs and Poisons) Regulation 1996 and Health Regulation 1996.³⁰ The penalty amounts are also within the range that is permitted by the Medicines and Poisons Act (which allows for regulations to impose penalties of not more than 100 penalty units).³¹

²⁰ SL No. 140, explanatory notes, p 42.

²¹ Office of the Queensland Parliamentary Counsel (OQPC), *Fundamental Legislative Principles: The OQPC Notebook*, p 120.

²² SL No. 140, explanatory notes, pp 31-33.

²³ SL No. 140, explanatory notes, pp 33-35.

²⁴ SL No. 140, explanatory notes, pp 35-37.

²⁵ SL No. 140, explanatory notes, pp 37-40.

²⁶ SL No. 140, explanatory notes, p 41.

²⁷ SL No. 140, explanatory notes, pp 41.

²⁸ SL No. 140, explanatory notes, pp 41-42.

²⁹ A penalty unit is \$137.85 - Penalties and Sentences Regulation 2015, s 3; *Penalties and Sentences Act 1992*, s 5A. See pages 31 to 42 of the explanatory notes for a detailed list of all the offences contained in SL No. 140 together with the corresponding maximum penalty amounts.

³⁰ SL No. 140, explanatory notes, p 30.

³¹ Medicines and Poisons Act, s 240(3).

The explanatory notes justify high penalty levels for some offences:

... given the level of potential harm to people and the environment that can be caused by mistakes with, or misuse of, medicines. The remaining offence provisions and corresponding maximum penalties have been reviewed and the penalties are proportionate to the seriousness of the offences.³²

Committee comment

The committee is satisfied that the penalties contained in SL No. 140 are proportionate and relevant to the offences to which they relate.

4.1.2 Institution of Parliament - Subdelegation of power

Whether legislation has sufficient regard to the institution of Parliament depends on whether, for example, the subordinate legislation allows the subdelegation of power only in appropriate cases and to appropriate persons, and if authorised by an Act.³³

Administrative powers

SL No. 140 provides the chief executive with a number of administrative powers to alter the way the provisions of SL No. 140 are to be carried out in practice.³⁴

The explanatory notes set out each of these powers and provide justification for their inclusion in SL 140.³⁵

These include, for example:

- the chief executive can approve, for an Indigenous health worker, an alternative course of training to the North Queensland Rural Health Training Unit Isolated Practice Course.³⁶ The explanatory notes justify the chief executive's power to approve an alternative course of training for Indigenous health workers on the basis it allows for a more flexible, responsive workplace.³⁷
- the chief executive can approve a professional body to accredit or certify a person to work as a clinical perfusionist, respiratory scientist or speech pathologist.³⁸ There is specific criteria that the chief executive must consider in making such a decision.³⁹

Committee comment

The committee is satisfied that the administrative powers provided to the chief executive in SL No. 140 are appropriate in the circumstances. These powers are administrative in nature, and appear necessary to allow the regime to be carried out in practice.

4.1.3 Institution of Parliament - External documents

Where subordinate legislation incorporates external documents, the issue of subdelegation of power commonly arises. Where these documents are not reproduced in full in subordinate legislation, and where changes to such documents can be made without the content of those changes coming to the attention of the House, it may be argued that the incorporation of these documents has insufficient regard to the institution of Parliament.

³² SL No. 140, explanatory notes, p 31.

³³ *Legislative Standards Act 1992* (LSA), s 4(5)(e).

³⁴ SL No. 140, explanatory notes, pp 23-25.

³⁵ See SL No. 140, explanatory notes, pp 23-25.

³⁶ SL No. 140, Schedule 3, s 4.

³⁷ SL No. 140, explanatory notes, 24.

³⁸ SL No. 140, Schedule 12, s 3, 9, and 12.

³⁹ SL No. 140, explanatory notes, 24.

The explanatory notes acknowledge that SL No. 140 raises this issue of fundamental legislative principle as it makes reference to EPAs, departmental standards, the Poison Standard and other external guidelines and standards.⁴⁰ These are discussed below.

Extended practice authorities

The Medicines and Poisons Act empowers the chief executive to make an extended practice authority (EPA), authorising an approved person to deal with a regulated substance.⁴¹

Schedule 1, part 1 of SL No. 140 sets out approved EPAs for the following professions:

- Midwives
- Registered nurses
- Pharmacists
- Aboriginal and Torres Strait Islander health practitioners
- Indigenous health workers
- Queensland Ambulance Service
- Physiotherapists.⁴²

According to the explanatory notes:

- an EPA is a document certified by the chief executive of Queensland Health that sets out matters of technical detail for how an approved person can carry out a regulated activity with a regulated substance, including details such as the route of administration, the specific dose, quantity, duration and restrictions placed on substances and the circumstances in which they may be administered.⁴³
- EPAs are monitored and updated where necessary, align with clinical best practice and are published on the Queensland health website.⁴⁴ SL No. 140 also prescribes the matters to be considered by the chief executive before making an EPA (for example, whether there is a community need for any service to be facilitated by the EPA, and the way in which any health risks associated with the dealing are to be managed).⁴⁵
- EPAs are not a new concept, and are known as Drug Therapy Protocols under the Health (Drugs and Poisons) Regulation. When making or amending an EPA, the explanatory notes state that relevant individuals or organisations with expertise in, or experience of, the matters under consideration will be consulted.⁴⁶

The explanatory notes acknowledge that the use of EPAs could breach the fundamental legislative principle relating to the subdelegation of power by prescribing requirements in subordinate legislation by reference to an external document. However, the explanatory notes provide the following justification for the subdelegation of power:

It is considered that the rigour surrounding the development of the extended practice authorities, their use in ensuring Queenslanders receive health care based on best clinical practice and the detailed nature

⁴⁰ SL No. 140, explanatory notes, pp 23-30.

⁴¹ Medicines and Poisons Act, s 232; SL No. 140, explanatory notes, p 25.

⁴² SL No. 140, explanatory notes, p 5.

⁴³ SL No. 140, explanatory notes, p 26.

⁴⁴ SL No. 140, explanatory notes, p 26.

⁴⁵ SL No. 140, s 236.

⁴⁶ SL No. 140, explanatory notes, p 26.

of the documents, justifies the need to sub-delegate by referring to external documents in the Medicines Regulation.⁴⁷

The significance of dealing with such matters other than by subordinate legislation is that, since the relevant documents are not 'subordinate legislation', they are not subject to the tabling and disallowance provisions in Part 6 of the *Statutory Instruments Act 1992*.

The explanatory notes indicate Parliament will have some level of oversight as updated departmental standards will be tabled when corresponding amendments to SL No. 140 are made:

The Medicines Regulation will be amended to reflect the name and version number of an EPA each time a new version is made. A copy of the updated extended practice authority will be tabled in Parliament as extrinsic material each time the regulation is amended, to reflect the revised document.⁴⁸

Committee comment

The committee is satisfied that any breach of fundamental legislative principle arising from the use of EPAs in this way is justified, having regard to the need to reflect current clinical practice and that a level of parliamentary oversight will be provided through the tabling of updated EPAs.

Departmental standards

The Medicines and Poisons Act empowers the chief executive to make departmental standards relevant to the objectives and administration of the new regulatory framework.⁴⁹

Schedule 1 of SL No. 140 prescribes the following departmental standards:

- Compounding
- Monitored medicines
- Pseudoephedrine recording
- Requirements for an electronic prescription management system
- Secure storage of S8 medicines (controlled medicines), and
- Substance management plans for medicines.⁵⁰

The explanatory notes state:

The standards will be outcomes-focused and set minimum safety and accountability criteria that must be met in relation to particular activities. Persons who deal with regulated substances will be required to comply with the departmental standards applicable to the activity they are performing.⁵¹

Prescribing requirements by reference to an external document in this manner could be seen to breach the fundamental legislative principle relating to subdelegation of power.⁵² However, the explanatory notes provide the following justification:

It is considered that the rigour surrounding the development of the standards, their use in ensuring Queenslanders receive health care based on industry best practice and the detailed nature of the documents, justifies the need to sub-delegate by referring to external documents in the Medicines Regulation.⁵³

⁴⁷ SL No. 140, explanatory notes, p 26.

