Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021

Explanatory notes for SL 2021 No. 141

made under the

Agricultural Chemicals Distribution Control Act 1966
Biosecurity Act 2014
Chemical Usage (Agricultural and Veterinary) Control Act 1988
Drugs Misuse Act 1986
Medicines and Poisons Act 2019

General Outline

Short title

Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021

Authorising law

Section 48 of the *Agricultural Chemicals Distribution Control Act 1966*
Section 503 of the *Biosecurity Act 2014*
Section 38 of the *Chemical Usage (Agricultural and Veterinary) Control Act 1988*
Section 134 of the *Drugs Misuse Act 1986*
Section 240 of the *Medicines and Poisons Act 2019*

Policy objectives and the reasons for them

Medicines, poisons and therapeutic goods are currently regulated in Queensland under the *Health Act 1937*, *Health (Drugs and Poisons) Regulation 1996* and *Health Regulation 1996*. The use of pesticides for pest management activities is regulated under the *Pest Management Act 2001* and the *Pest Management Regulation 2003* (Pest Management Regulation).

Following a review of the existing legislation, it was determined that the Health Act, Pest Management Act, Health (Drugs and Poisons) Regulation, Health Regulation and Pest Management Regulation would be repealed and replaced with a suite of legislation comprising the:

- *Medicines and Poisons Act 2019* (Act);
- *Therapeutic Goods Act 2019*;

- *Medicines and Poisons (Medicines) Regulation 2021*;
- *Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021* (Poisons Regulation);
- *Medicines and Poisons (Pest Management Activities) Regulation 2021*; and
- *Therapeutic Goods Regulation 2021*.

The Act and Therapeutic Goods Act were passed by the Legislative Assembly on 17 September 2019 and received Royal Assent on 26 September 2019.

On 13 August 2020, a postponement regulation (SL 2020 No. 150) was made under section 15DA of the *Acts Interpretation Act 1954* postponing the automatic commencement of the Act by one year, until the end of the day on 26 September 2021. The scheme was originally planned to commence in mid-2020 but was delayed due to the impact of COVID-19.

The Act and Therapeutic Goods Act automatically commence on 27 September 2021 Their supporting regulations will also commence on 27 September 2021. At this time, the Health Act, Pest Management Act, Health (Drugs and Poisons) Regulation, Health Regulation and Pest Management Regulation will be repealed.

Medicines and poisons are scheduled by the Therapeutic Goods Administration in the Commonwealth *Standard for the Uniform Scheduling of Medicines and Poisons* (Poisons Standard). Chemicals used for pest management activities, are registered or permitted for use as pesticides or fumigants by the Australian Pesticides and Veterinary Medicines Authority. Also, many pesticides and fumigants are scheduled poisons and listed in the Poisons Standard.

A key objective of the Act is to ensure substances, including medicines and poisons are used safely and effectively and do not cause harm to human health. The Act and Regulations cover activities that involve substances scheduled by the Therapeutic Goods Administration and substances registered or permitted by the Australian Pesticides and Veterinary Medicines Authority. Collectively, these substances will be referred to as 'regulated substances'.

The Poisons Regulation regulates poisons and prohibited substances and gives effect to the Act's objectives. Key policy objectives of the Poisons Regulation include:

- 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.

Achievement of policy objectives

Adoption of the Poisons Standard

The Poisons Standard provides for the uniform scheduling of substances classified from Schedule 2 (S2) to Schedule 10 (S10). All States and Territories refer to the Poisons Standard when regulating possession, access and use of scheduled substances.
The Poisons Regulation will achieve the policy objectives by adopting parts 2 and 4 and parts of Appendix J of the Poisons Standard.

Part 2 of the Poisons Standard includes provisions about standard controls for the management of medicines and poisons risks. It covers matters such as labelling, containers, storage and disposal. The matters predominantly apply to sale and supply and most sections are specific to poisons (that is, S5, S6 and S7 substances). The Poisons Regulation also includes additional controls for the use and disposal of the poisons (for example, labelling requirements for a substance that has been decanted or transferred to another container, proper accounting of use and disposal of high-risk poisons).