⁴⁸ SL No. 140, explanatory notes, p 5.

⁴⁹ Medicines and Poisons Act, s 233; SL No. 140, explanatory notes, p 26.

⁵⁰ SL No. 140, explanatory notes, p 5.

⁵¹ SL No. 140, explanatory notes, p 5.

⁵² LSA, s 4(5)(e).

⁵³ SL No. 140, explanatory notes, p 28.

In terms of accessibility and consultation, the explanatory notes state:

The standards are monitored and updated when necessary, align with industry best practice and are published on the Queensland Health website. When making or amending a standard, relevant individuals and organisations with expertise in, or experience of, the matters under consideration will be consulted. Consultation with stakeholders was undertaken on the proposed departmental standards at the same time as consultation was undertaken on the Medicines Regulation.⁵⁴

The explanatory notes indicate Parliament will have some level of oversight as updated departmental standards will be tabled in the event amendments to SL No. 140 are made:

The Medicines Regulation will be amended to reflect the updated name and version number each time a new version of a standard is made. A copy of the updated standard will be tabled in Parliament as extrinsic material each time the regulation is amended, to reflect the revised standard. All departmental standards will be published on the Queensland Health website.⁵⁵

Committee comment

The committee is satisfied that any breach of fundamental legislative principle arising from the incorporation of departmental standards is justified, having regard to the need for flexibility, the accessibility of the standards and the fact that copies of updated standards will be tabled.

Poisons Standard

The explanatory notes state that, in accordance with the National Scheduling Policy Framework for Medicines and Chemicals, Queensland will continue to adopt the classification system for medicines and poisons under the current version of the Poisons Standard.⁵⁶ The Poisons Standard provides for the uniform scheduling of substances, and all states and territories refer to the Poisons Standard when regulating possession, access and use of scheduled substances.⁵⁷

SL No. 140 makes reference to the Poisons Standard in a number of provisions.⁵⁸ The explanatory notes acknowledge that these provisions could be considered to breach fundamental legislative principles by failing to state requirements directly in the regulation.⁵⁹

However, the explanatory notes provide the following justification:

By referencing the Poisons Standard, as opposed to stating requirements directly in the Regulation, ensures the Regulation will always be consistent with the Poisons Standard and relevant to national requirements. It is also necessary to refer to the Poisons Standard in the Regulation rather than to duplicate it in the Medicines and Poisons scheme, as it is technical and detailed in nature.⁶⁰

Committee comment

The committee is satisfied that references to the Poisons Standard are justified, having regard to the need to maintain consistency with other jurisdictions and the technical and detailed nature of the Poisons Standard.

Other external guidelines and standards

The explanatory notes state that in some cases, it is necessary to adopt or specify standards that have been developed by relevant industry bodies.⁶¹

⁵⁴ SL No. 140, explanatory notes, p 28.

⁵⁵ SL No. 140, explanatory notes, p 5.

⁵⁶ Made under section 52D of the *Therapeutic Goods Act 1989* (Cwlth); SL No. 140, explanatory notes, p 28.

⁵⁷ SL No. 140, explanatory notes, p 6.

⁵⁸ SL No. 140, ss 6, 73, 118, 134, 154 and 234.

⁵⁹ LSA, s 4(5)(e); SL No. 140, explanatory notes, p 29.

⁶⁰ SL No. 140, explanatory notes, p 29.

⁶¹ SL No. 140, explanatory notes, p 29.

Schedule 8 of SL No. 140 provides that an optometrist may administer certain topical medicines as outlined in the *Guidelines for use of scheduled medicines* made by the Optometry Board of Australia; and may prescribe, give a treatment dose of and administer certain medicines under those guidelines.⁶²

Schedule 10 of SL No. 140 provides that an endorsed podiatrist may prescribe, give a treatment dose of and administer certain medicines mentioned in the *Registration standard: endorsement for schedule medicines* made by the Podiatry Board of Australia.⁶³

The explanatory notes acknowledge prescribing requirements by reference to an external document in this manner could be seen to breach fundamental legislative principles because those documents are not subject to parliamentary scrutiny.⁶⁴ However, the explanatory notes indicate Parliament will have some level of oversight of the external standards and guidelines any time they are updated:

The Podiatry Board of Australia and the Optometry Board of Australia publish lists of classes of scheduled medicines, which are updated from time to time. To ensure the Medicines Regulation is kept up to date, it will be updated to reflect the date of the new version each time a new version is made. A copy of the updated guidelines and standard will be tabled as extrinsic material each time the regulation is amended, to reflect the changed standard or guideline.

There is a rigorous process that National Registration Boards must follow to amend registration standards and guidelines.⁶⁵

According to the explanatory notes, any potential breach of fundamental legislative principle is justified because the use of the guidelines and standards supports national consistency.⁶⁶ Further, the documents are available to the general public online.⁶⁷

Committee comment

The committee is satisfied that the references to other guidelines and standards in SL No. 140 are justified in the circumstances, given they are limited in scope and support national consistency.

4.2 Explanatory notes

The explanatory notes comply with part 4 of the *Legislative Standards Act 1992*.

4.3 Consideration of human rights compatibility

The human rights certificate discusses several human rights (including the rights to property, equality before the law, privacy and freedom of movement and cultural rights). However, the impacts on these rights are considered to be minor.

Committee comment

The committee is satisfied the subordinate legislation is compatible with human rights.⁶⁸

⁶² SL No. 140, Schedule 8, s 3 and 5; explanatory notes, pp 29-30.

⁶³ SL No. 140, explanatory notes, p 30.

⁶⁴ LSA, 4(5)(e); SL No. 140, explanatory notes, p 30.

⁶⁵ SL No. 140, explanatory notes, p 30.

⁶⁶ SL No. 140, explanatory notes, p 30.

⁶⁷ SL No. 140, explanatory notes, p 30.

⁶⁸ Section 8 of the HRA relevantly provides that a statutory provision is compatible with human rights if the provision does not limit a human right or limits a human right only to the extent that is reasonable and demonstrably justifiable in accordance with section 13 of the HRA. Section 13 of the HRA provides that a human right may be subject under law only to reasonable limits that can be demonstrably justified in a free and democratic society based on human dignity, equality and freedom.

4.4 Human rights certificate

Section 41 of the *Human Rights Act 2019* requires that the responsible Minister for the subordinate legislation must prepare a human rights certificate for the legislation.

The human rights certificate tabled with the subordinate legislation provides a sufficient level of information to facilitate understanding of the subordinate legislation in relation to its compatibility with human rights.

5 Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021 - SL No. 141

The w commenced on 27 September 2021 to form part of a new legislative framework to regulate medicines, poisons and therapeutic goods in Queensland.⁶⁹ This framework includes the Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021 (SL No. 141).

According to the explanatory notes, the policy objectives of SL No. 141 are:

- protecting the public from the health risks associated with inappropriate access to, and use of, poisons;
- adopting a contemporary approach to regulating poisons in Queensland that introduces a more responsive and outcomes-focused regulatory framework;
- streamlining the regulatory controls governing poisons to reduce the associated regulatory costs for industry, consumers and government;
- enhancing consistency with national regulatory frameworks by implementing nationally agreed decisions in relation to the regulation of poisons and pest management activities;
- improving security controls in the use and storage of poisons to prevent diversion for unlawful purposes; and
- ensuring legislation accords with modern drafting practices and has sufficient regard to fundamental legislative principles.⁷⁰

To achieve these policy objectives, SL No. 141:

- adopts part of the Commonwealth *Standard for the Uniform Scheduling of Medicines and Poisons* (Poisons Standard)⁷¹
- provides for some offences that are not covered by the Medicines and Poisons Act⁷²
- rationalises the licensing requirements for medicines and poisons that existed under the previous legislative framework⁷³
- prescribes standard conditions for general approval holders⁷⁴
- prescribes classes of approved persons to undertake regulated activities⁷⁵

⁶⁹ SL No. 141, explanatory notes, pp 1-2. This new suite of legislation replaces the existing legislative framework which was comprised of the *Health Act 1937*, Health (Drugs and Poisons) Regulation 1996, Health Regulation 1996, *Pest Management Act 2001* and the Pest Management Regulation 2003.

⁷⁰ SL No. 141, explanatory notes, pp 2-3.

⁷¹ SL No. 141, explanatory notes, pp 3-4.

⁷² SL No. 141, explanatory notes, pp 4-5.

⁷³ SL No. 141, explanatory notes, p 5.

⁷⁴ SL No. 141, explanatory notes, pp 5-6.

⁷⁵ SL No. 141, explanatory notes, p 6.

- sets out the licensing fees payable under the Medicines and Poisons Act and provides a process for the refund of fees in certain cases⁷⁶
- refers to departmental standards as acceptable methods by which to achieve prescribed outcomes⁷⁷
- sets out requirements as to who is required to have a substance management plan⁷⁸
- sets out provisions related to dealing with high-risk poisons, buying regulated poisons, the retail and wholesale supply of regulated poisons, storage of poisons and prohibited substances, disposal of poisons, notifiable conditions for substance authorities, label and container requirements, and record keeping.⁷⁹

5.1 Consistency with fundamental legislative principles

5.1.1 Rights and liberties of individuals - penalties

Whether legislation has sufficient regard to rights and liberties of individuals depends on whether, for example, penalties and other consequences imposed by legislation are proportionate and relevant. A penalty should be proportionate to the offence:

In the context of supporting fundamental legislative principles, the desirable attitude should be to maximise the reasonableness, appropriateness and proportionality of the legislative provisions devised to give effect to policy.

... Legislation should provide a higher penalty for an offence of greater seriousness than for a lesser offence. Penalties within legislation should be consistent with each other.⁸⁰

While the majority of offences under the new legislative framework are contained in the Medicines and Poisons Act, SL No. 141 does contain some offences.⁸¹ Specifically, SL No. 141 includes offence provisions for non-compliance with the following:

- covering, defacing, removing or changing any label affixed in accordance with the requirements of part 2 of the Poisons Standard;
- poisons must be held in packages that are in good condition, and if damaged must be decanted into another container that is appropriate for the poison under the requirements of part 2 of the Poisons Standard;
- poison containers must not be washed, soaked or treated in a receptacle that is used to hold human or animal food or drink; and
- record keeping and notification requirements.⁸²

The maximum penalties for the offence provisions are all 20 penalty units (\$2,757) to 80 penalty units (\$11,028).⁸³ According to the explanatory notes, the offences and penalty amounts in SL No. 141 are generally consistent with similar offence and penalty provisions in the previous Health (Drugs and Poisons) Regulation 1996 and Health Regulation 1996.⁸⁴

⁷⁶ SL No. 141, explanatory notes, pp 6-8; SL No. 141, schedule 6.

⁷⁷ SL No. 141, explanatory notes, p 8.

⁷⁸ SL No. 141, explanatory notes, p 8.

⁷⁹ SL No. 141, explanatory notes, pp 10-13.

⁸⁰ OQPC, *Fundamental Legislative Principles: The OQPC Notebook*, p 120.

⁸¹ See SL No. 141, chapter 5; SL No. 141, explanatory notes, p 4.

⁸² SL No. 141, explanatory notes, p 5. See pages 18 to 21 of the explanatory notes for a detailed explanation of the offences.

⁸³ A penalty unit is \$137.85 - Penalties and Sentences Regulation 2015, s 3; *Penalties and Sentences Act 1992*, s 5A.

⁸⁴ SL No. 141, explanatory notes, p 18.

Further, the penalty amounts are within the range that is permitted by the Medicines and Poisons Act (which allows for regulations to impose penalties of not more than 100 penalty units).⁸⁵

The explanatory notes provide this overall justification for the offence and penalty provisions:

The penalty levels in the Poisons Regulation are justifiable given the level of serious harm to health that can be caused by poisons and prohibited substances, for example, cyanide and strychnine, and the potential impacts that failure to comply with the Act and Poisons Regulation can have on public health. The penalties reflect the importance of correctly labelling, packaging and storing poisons and prohibited substances. Many of the offences with high penalties relate to keeping poisons in appropriate containers and preventing contamination of food and accidental ingestion. The remaining offence provisions and corresponding maximum penalties have been reviewed to ensure the penalties are proportionate to the seriousness of the offences.⁸⁶

Committee comment

The committee is satisfied that the penalties contained in SL No. 141 are proportionate and relevant to the offences to which they relate.

5.1.2 Institution of Parliament - Subdelegation of power

Whether legislation has sufficient regard to the institution of Parliament depends on whether, for example, the subordinate legislation allows the subdelegation of power in appropriate cases and to appropriate persons.⁸⁷

For Parliament to confer on someone other than Parliament the power to legislate as the delegate of Parliament, without a mechanism being in place to monitor the use of the power, raises obvious issues about the safe and satisfactory nature of the delegation.⁸⁸

This issue of fundamental legislative principle arises often in circumstances where subordinate legislation incorporates external documents. Where these documents are not reproduced in full in subordinate legislation, and where changes to such documents can be made without the content of those changes coming to the attention of the House, it may be argued that the incorporation of these documents has insufficient regard to the institution of Parliament.

The explanatory notes acknowledge that SL No. 141 raises this issue of fundamental legislative principle, as it makes reference to departmental standards, the Poison Standard and other external standards and guidelines.⁸⁹ These are discussed below.

Departmental standards

The Medicines and Poisons Act empowers the chief executive to make standards about carrying out regulated activities with regulated substances and other matters related to the Act.⁹⁰

Schedule 3 of SL No. 141 prescribes three departmental standards:

- competency requirements for authority holders dealing with poisons
- dealing with restricted S7 poisons for invasive animal control
- substance management plans for regulated poisons.⁹¹

⁸⁵ Medicines and Poisons Act, s 240(3).

⁸⁶ SL No. 141, explanatory notes, p 18.

⁸⁷ LSA, s 4(5)(e).

⁸⁸ OQPC, *Fundamental Legislative Principles: the OQPC Notebook*, p 154.

⁸⁹ SL No. 141, explanatory notes, pp 15-18.

⁹⁰ Medicines and Poisons Act, s 233; SL No. 141, explanatory notes, p 15.

⁹¹ SL No. 141, s 12 and schedule 3.

According to the explanatory notes, the purpose of having departmental standards is to provide guidance on acceptable methods by which individuals can achieve prescribed outcomes under SL No. 141.⁹²

While the notes acknowledge that the incorporation of these external documents may breach fundamental legislative principles, they justify this on the basis of flexibility:

A standard is a document certified by the chief executive of Queensland Health that is relevant to the object and administration of the new legislative regime and provides guidance, allows flexibility on activities and applies to individuals and entities.⁹³

Further, in terms of accessibility, the explanatory notes state:

The standards will be monitored and updated when necessary, align with industry best practice and are published on the Queensland Health website ... When making or amending a standard, relevant individuals and organisations with expertise in, or experience of, the matters under consideration will be consulted.

...

The inclusion of the name of each departmental standard and its version number in the Regulation creates certainty for professionals and the public about the status of standards published on Queensland Health's website and the date they took effect.⁹⁴

The significance of dealing with such matters other than by subordinate legislation is that, since the relevant documents are not 'subordinate legislation', they are not subject to the tabling and disallowance provisions in Part 6 of the *Statutory Instruments Act 1992*.