Part 4 of the Poisons Standard includes the Schedules of medicines and poisons:

- Schedule 2 – pharmacy medicine (S2);
- Schedule 3 – pharmacist only medicine (S3);
- Schedule 4 – prescription only medicine or prescription animal remedy (S4);
- Schedule 5 – low harm poison (S5);
- Schedule 6 – moderate harm poison (S6);
- Schedule 7 – dangerous poison (S7);
- Schedule 8 – controlled medicine (S8);
- Schedule 9 – prohibited substance, should only be available for medical or scientific research, or for analytical, teaching or training purposes (S9); and
- Schedule 10 – prohibited substance, known for their dangerous properties (S10).

Appendix J identifies S7 agricultural and industrial poisons which are highly dangerous and require additional controls. The Poisons Regulation prescribes those Appendix J poisons that are either obsolete or banned under international treaties or pose an unacceptable risk to public health. Not all Appendix J poisons have been included in the Regulation due to existing controls under other state laws, such as for 4-aminopyridine that is also regulated under the *Chemical Usage (Agricultural and Veterinary) Control Regulation 2017*. The list of high-risk poisons is referred to as restricted S7 poisons and replace the list of regulated poisons in Appendix 7 of the Health (Drugs and Poisons) Regulation.

To achieve the policy objectives, the Poisons Regulation:

- includes a penalty provision for non-compliance with relevant provision of part 2 of the Poisons Standard;
- provides that despite the labelling requirements, a person does not commit an offence if a substance has been rescheduled and the person labelled and packaged the substance prior to the rescheduling taking place;
- provides a person who supplies an S6 or S7 poison by retail does not commit an offence if the poison is stored in accordance with the *National guideline for retail storage of Schedule 6 and Schedule 7 poisons*;
- provides a person must not cover, deface, remove or change any label on a regulated substance container affixed in accordance with part 2 of the Poisons Standard;
- provides poisons must be held in packages that are in good condition. If a person becomes aware that a package containing a poison is damaged, the poison must be decanted into another container that is appropriate for the poison under the requirements of part 2 of the Poisons Standard, or if the contents are to be disposed of, disposal must be in accordance with the disposal requirements in the Poisons Regulation or other relevant law;
- provides a poison container must not be washed, soaked or treated in a tank or receptacle that is used to hold human or animal food or drink;
- provides a person must store a poison in a manner that minimises or prevents contamination, degradation or adulteration risks, or for S7 poisons, the risk of diversion of the substance; and
- adopts the classification system of the Poisons Standard and the substances that are scheduled under the classification system in part 4 of the Poisons Standard.

Offences

The Act introduces a simplified and consistent series of general offences, to replace the numerous offences in the Health (Drugs and Poisons) Regulation, Health Regulation and the Pest Management Regulation.

The Act and Regulations provide that no offence is committed if a person holds the necessary authority, licence or approval to perform the activity in question.

The Act makes provision for authorities to have conditions which may be prescribed in a regulation or may be set out in the authority instrument. Failure to comply with a condition of an authority is an offence under the Act.

While the Act broadly addresses offences associated with authorities or performing regulated activities with regulated substances, the Poisons Regulation provides for some offences that are not covered by the Act. These relate principally to the standard controls for poisons that are in part 2 of the Poisons Standard, or other similar requirements about standard controls. Offences for pest management businesses have been strengthened under the Pest Management Regulation.

The Poisons Regulation 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.

Licensing

The new regulatory regime rationalises the licensing requirements for medicines and poisons. Under the Health (Drugs and Poisons) Regulation, manufacturers of medicines, including veterinary medicines, are required to hold a licence, in addition to a manufacturing licence under the *Therapeutic Goods Act 1989* (Cwlth) or the *Agricultural and Veterinary Chemicals Code Act 1994* (Cwlth). The Medicines and Poisons Act provides that if a Commonwealth licence is held, the manufacturer is not required to hold a separate Queensland manufacturing licence.

The new regulatory provisions will achieve the policy objectives by streamlining the licensing regime. For example, a manufacturing licence will only be required by a manufacturer of regulated substances intended for non-therapeutic use, other than S5 and S6 substances.