While departmental standards are not subordinate legislation, the explanatory notes indicate Parliament will have some level of oversight as updated departmental standards will be tabled when corresponding amendments to SL No. 141 are made:

The Regulation will be amended to reflect the updated version number each time a new version of a standard is made. A copy of the updated standard will be tabled as extrinsic material each time the regulation is amended, to reflect the changed standard.⁹⁵

Overall, the explanatory notes conclude:

It is considered that the rigour surrounding the development of the standards, their use in ensuring Queenslanders receive health care based on industry best practice and the detailed nature of the documents, justifies the need to sub-delegate by referring to external documents.⁹⁶

Committee comment

The committee is satisfied that any breach of fundamental legislative principle arising from the incorporation of departmental standards is justified, having regard to the need for flexibility, the accessibility of the standards and the fact that copies of updated standards will be tabled.

Poisons Standard

The Poisons Standard provides for the uniform scheduling of substances, and all states and territories refer to the Poisons Standard when regulating possession, access and use of scheduled substances.⁹⁷

⁹² SL No. 141, explanatory notes, p 8.

⁹³ SL No. 141, explanatory notes, p 16.

⁹⁴ SL No. 141, explanatory notes, p 16.

⁹⁵ SL No. 141, explanatory notes, p 16.

⁹⁶ SL No. 141, explanatory notes, p 16.

⁹⁷ SL No. 141, explanatory notes, p 3.

Whilst SL No. 141 adopts parts of the contents of the Poisons Standard into the regulation,⁹⁸ there are other sections of SL No. 141 that simply refer to the Poisons Standard. For example:

- Section 54 provides that the supplier must not supply a regulated poison to a buyer unless the poison is labelled in accordance with the requirements for labelling in part 2, section 1 of the Poisons Standard or the container for the poison complies with the requirements for a container of the poison stated in part 2, section 2 of the Poisons Standard.⁹⁹
- Section 69 provides a person must not supply an S5 or S6 poison unless the poison is labelled in accordance with the labelling requirements in part 2, section 1 of the Poisons Standard or the container for the poison complies with the requirements for containers for the poison stated in part 2, section 2 of the Poisons Standard.¹⁰⁰

The explanatory notes acknowledge the adoption of, and references to parts of, the Poisons Standard potentially breaches fundamental legislative principles.¹⁰¹ However, the notes state that any breach is justified by the need for national consistency:

Adopting the current version of the Poisons Standard will ensure key regulatory controls governing the availability and accessibility of medicines and poisons in Queensland will continue to be consistent with those in other states and territories. Reference to the Poisons Standard provides national consistency.¹⁰²

Further, the explanatory notes highlight the detailed and technical nature of Poisons Standard and that references to it by name in some instances rather than incorporating the entire standard into the regulation ensures SL No. 141 remains current and relevant to national requirements.¹⁰³

Committee comment

The committee is satisfied that references to the Poisons Standard are justified, having regard to the need to maintain consistency with other jurisdictions and the technical and detailed nature of the Standard.

Other external guidelines and standards

Section 70 of SL No. 141 provides that a person does not commit an offence of selling an S6 poison by retail if the person stores the S6 poison in compliance with *the National guideline for retail storage of Schedule 6 and Schedule 7 poisons* made by the Australian Health Ministers' Advisory Council.¹⁰⁴

The explanatory notes justify the reference to external guidelines on the basis of national consistency:

This guideline aligns with the hierarchy of controls over poisons in the Poisons Standard and provides for a nationally uniform approach to retail storage that meets the expectations of consumers, regulators and other stakeholders while retaining flexibility for business where possible. To ensure Queensland aligns with the national approach on this issue, it is appropriate to refer to this guideline in the Poisons Regulation. This assists retailers who operate across state and territory borders.¹⁰⁵

Section 13 of SL No. 141 includes definitions for 'accredited laboratory' and 'reference material' which refer to external standards published by the International Organization for Standardization (ISO).¹⁰⁶

⁹⁸ SL No. 141, explanatory notes, pp 3-4.

⁹⁹ SL No. 141, s 54; SL No. 141 explanatory notes, p 16.

¹⁰⁰ SL No. 141, s 69; SL No. 141, explanatory notes, p 17.

¹⁰¹ SL No. 141, explanatory notes, p 17.

¹⁰² SL No. 141, explanatory notes, p 17.

¹⁰³ SL No. 141, explanatory notes, p 17.

¹⁰⁴ This guideline is publicly accessible on the Therapeutic Goods Administration's website.

¹⁰⁵ SL No. 141, explanatory notes, p 18.

¹⁰⁶ ISO/IEC 17011:2018 (Conformity assessment—Requirements for accreditation bodies accrediting conformity assessment bodies), AS ISO/IEC 17025:2018 (General requirements for the competence of testing and calibration laboratories); and AS ISO/IEC 17034:2018 (General requirements for the competence of reference material producers).

These standards are not freely available to laboratories or organisations (though can be purchased from ISO or Standards Australia).

Committee comment

The committee is satisfied that the references to other guidelines and standards in SL No. 141 are justified in the circumstances, given they are limited in scope and align with national or international practice.

5.2 Explanatory notes

The explanatory notes comply with part 4 of the LSA.

5.3 Consideration of human rights compatibility

The human rights certificate discusses several human rights (including the right to property, right to equality before the law, right to privacy, freedom of expression and cultural rights). However, the impacts on these rights are considered to be minor.

Committee comment

The committee is satisfied that the subordinate legislation is compatible with human rights.

5.4 Human rights certificate

The human rights certificate tabled with the subordinate legislation provides a sufficient level of information to facilitate understanding of the subordinate legislation in relation to its compatibility with human rights.

6 Medicines and Poisons (Pest Management Activities) Regulation 2021 SL No. 142

The Medicines and Poisons Act commenced on 27 September 2021 to form part of a new legislative framework to regulate medicines, poisons and therapeutic goods in Queensland.¹⁰⁷ This framework also includes the Medicines and Poisons (Pest Management Activities) Regulation 2021 (SL No. 142).

According to the explanatory notes, the policy objectives of SL No. 142 are:

- protecting the public from the health risks associated with inappropriate access to, and use of, pesticides and fumigants
- adopting a contemporary approach to regulating pesticides and fumigants in Queensland that introduces a more responsive and outcomes-focused regulatory framework
- streamlining the regulatory controls governing pesticides and fumigants to reduce the associated regulatory costs for industry, consumers and government
- improving security controls in the use and storage of pesticides and fumigants to prevent diversion for unlawful purposes; and
- ensuring legislation accords with modern drafting practices and has sufficient regard to fundamental legislative principles.¹⁰⁸

To achieve these policy objectives, SL No. 142:

- contains the terms and requirements for pest management¹⁰⁹
- prescribes classes of approved persons to undertake regulated activities¹¹⁰

¹⁰⁷ SL No. 142, explanatory notes, pp 1-2. This new suite of legislation replaces the existing legislative framework which was comprised of the *Health Act 1937*, Health (Drugs and Poisons) Regulation 1996, Health Regulation 1996, *Pest Management Act 2001* and the Pest Management Regulation 2003.

¹⁰⁸ SL No. 142, explanatory notes, p 2.

¹⁰⁹ SL No. 142, explanatory notes, pp 2-3.

¹¹⁰ SL No. 142, explanatory notes, p 3.

- continues the licensing requirements for fumigants and pesticides¹¹¹
- provides for some offences that are not covered by the Medicines and Poisons Act¹¹²
- sets out the licensing fees payable under the Medicines and Poisons Act¹¹³
- refers to the departmental standard *Competency requirements for licensed technicians undertaking pest management activities with pesticides and fumigants* as an acceptable method by which to achieve prescribed outcomes¹¹⁴
- sets out provisions related to storage of fumigants and pesticides, label and container requirements, disposal of fumigants and pesticides, record keeping, pest control advices, activity risk management plans, fumigation requirements, incident notifications and general pest management business obligations.¹¹⁵

6.1 Consistency with fundamental legislative principles

6.1.1 Rights and liberties of individuals - Penalties

Whether legislation has sufficient regard to rights and liberties of individuals depends on whether, for example, penalties and other consequences imposed by legislation are proportionate and relevant. A penalty should be proportionate to the offence:

In the context of supporting fundamental legislative principles, the desirable attitude should be to maximise the reasonableness, appropriateness and proportionality of the legislative provisions devised to give effect to policy.

... Legislation should provide a higher penalty for an offence of greater seriousness than for a lesser offence. Penalties within legislation should be consistent with each other.¹¹⁶

While the majority of offences under the new legislative framework are contained in the Medicines and Poisons Act, SL No. 142 does contain some offences.¹¹⁷ Specifically, SL No. 142 includes offence provisions for non-compliance with the following:

- pest management businesses who employ a trainee, but do not ensure the trainee is appropriately supervised;
- pest management businesses not providing adequate equipment, documents or vehicles suitable for carrying out a pest management activity;
- pest management businesses not ensuring a fumigant or pesticide is safely secured at the business premises or in an appropriately marked vehicle;
- interfering with fumigation barricades or warning signs; and
- recordkeeping and notification requirements.¹¹⁸

The maximum penalties for the offence provisions contained in SL No. 142 are all 20 penalty units (\$2,757).¹¹⁹ According to the explanatory notes, the offences and penalty amounts in SL No. 142 are generally consistent with similar offence and penalty provisions in the previous Health (Drugs and

¹¹¹ SL No. 142, explanatory notes, pp 3-4.

¹¹² SL No. 142, explanatory notes, p 4.

¹¹³ SL No. 142, explanatory notes, pp 4-5; SL No. 142, schedule 6.

¹¹⁴ SL No. 142, explanatory notes, p 5.

¹¹⁵ SL No. 142, explanatory notes, pp 5-10.

¹¹⁶ OQPC, *Fundamental Legislative Principles: The OQPC Notebook*, p 120.

¹¹⁷ SL No. 142, part 5; SL No. 142, explanatory notes, p 4.

¹¹⁸ SL No. 142, explanatory notes, p 4. See pages 15 to 20 of the explanatory notes for a detailed explanation of the offences.

¹¹⁹ A penalty unit is \$137.85 - Penalties and Sentences Regulation 2015, s 3; *Penalties and Sentences Act 1992*, s 5A.

Poisons) Regulation 1996, Health Regulation 1996 and the Pest Management Regulation 2003.¹²⁰ The explanatory notes provide detailed justifications for each offence and penalty provision,¹²¹ and the penalties appear to be proportionate and relevant to the conduct being prescribed.

Further, the penalty amounts are within the range that is permitted by the Medicines and Poisons Act (which allows for regulations to impose penalties of not more than 100 penalty units).¹²²

Committee comment

The committee is satisfied that the penalties contained in SL No. 142 are proportionate and relevant to the offences to which they relate.

6.1.2 Institution of Parliament - Subdelegation of power

Whether legislation has sufficient regard to the institution of Parliament depends on whether, for example, the subordinate legislation allows the subdelegation of power in appropriate cases and to appropriate persons.¹²³

For Parliament to confer on someone other than Parliament the power to legislate as the delegate of Parliament, without a mechanism being in place to monitor the use of the power, raises obvious issues about the safe and satisfactory nature of the delegation.¹²⁴

This issue of fundamental legislative principle arises often in circumstances where subordinate legislation incorporates external documents. Where these documents are not reproduced in full in subordinate legislation, and where changes to such documents can be made without the content of those changes coming to the attention of the House, it may be argued that incorporation of the documents has insufficient regard to the institution of Parliament.

The explanatory notes acknowledge that SL No. 142 raises this issue of fundamental legislative principle, as it makes reference to a departmental standard and other external standards.¹²⁵ These are discussed below.

Departmental standard

As noted above in relation to SL No. 141, the Medicines and Poisons Act empowers the chief executive to make standards about carrying out regulated activities with regulated substances and other matters related to the Act.¹²⁶

Section 8 of SL No. 142 approves the departmental standard *Competency requirements for licensed technicians undertaking pest management activities with pesticides and fumigant* for the purposes of the Medicines and Poisons Act.

Section 10 provides that a licenced technician must satisfy, and continue to satisfy, the competency requirements stated in the competency standard that relate to the type of pest management licence held by the technician.

While the explanatory notes acknowledge that the reference to a departmental standard in this way may breach fundamental legislative principles, they justify this on the basis of national consistency:

The competencies prescribed in the *Competency requirements for licensed technicians undertaking pest management activities with pesticides and fumigants* departmental standard are nationally agreed and

¹²⁰ SL No. 142, explanatory notes, p 15.

¹²¹ SL No. 142, explanatory notes, pp 15-20.

¹²² Medicines and Poisons Act, s 240(3).

¹²³ LSA, s 4(5)(e).

¹²⁴ OQPC, *Fundamental Legislative Principles: the OQPC Notebook*, p 154.

¹²⁵ SL No. 142, explanatory notes, pp 11-14.

¹²⁶ Medicines and Poisons Act, s 233; SL No. 142, explanatory notes, p 12.

set out under various state or Commonwealth laws, such as the *Chemical Usage (Agricultural and Veterinary) Control Act 1988*.¹²⁷

The explanatory notes also highlight the flexibility offered by the departmental standard, in that it is 'outcomes focused and lists options to achieve the desired outcome which would not be suitable for inclusion in a prescriptive requirement in a regulation'.¹²⁸

Further, in terms of accessibility, the explanatory notes state:

The standards will be monitored and updated when necessary, align with industry best practice and are published on the Queensland Health website ... When making or amending a standard, relevant individuals and organisations with expertise in, or experience of, the matters under consideration will be consulted.

...

The inclusion of the name of each departmental standard and its version number in the regulation creates certainty for professionals and the public about the status of standards published on Queensland Health's website and the date they took effect.¹²⁹

The significance of dealing with such matters other than by subordinate legislation is that, since the relevant document is not 'subordinate legislation', it is not subject to the tabling and disallowance provisions in Part 6 of the *Statutory Instruments Act 1992*.

While the departmental standard is not subordinate legislation, the explanatory notes indicate Parliament will have some level of oversight as updated departmental standards will be tabled when corresponding amendments to SL No. 142 are made:

The Pest Management Activities Regulation will be amended to reflect the updated version number each time a new version of a standard is made. A copy of the updated standard will be tabled as extrinsic material each time the regulation is amended, to reflect the changed standard.¹³⁰

Overall, the explanatory notes conclude:

It is considered that the rigour surrounding the development of the competency standard and the need to be responsive to changes in national training requirements justifies the need to sub-delegate by referring to an external document.¹³¹

Committee comment

The committee is satisfied that any breach of fundamental legislative principle arising from the incorporation the departmental standard is justified, having regard to the need for national consistency and flexibility, that the standard is accessible and that any changes to the standard will come to the attention of the House when the standard is tabled as extrinsic material.

Other external standards

Section 46 of SL No. 142 provides that a qualified person who conducts pest management activities using a fumigant or pesticide for termite management must make a record of the pest management activity in accordance with the termite management certificate. A 'termite management certificate' means a certificate of installation, or certificate of termite treatment, issued under the relevant termite management standard:

- AS 3660.1 (Termite management: New building work)
- AS 3660.2 (Termite management: In and around existing buildings and structures)

¹²⁷ SL No. 142, explanatory notes, p 12.

¹²⁸ SL No. 142, explanatory notes, p 12.

¹²⁹ SL No. 142, explanatory notes, pp 12-13.

¹³⁰ SL No. 142, explanatory notes, p 13.

¹³¹ SL No. 142, explanatory notes, p 12.