Wholesale licences will be required by any person or entity wholesaling medicines or poisons, other than S5 and S6 substances, in Queensland. If an entity is based in another state or overseas jurisdiction, it will not require a Queensland wholesale licence if it holds an equivalent authority in its respective jurisdiction and does not hold stock in Queensland.

The Poisons Regulation prescribes standard conditions for the holder of a manufacturing licence. These standard conditions relate to:

- Manufacturing supervisors – the holder of a manufacturing licence must not appoint a manufacturing supervisor unless the person satisfies the competency standard set out in the departmental standard titled *Competency requirements for authority holders dealing with poisons*. The licence holder must also ensure that the poison is manufactured under the supervision of the manufacturing supervisor.
- Quality control and records – The holder of a manufacturing licence must take all reasonable steps to ensure the manufactured poison is fit for purpose and free from contamination. Batch manufacturing records are required to be kept so that any out-of-specification poisons can be identified and recalled, or other appropriate actions taken.

The intent of the regulation is to ensure that any manufactured poisons are not a risk to public health.

General approvals

A general approval authorises the holder of the approval to undertake a regulated activity with the regulated substance stated in the approval, under the conditions stated in the approval. The Poisons Regulation will prescribe standard conditions for general approval holders. Additional conditions may be prescribed on the authority instrument depending on the substance involved, the purpose of use and any other relevant criteria.

General approvals will be granted to persons, including entities, for a range of regulated activities, including possession and applying restricted S7 poisons for animal baiting.

General approvals may be able to be renewed or not renewable. Approvals that are not renewable will be assessed on a case-by-case basis and granted for specific, time-limited requirements, such as a research project. Approvals that can be renewed may be granted if there is an on-going business need, for example, for the use of cyanide by an electroplating business.

The holder of a general approval for invasive animal control must comply with the departmental standards titled *Dealing with restricted S7 poisons for invasive animal control* and *Competency requirements for authority holders dealing with poisons*.

Approved persons

The Poisons Regulation provides for particular classes of persons to be authorised to carry out specific regulated activities with regulated substances because of their profession, qualifications or authorisation under relevant Queensland legislation. These persons are known as 'approved persons'.

The classes of approved persons prescribed to undertake regulated activities under the Poisons Regulation include:

- a veterinary surgeon may possess or dispose of waste from a non-restricted S7 substance or supply, apply or buy a non-restricted S7 substance if the poison is used for animal treatment;
- a pharmacist may supply, buy, possess and dispose of waste from a non-restricted S7 substance, cyanide or strychnine;
- authorised officers under the *Biosecurity Act 2014* who have completed specified baiting competencies may supply, apply, possess and dispose of waste of low-risk fluoroacetic acid baits, a restricted S7 substances;
- a local government, or a chief executive of a local government, may possess and dispose of waste from a non-restricted S7 substance or supply a non-restricted S7 substance if the poison is supplied to a person delivering a service provided by the local government to the public or to an owner or occupier of private land for managing weeds or vegetation on the land.

The approved persons provision fulfills the policy objective of minimising the regulatory burden on affected persons by authorising appropriately trained and competent individuals to undertake specific activities without requiring an approval.

Fees

A fee is payable for all licences granted under the Act. For existing licence holders, the amount paid will not change and there will be no changes to the poison licences. No fees will continue to be payable for general approvals. The aim of the revised fee structure is to streamline and simplify the existing licence process, while ensuring no new fees or charges.

Under the medicines and poisons regulatory framework, licences are required for:

- manufacturing of S2, S3, S4 and/or S8 substances;

- manufacturing of S7 substances (including pesticides and fumigants);
- wholesale of S2, S3, S4 and/or S8 substances;
- wholesale of S7 substances;
- retail of S2 medicines;
- retail of S7 substances; and
- pest management technicians.

Existing holders of a Commonwealth manufacturing licence (from the Therapeutic Goods Administration or Australian Pesticides and Veterinary Medicines Authority) must also hold a Queensland manufacturer licence and pay the applicable licence fee. Under the medicines and poisons regulatory framework, Commonwealth manufacturing licences will be recognised. As a consequence, the holders of these licences will not be required to hold a separate Queensland manufacturing licence.

In line with the Health (Drugs and Poisons) Regulation, if a Queensland manufacturer does not have a Commonwealth licence, the Queensland licences authorising the manufacture and wholesale of medicines will attract a specific fee if the licence authorises the manufacture or wholesaling of S8 medicines in addition to S2, S3 or S4 medicines. Where only S8 medicines are manufactured or sold, the specific S8 fee would only apply. For example:

- manufacture of an S2, S3 or S4 poison – one licence, one fee;
- manufacture of an S8 poison – one licence, one fee;
- manufacture of an S2, S3 or S4 poison and manufacture of an S8 poison – one licence, two fees; and
- manufacture of an S7 poison – one licence, one fee.

Under the Health (Drugs and Poisons) Regulation, manufacturing licence holders with multiple sites must have a separate licence, and pay a separate licence fee, for each site. The same licence structure applies to state-based wholesale licences.

In a small number of cases, an existing licence holder with one licence will need two licences to perform the same activity. For example, the wholesaler of both S4 medicated animal feed and an S7 poison for agricultural purposes only requires a restricted drug wholesaler licence under the Health (Drugs and Poisons) Regulation, but will require an S2, S3 or S4 medicines wholesale licence and an S7 wholesale licence under the medicines and poisons regulatory framework. To ensure authority holders are not disadvantaged by this change, the new framework will allow two licences to be issued, and one fee charged, in situations where only one licence is required under the Health (Drugs and Poisons) Regulation. This will apply to both existing licence holders and new industry entrants.

Advantages of the revised fee structure under the new framework compared to the fees charged under the Health (Drugs and Poisons) Regulation include:

- one licence can cover multiple sites, which streamlines the application process;
- Queensland will now recognise Commonwealth manufacturing licences;

- a Queensland manufacturing licence still includes a deemed wholesale licence;
- there are no fees or licensing requirements for wholesale representatives;
- there is no increase in fees for licence holders; and
- there are no new fees for approval and permit holders.

The Poisons Regulation includes provision for refunding licence fees if a licence is not granted or if the applicant withdraws the application. However, the processing fee will not be refunded. The licensee would be able to gain a refund of fees if the licence was surrendered prior to the term of the licence.

Departmental standards

The Poisons Regulation is more outcome-focused, with many of the prescriptive requirements contained in the Health (Drugs and Poisons) Regulation being repealed. Where possible, the Poisons Regulation prescribes particular outcomes that must be met in order to achieve compliance and will refer to departmental standards for acceptable methods by which to achieve prescribed outcomes.

The Act empowers the chief executive to make standards relevant to the objects and administration of the new regulatory framework. The Poisons 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. The Act provides that the standard does not take effect until it is approved by the regulation or a date stated in the standard and is published on the Queensland Health website.

The standards which support the Poisons Regulation include:

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

Substance management plans

The Act contains a new requirement for particular authority holders to develop a substance management plan. A substance management plan allows authority holders to achieve compliance while allowing them the flexibility to identify and manage the risks relevant to them. It recognises that there are many options for how compliance can be met rather than the current prescriptive approach. A substance management plan must also document accountabilities and responsibilities of persons employed or engaged by the authority holder.

A substance management plan demonstrates that an authority holder has considered risks involving regulated substances and taken steps to ensure these are adequately managed in the particular context of the practice and work environment of the authority holder. In developing and implementing a substance management plan, there must be compliance with any relevant standards.

The Poisons Regulation requires the following persons to have a substance management plan:

- a holder of a poison manufacturing licence;
- a holder of a poison wholesale licence;
- the holder of a general approval that authorises a regulated activity with a high-risk poison;
- the holder of a substance authority if required as a condition of a substance authority.

A substance management plan must be reviewed at least every five years. Reviews must also occur after a significant event such as an identified risk occurring, an audit identifying gaps in the management of risks, the entity changing premises, organisational restructure or employee accountability or a change in major contracts such as supply or delivery agreements.