- AS 3660.3 (Termite management: Assessment criteria for termite management systems).¹³²

The explanatory notes state that this means the termite management certificate will meet the record keeping requirements of SL No. 142, without duplicating the information already required under Australia Standard 3660 series.¹³³ According to the explanatory notes, most pest management technicians would already have a copy of the A3660 series or could purchase it online.¹³⁴

SL No. 142 also refers to another external standard in the definition of 'safe exposure concentration', which is defined as 'the concentration of the fumigant in the air that is stated on the approved label for the fumigant or in accordance with the *Workplace exposure standards for airborne contaminants* published by Safe Work Australia if no exposure standard is stated on the approved label.'¹³⁵

The explanatory notes acknowledge that references to these external standards may breach fundamental legislative principles, but provide the following justification:

Australian Standards and standards developed by Safe Work Australia are recognised and accepted industry standards and developed by technical experts with industry and government consultation. The standards are accredited by Standards Australia and Safe Work Australia, which are nationally recognised peak bodies for standards. The prescribed standards in clause 46 and the definition of safe exposure concentration deal with termite treatment and safe exposure to fumigants. The content is technical and detailed in nature. It is considered that the rigour surrounding the development of Australian Standards and standards by Safe Work Australia and the need to be responsive to changes in the standards justify the need to subdelegate by referring to an external document, rather than set out the requirements in the Pest Management Activities Regulation.¹³⁶

Committee comment

The committee is satisfied that the references to external standards in SL No. 142 are justified in the circumstances, having regard to the technical nature of the standards and that they represent accepted industry practice.

6.2 Explanatory notes

The explanatory notes comply with part 4 of the LSA.

6.3 Consideration of human rights compatibility

The human rights certificate discusses several human rights (including the right to property, right to equality before the law, right to privacy, freedom of expression and cultural rights). However, the impacts on these rights are considered to be minor.

Committee comment

The committee is satisfied that the subordinate legislation is compatible with human rights.

6.4 Human rights certificate

The human rights certificate tabled with the subordinate legislation provides a sufficient level of information to facilitate understanding of the subordinate legislation in relation to its compatibility with human rights.

7 Therapeutic Goods Regulation 2021 – SL No. 143

The *Therapeutic Goods Act 2019* (Therapeutic Goods Act) adopts the *Therapeutic Goods Act 1989* (Cwlth) and associated instruments as laws of Queensland (the Commonwealth Therapeutic Goods Laws), to ensure that national regulatory controls apply consistently to Queensland-based

¹³² SL No. 142, s 46; SL No. 142, explanatory notes, p 13.

¹³³ SL No. 142, explanatory notes, p 13.

¹³⁴ SL No. 142, explanatory notes, p 13.

¹³⁵ SL No. 142, schedule 3; SL No. 142, explanatory notes, p 14.

¹³⁶ SL No. 142, explanatory notes, p 14.

manufacturers of therapeutic goods.¹³⁷ The Therapeutic Goods Act allows a regulation to modify the application of the Commonwealth Therapeutic Goods Laws as laws of Queensland.¹³⁸

The Therapeutic Goods Regulation 2021 (SL No. 143) modifies the application of Commonwealth Therapeutic Goods Laws so that they do not apply to departmental employees involved in the manufacture, supply or use of unregistered therapeutic goods, or to other individuals supplying or using unregistered therapeutic goods manufactured by a departmental employee.¹³⁹ This is so the Central Pharmacy¹⁴⁰ can continue to conduct bespoke manufacturing for the benefit of patients in health services across Queensland.¹⁴¹

According to the explanatory notes:

Exempting Central Pharmacy from the application of the Commonwealth Act is not expected to impact on the safety and quality of the products manufactured. Medicines that are manufactured and repackaged within Queensland Health are done with the highest standards of safety and quality. Central Pharmacy currently holds a manufacturing licence under the *Health (Drugs and Poisons) Regulation 1996* which will be replaced by a manufacturing licence under the *Medicines and Poisons Act 2019*. This will ensure Central Pharmacy is required to adhere to the provisions of the Medicines and Poisons framework including safe packaging and labelling, and appropriate storage and record keeping for wholesale supply. It will also be subject to offences under the Medicines and Poisons Act. Central Pharmacy will also be required to manufacture goods under the relevant code of good manufacturing practice (PIC/S10 - Guide to good practices for the preparation of medicinal products in healthcare establishments).¹⁴²

7.1 Consistency with fundamental legislative principles

No issues of fundamental legislative principle were identified.

7.2 Explanatory notes

The explanatory notes comply with part 4 of the LSA.

7.3 Consideration of human rights compatibility

The subordinate legislation raises no human rights issues.

7.4 Human rights certificate

The human rights certificate tabled with the subordinate legislation provides a sufficient level of information to facilitate understanding of the subordinate legislation in relation to its compatibility with human rights.

8 Nature Conservation and Other Legislation (COVID-19—Fee Waiver) Amendment Regulation 2021 – SL No. 145

On 10 August 2021, the Queensland Government announced the Tourism and Hospitality Sector COVID-19 Lockdown Support Package (the Package), following the impacts on Queensland businesses due to the continuing outbreaks of the COVID-19 pandemic. The Package includes a 12-month fee

¹³⁷ SL No. 143, explanatory notes, p 1.

¹³⁸ SL No. 143, explanatory notes, p 2. See also *Therapeutic Goods Act 2019*, s 7(2).

¹³⁹ SL No. 143, s 3.

¹⁴⁰ The Central Pharmacy Manufacturing Unit (Central Pharmacy) is a commercialised business unit of Queensland Health. Central Pharmacy conducts bespoke manufacturing of individual medicines for individual patients, small-scale batch manufacturing of products that are not commercially available and the repackaging of some medicines. These medicines are provided for patients in Hospital and Health Services, dental clinics, Queensland Ambulance Service sites and private patients of hospitals within Queensland (SL No. 143, explanatory notes, p 2).

¹⁴¹ SL No. 143, explanatory notes, p 2.

¹⁴² SL No. 143, explanatory notes, p 3.

waiver for daily activity/passenger fees levied by the Department of Environment and Science on commercial tour operators using protected areas, recreation areas and State forests.¹⁴³

The Nature Conservation and Other Legislation (COVID-19—Fee Waiver) Amendment Regulation 2021 (SL No. 145) makes necessary amendments to the Forestry Regulation 2015, the Nature Conservation (Protected Areas Management) Regulation 2017 and the Recreation Areas Management Regulation 2017 to enable the fee relief to be implemented.¹⁴⁴

The cost of providing the fee relief to commercial tour operators from 1 July 2021 to 30 June 2022 is expected to be approximately \$1.2 million.¹⁴⁵

8.1 Consistency with fundamental legislative principles

8.1.1 Retrospectivity

Whether legislation has sufficient regard to rights and liberties of individuals depends on whether, for example, the legislation does not adversely affect the rights and liberties, or impose obligations retrospectively.¹⁴⁶

The explanatory notes discuss this fundamental legislative principle, in that the fee waivers will apply retrospectively from 1 July 2021 (SL No. 145 was notified on 17 September 2021), but conclude:

... the amendments are not considered to breach the rights and liberties of the tourism industry operators or others, as the legislation creates a beneficial policy outcome by providing financial relief in recognition of ongoing impacts to their businesses associated with the COVID-19 pandemic. Without retrospective application, operators would be unable to obtain the full benefit of the fee waiver.¹⁴⁷

Further, the fee waivers apply to those holding a commercial activity permit (which may be businesses rather than individuals).

Committee comment

The committee is satisfied that SL No. 145 has sufficient regard to the rights and liberties of individuals as it provides the benefit of fee relief.

8.2 Explanatory notes

The explanatory notes comply with part 4 of the LSA.

8.3 Consideration of human rights compatibility

The subordinate legislation raises no human rights issues.

8.4 Human rights certificate

The human rights certificate tabled with the subordinate legislation provides a sufficient level of information to facilitate understanding of the subordinate legislation in relation to its compatibility with human rights.

9 Public Health (Further Extension of Declared Public Health Emergency—COVID-19) Regulation (No. 3) 2021 – SL 148

The Public Health (Further Extension of Declared Public Health Emergency—COVID-19) Regulation (No. 3) 2021 (SL No. 148) further extends the period of a declared public health emergency to allow for emergency powers to be used to reduce the risk of COVID-19 spreading. The regulation extends

¹⁴³ SL No. 145, explanatory notes, p 1.

¹⁴⁴ SL No. 145, explanatory notes, p 2; SL No. 145, ss3, 6, 9.

¹⁴⁵ SL No. 145, explanatory notes, p 3.

¹⁴⁶ LSA, s 4(3)(g).