Entities will have one year after the Act commences to comply with the substance management plan requirements, to give entities sufficient time to make their plan, so that their activities will not be interrupted.

Substance authorities for dealing with high-risk poisons

The holder of a substance authority for a high-risk poison must keep a poison register to record each dealing with a high-risk poison, from buying to disposal, to track the use of the poison until it is completely used or destroyed.

If the poison register is amended, information related to the amendment must be recorded in the register. For example, the date of the amendments, name and position of the person who made the amendment and the reason for the amendment. Any amendments must be witnessed by another person.

The poison register can be kept in either an electronic or paper form. If a register is in an electronic form, each person who is authorised to make entries and edits must have a unique secure system identifier so that each entry or amendment is automatically tracked. If a register is in paper form, pages must be numbered or not able to be removed without detection.

The substance authority holder must reconcile the register at least once a month.

If the poison register is lost, stolen or destroyed, the substance authority holder must give the chief executive notice about the incident. The notice must be given to the chief executive no later than seven days after an incident has occurred.

The holder of a substance authority for manufacturing or wholesaling a high-risk poison must have additional security in place to ensure the premises are constantly monitored by an alarm system or person located at the premises.

Wholesale buying

All persons that buy regulated poisons, including holders of a substance authority and approved persons, must comply with the provisions that relate to buying regulated poisons.

The regulation of wholesale buying of regulated poisons relates to purchase orders, receipting and invoicing and includes the following requirements:

- Purchase orders – wholesale buyers of regulated poisons must provide a purchase order to the supplier before or at the time of purchase and must be in writing. The purchase order must state details such as date of the purchase order, details of the buyer, the buyer's authority and the form, strength and amount of the poison. The purchase order must also be prepared in a way that reasonably minimises fraud or tampering, allow the purchaser order to be amended only by the buyer or supplier and be signed or marked in a way that identifies the buyer and supplier.
- Buyer authorisation, receipts and invoices – wholesale buyers of regulated poisons must provide evidence of authorisation and acknowledge receipt of the poison to suppliers and retain information regarding proof of purchase of poisons and authorisation.

Wholesale and retail supplying

The holder of a wholesale licence, an S7 retail licence or a general approval to supply a restricted S7 poison must comply with provisions that relate to supplying poisons. The regulation of wholesale and retail supply of regulated poisons relates to the direct delivery, invoicing, authorisation and acknowledging receipt of poisons and includes the following requirements.

- Direct delivery – A supplier must ensure the poison is delivered directly to the buyer. If the poison is delivered by a carrier then the supplier must ensure the carrier has established procedures that enable direct delivery to the buyer.
- Supplier to give invoice – A supplier must give the buyer an invoice for the supply of the poison that includes details such as a unique identifying number, supply date, details of the buyer and the name and amount of the poison. The supplier must also keep a copy of the invoice or a copy of the information contained in the invoice.
- Supply to authorised buyer only – A supplier must only supply a poison to a buyer if the buyer is authorised to buy the poison, or it is not unlawful for the buyer to buy the poison.
- Failure to give receipt – A buyer must provide the supplier with a notice for the receipt of the wholesale supply of a restricted S7 poison or high-risk poison. If the supplier has not received the notice within seven days after the date of supply, the supplier must notify the chief executive about the buyer's failure to acknowledge receipt of the poison.

Storage

The Poisons Regulation includes requirements about the storage of poisons and prohibited substances to prevent unauthorised access, inappropriate use, contamination, deterioration or theft, which may result in risks to public health or the substance being diverted for illicit activities, as follows:

- Storage of S2, S3 or S4 poisons – Substance authority holders are required to store all regulated S2, S3 or S4 poisons in a way that prevents unauthorised access, for example storage in a locked cabinet.