¹⁴⁷ SL No. 145, explanatory notes, p 3.

the declared public health emergency for a further period of 90 days (until the end of 26 December 2021).¹⁴⁸

The declaration of the public health emergency was made by the Minister for Health and Minister for Ambulance Services, Hon Steven Miles MP, on 29 January 2020, and notified in the gazette on 31 January 2020. It has previously been extended multiple times. (See SL Nos 7, 8, 13, 75, 154, 249 and 260 of 2020, and SL Nos 26 and 77 of 2021).

Note that the further extension regulation raises the same fundamental legislative principles and human rights issues as the first extension regulation (SL No. 7 of 2020) and the analysis provided for that regulation applies here. That analysis is substantially set out again below.

9.1 Consistency with fundamental legislative principles

9.1.1 Emergency powers – powers to require a person to leave or remain or not enter, and power of entry

The effect of declaring (and also of extending) a public health emergency is that a number of powers in the *Public Health Act 2005* (Public Health Act) are vested in an ‘emergency officer’ who is responding to the declared public health emergency. These powers include the power to require a person to:

- not enter or not to remain within a place
- stop using a place for a stated purpose
- go to or stay in a stated place
- answer questions.¹⁴⁹

An emergency officer also has the power to enter a place to save a human life, prevent or minimise serious adverse effects on human health, or do anything else to relieve suffering or distress. Reasonable force is permitted to be used to enter a place.¹⁵⁰

The emergency officer must make a reasonable attempt to seek consent for entry, but need not do so if the officer believes on reasonable grounds that immediate entry is required.¹⁵¹

The right to personal liberty is the most elemental and important of all common law rights.¹⁵²

Entry without consent into any place where a person lives requires the highest justification.¹⁵³

An individual would normally expect to be able to enjoy freedom of movement and any removal of this right must be fully justified.¹⁵⁴

The explanatory notes provide the following advice regarding protections to limit the exercise of the powers of emergency officers:

The powers of emergency officers are discretionary and are only expected to be exercised if there are significant risks to public health. Additionally, the Public Health Act includes protections to limit the exercise of emergency officers’ powers. For example:

- emergency officers can only enter places to save human life, prevent or minimise serious adverse effects on human health, or do anything else to relieve suffering or distress. Emergency officers are also required to make a reasonable attempt to seek an occupier’s consent to the entry (section 344);

¹⁴⁸ SL No. 148, s 2.

¹⁴⁹ Public Health Act, s 345.

¹⁵⁰ Public Health Act, s 343.

¹⁵¹ Public Health Act, s 344.

¹⁵² OQPC, *Fundamental Legislative Principles: the OQPC Notebook*, p 96.

¹⁵³ OQPC, *Fundamental Legislative Principles: the OQPC Notebook*, p 45.

¹⁵⁴ OQPC, *Fundamental Legislative Principles: the OQPC Notebook*, p 99.

- certain powers can only be exercised with the written approval of the chief executive (section 345(2));
- a person must be given the opportunity to voluntarily comply with a detention order before it is enforced against them (section 353); and
- a person who is detained must be given the opportunity of receiving medical treatment including by a doctor chosen by the person (section 354(4)).¹⁵⁵

The explanatory notes offer the following justification for the inconsistency with fundamental legislative principles:

... it is considered that any potential impact the Regulation has on the rights and liberties of individuals in this context is justified, given the need to protect the health of the public by managing the potential spread of COVID-19.¹⁵⁶

It should be noted that the powers described above are already contained within the Public Health Act, and are triggered by the declaration (and any extension) of a public health emergency, in this case due to the outbreak of COVID-19.

Committee comment

Given the ongoing nature of the COVID-19 public health emergency, the committee considers the breaches of fundamental legislative principle which arise from the restrictions on a person's rights and liberties are justified.

9.1.2 Matters appropriate to subordinate legislation

Subordinate legislation should contain only matters appropriate to that level of legislation. This issue is the corollary of the issue that a Bill should allow the delegation of legislative power in appropriate cases and to appropriate persons.¹⁵⁷

Generally, the greater the level of political interference with individual rights and liberties, or the institution of Parliament, the greater the likelihood that the power should be prescribed in an Act of Parliament and not delegated below Parliament.

The explanatory notes acknowledge that there is a potential breach of the fundamental legislative principle that legislation has sufficient regard to the institution of Parliament, given the extensive powers enlivened when a public health emergency is declared or extended.¹⁵⁸ It is regulations, not Acts of Parliament, which have generally been the mechanism by which the public health emergency has been extended.

The explanatory notes offer the following justification:

The potential breach is considered justified given the need to protect the health of the Queensland community by being able to respond swiftly to manage the ongoing evolving public health risk from COVID-19. The power to extend by regulation rather than an Act of Parliament allows the Government to discharge its key responsibility of protecting the health and safety of the public.

A Regulation extending the declared public health emergency may be made only if the Minister is satisfied it is necessary for a purpose of the Public Health Act. Having the ability to respond at short notice to an evolving epidemiological situation will continue to help ensure the public health objectives of the Public Health Act can be met.¹⁵⁹

The explanatory notes also highlight that on 2 September 2021 the *Public Health and Other Legislation (Further Extension of Expiring Provisions) Amendment Act 2021* was passed by the Legislative

¹⁵⁵ SL No. 148, explanatory notes, p 5.

¹⁵⁶ SL No. 148, explanatory notes, p 5.

¹⁵⁷ OQPC, *Fundamental Legislative Principles: The OQPC Notebook*, p 165.

¹⁵⁸ SL No. 148, explanatory notes, p 5.

¹⁵⁹ SL No. 148, explanatory notes, p 5.

Assembly. This Act further extended the ability of regulations to extend periods of declared public health emergencies for up to 90 days, until 30 April 2022.¹⁶⁰

Committee comment

Given the ongoing nature of the COVID-19 public health emergency, the committee considers the breaches of fundamental legislative principle relating to the institution of Parliament are justified.

9.2 Explanatory notes

The explanatory notes comply with part 4 of the LSA.

9.3 Consideration of human rights compatibility

It is for the committee to consider whether it is satisfied that the subordinate legislation is compatible with human rights.

The human rights issues raised by SL No. 148 are summarised below, followed by the collective response of the Minister for Health and Ambulance Services, Hon Yvette D'Ath MP, to all of those issues.

9.3.1 Freedom of movement

Every person has the right to move freely within Queensland and to enter and leave it.¹⁶¹

Under the regulation, emergency officers have the power to do the following:

- require a person to not enter or not remain within a place
- stay in a stated place
- stop using a place for a stated purpose.¹⁶²

This will impact on a person's right to freedom of movement.

9.3.2 Freedom of thought, conscience, religion and belief

Every person has the right to freedom of thought, conscience, religion and belief.¹⁶³

The regulation provides emergency officers with the power to order a person to self-isolate or to otherwise restrict a person's or group's movements. This may limit the ability of people to publicly demonstrate and practise their religion or beliefs.

9.3.3 Peaceful assembly and freedom of association

Every person has the right to peaceful assembly.¹⁶⁴

The restriction on a person's movements may limit their ability to assemble peacefully.

9.3.4 Cultural rights

Persons with a particular cultural, religious, racial or linguistic background must not be denied the right to enjoy their culture and to practise their religion.¹⁶⁵

The HRA recognises that Aboriginal and Torres Strait Islander peoples hold distinct cultural rights.¹⁶⁶

¹⁶⁰ SL No. 148, explanatory notes, pp 2, 6. See also *Public Health and Other Legislation (Further Extension of Expiring Provisions) Amendment Act 2021*, ss 49 - 51.

¹⁶¹ HRA, s 19.

¹⁶² SL No. 148, human rights certificate, p 4.

¹⁶³ HRA, s 20.

¹⁶⁴ HRA, s 22.

¹⁶⁵ HRA, s 27.

¹⁶⁶ HRA, s 28.

As noted above, SL No. 148 provides emergency officers with the power to order a person to self-isolate or to otherwise restrict a person's or group's movements. This may limit the ability of people to publicly demonstrate and practise their religion or beliefs.

The restrictions on a person's movement could limit a person's cultural rights to engage with community and their traditionally owned or otherwise occupied lands and waters.

9.3.5 Taking part in public life

Every person has the right to participate in the conduct of public affairs.¹⁶⁷

The restrictions on a person's movement or ability to interact with other persons may impact on a person's right to take part in public life.

9.3.6 Property rights

A person must not be arbitrarily deprived of their property.¹⁶⁸

Emergency officers have the power to:

- demolish structures or other property
- remove an animal, substance or thing from a place
- dispose of an animal, substance or thing at a place
- destroy animals at a place or remove animals for destruction at another place
- take action in relation to property.¹⁶⁹

All these actions will impact on a person's property rights and will deprive them of their property.

9.3.7 Right to privacy

A person has the right not to have their privacy unlawfully or arbitrarily interfered with.¹⁷⁰

Being compelled to provide a name and address and to answer questions limits a person's human right to privacy.

9.3.8 Right to liberty and security of person

A person must not be subject to arbitrary arrest or detention.¹⁷¹

The regulation provides powers to emergency officers to restrict people's movements, including requiring a person to self-isolate at home or another premises. This may limit the right to liberty and security because preventing people from leaving their homes or other premises may constitute detention.

9.3.9 Protection of families and children

Every child has the right to protection that is in their best interests as a child.¹⁷²

The power to restrict a person's movement may impact children through restriction of movement, contact with other people or restricting access to facilities, such as schools, and events.

¹⁶⁷ HRA, s 23.

¹⁶⁸ HRA, s 24.

¹⁶⁹ SL No. 148, human rights certificate, p 6.

¹⁷⁰ HRA, s 25.

¹⁷¹ HRA, s 29.

¹⁷² HRA, s 26.

9.3.10 Humane treatment when deprived of liberty

A person deprived of liberty must be treated with humanity and respect.¹⁷³

Emergency officers (medical) have the power to order the detention of a person if that person has or may have a serious disease or illness. The use of force to enforce self-isolation or other directions could limit the right to humane treatment when deprived of liberty.¹⁷⁴

9.3.11 Right to education

A child has the right to access primary and secondary education appropriate to their needs.¹⁷⁵

A child's educational activities may be limited due to restrictions on movement.

The Minister's justification for the limitations on human rights

The Minister provides the following collective justification for all these limitations on human rights:

The limitation of human rights is necessary to ensure that public health officials can implement effective containment and mitigation measures in response to the COVID-19 pandemic. These measures will protect Queenslanders where possible from exposure to COVID-19 and, in the event of significant community exposure, slow the rate of transmission, particularly to vulnerable persons who may develop complications or otherwise require emergency or life-sustaining treatment.¹⁷⁶

The Minister further states:

The benefits of significantly reducing Queenslanders' exposure to disease and preserving access to emergency and life-sustaining treatment for persons who develop serious health complications as a result of a COVID-19 outbreak substantially outweigh the limitations on human rights.

Although the Regulation potentially limits many rights, these limitations are minor in nature and the need to protect the right to life for all Queenslanders substantially outweighs any limitation on human rights.¹⁷⁷

The Minister also notes these safeguards:

The Public Health Act states that the Regulation can extend the declared public health emergency and related powers of emergency officers for a period of no more than 90 days. This requirement is an important safeguard as it places an obligation on the Queensland Government to repeatedly assess the need for the declared public health emergency to continue, based on the current threat of COVID-19 in Queensland.¹⁷⁸

Committee comment

Given the imperative to protect the health of Queenslanders from the COVID-19 pandemic, the committee is satisfied that any limitation to human rights in the regulation is reasonable and justifiable. The committee notes that the extension regulation is limited by *the Public Health and Other Legislation (Extension of Expiring Provisions) Amendment Act 2021*.¹⁷⁹

9.4 Human rights certificate

The human rights certificate tabled with the subordinate legislation provides a sufficient level of information to facilitate understanding of the subordinate legislation in relation to its compatibility with human rights.

¹⁷³ HRA, s 30.

¹⁷⁴ SL No. 148, human rights certificate, p 8.

¹⁷⁵ HRA, s 36.

¹⁷⁶ SL No. 148, human rights certificate, p 9.

¹⁷⁷ SL No. 148, human rights certificate, p 10.

¹⁷⁸ SL No. 148, human rights certificate, p 10.

¹⁷⁹ *Public Health and Other Legislation (Extension of Expiring Provisions) Amendment Act 2021*, ss 49-51.

10 Nature Conservation (Protected Areas) Amendment Regulation (No. 3) 2021 – SL No. 150

The objectives of the Nature Conservation (Protected Areas) Amendment Regulation (No. 3) 2021 (SL No. 150) are to:

- dedicate part of Daintree National Park, as Daintree National Park (Cape York Peninsula Aboriginal Land)
- dedicate the entirety of the existing Hope Islands National Park, as Hope Islands National Park (Cape York Peninsula Aboriginal Land)
- dedicate part of Black Mountain National Park, as Kalkajaka National Park (Cape York Peninsula Aboriginal Land)
- dedicate part of Ngalba Bulal National Park, as Ngalba-bulal National Park (Cape York Peninsula Aboriginal Land), and
- effect a revocation approved by the Legislative Assembly on 13 May 2021.¹⁸⁰

According to the explanatory notes, the benefits of SL No. 150 are:

... that the areas will enable joint management of the national parks between the Aboriginal Traditional Owners and Aboriginal people particularly concerned with the land and the Queensland Government. The action facilitates an opportunity for Traditional Owners to explore economic sustainability through expansion of local commercial recreation and ecotourism ventures. The revocation of part of the Daintree National Park has community benefits as this will allow for the gazettal of an existing road in the upper Daintree Valley, and which is essential for property access.¹⁸¹

In regard to consultation, the explanatory notes state:

The Queensland Government has discussed the proposal with the First Nations peoples particularly concerned with this land as well as the native title holders. The Traditional Owners understand and support that this amendment action is needed to rename and redescribe the land.

...

Cook Shire Council, Douglas Shire Council, Cape York Land Council Aboriginal Corporation, North Queensland Land Council Native Title Representative Body Aboriginal Corporation and the National Native Title Tribunal were also consulted.

All parties consulted support the amendments. No further changes to the Amendment Regulation were required as a result of the consultation.¹⁸²

10.1 Consistency with fundamental legislative principles

No issues of fundamental legislative principle were identified.

10.2 Explanatory notes

The explanatory notes comply with part 4 of the LSA.

10.3 Compatibility with human rights

The subordinate legislation raises no human rights issues.

¹⁸⁰ SL No. 150, explanatory notes, p 1. According to the explanatory notes, the Daintree National Park revocation proposal was tabled in the Legislative Assembly of Queensland on 24 March 2021 (in accordance with section 32 of the *Nature Conservation Act 1992*). The Legislative Assembly passed a resolution on 13 May 2021 requesting the Governor in Council revoke the area. The proposal was advertised within 10 days after the notice of motion for the revocation being given in the Cairns Post and The Courier-Mail on 31 March 2021 (in accordance with section 173Q of the *Nature Conservation Act 1992*).

¹⁸¹ SL No. 150, explanatory notes, p 4.

¹⁸² SL No. 150, explanatory notes, p 5.

10.4 Human rights certificate

The human rights certificate tabled with the subordinate legislation provides a sufficient level of information to facilitate understanding of the subordinate legislation in relation to its compatibility with human rights.

11 Recommendation

The committee recommends that the House notes this report.



Aaron Harper MP

Chair

January 2022

Health and Environment Committee

Chair	Mr Aaron Harper MP, Member for Thuringowa
Deputy Chair	Mr Robert (Rob) Molhoek MP, Member for Southport
Members	Mr Stephen (Steve) Andrew MP, Member for Mirani
	Ms Ali King MP, Member for Pumicestone
	Ms Joan Pease MP, Member for Lytton
	Dr Mark Robinson MP, Member for Oodgeroo