- Storage of S7 and high-risk poisons – If a substance authority is for a wholesale licence to supply an S7 substance or the substance holder possesses a restricted S7 poison or a high-risk poison then the poison must be kept in a secure area unless a person is otherwise dealing with a poison. The substance authority holder must ensure the secure area is locked and take reasonable steps to prevent unauthorised access to the secure area.
- Storage for transport – A holder of a substance authority that authorises possession of a restricted S7 poison or high-risk poison when transporting substances must ensure the poison is kept in a secure area of a vehicle and the secure area of the vehicle is kept locked when the poison is not being accessed. Reasonable steps must also be taken to prevent unauthorised access.
- Retail sale of S6 poisons – S6 poisons for retail sale must be stored so that they are out of reach of children or kept in child resistant packaging.

Notification conditions for substance authorities

The holder of a substance authority must notify the chief executive of the following events:

- a change to the place authorised under the substance authority;
- if the authority is a manufacturing licence, a change in manufacturing supervisor;
- a change of director, chairperson or partner as indicated on the authority holder's initial application form;
- if the holder of the authority intends to stop dealing with one or more regulated poisons stated on the authority;
- loss of any amount of a restricted S7 or high-risk poison; and
- a release of any amount of restricted S7 or high-risk poison that causes, or is likely to cause, a person to require medical treatment.

Notification must be made as soon as practicable after the event and may be made in writing or orally. Oral notifications must be followed by a written notification within seven days. Information about how to notify the chief executive will be published on the Queensland Health website.

Disposal

The Poisons Regulation prescribes the requirements for disposing of poisons. These requirements aim to prevent inappropriate disposal which may result in risks to public safety or the environment or diversion of the substance for illegal purposes.

- Destroying high-risk poisons – The holder of a substance authority must ensure waste from a high-risk poison is only destroyed if the destruction is lawful under the *Environmental Protection Act 1994* and the destruction is supervised by an inspector or another person approved by the chief executive.
- Disposal of S2, S3 or S4 poisons or an S7 substance – The holder of a substance authority must ensure waste from an S2, S3 or S4 poison or an S7 substance is only disposed of if the disposal is lawful under the *Environmental Protection Act 1994* and the waste is given to a person authorised under a substance authority to dispose of it.

If the poison is used for invasive animal control, then the poison may also be disposed of as stated in the departmental standard titled *Dealing with restricted S7 poisons for invasive animal control*. This includes allowing approved landowners to bury hazardous poisons used for pest management on their own property.

Record keeping

The Poisons Regulation prescribes the type of record, the details to be recorded and the length of time that the records must be kept for poisons regulated by the scheme, for example purchase orders, invoices, etc. The regulation provides for the following requirements.

- Recording information – a person must ensure the information is written in English and, if recorded in hard copy, is legibly recorded in ink.
- Keeping information – a person responsible for controlling the recording and keeping of information must ensure that information is readily retrievable, cannot be altered, deleted or removed without detection and is kept for five years after the day it is recorded unless otherwise stated in a specific requirement.

Label and container requirements

The Poisons Regulation prescribes the requirements for labelling and packaging poisons. The regulation provides for the following requirements.

- Compliance with part 2 of the Poisons Standard – all persons labelling or packaging a poison must comply with a part 2 requirement of the Poisons Standard that relates to labels and containers. The chief executive may approve an alternative labelling or packaging requirement if the alternative is as safe as the original.
- Interfering with labelling – a person must not change, cover, deface or remove a label, brand or mark that is required under part 2 of the Poisons Standard.
- Labelling for S5 and S6 poisons – a person applying or disposing of an S5 or S6 poison must comply with the approved label.
- Decanting poisons – a person supplying a poison must not decant a poison from one container into another unless the new container complies with part 2 of the Poisons Standard and is labelled appropriately.

Savings and transitional arrangements

If the chief executive certified a container for packing a poison under section 10(3) of the Health (Drugs and Poisons) Regulation and the certification was in effect immediately before the commencement of the Poisons Regulation, then the certification is taken to be an alternative way for packaging the poison under section 82 of the Poisons Regulation. The certification expires on the day stated in the certification, or one year after commencement if no date is specified. For example, if a certificate for approval for an alternative packaging for a poison issued by the chief executive expired on 2 February 2022 under the Health (Drugs and Poisons) Regulation, then this certificate of approval is valid until the 2 February 2022 under the Poisons Regulation. If, however there was no expiry date for the approval, then the certificate is valid until one year after the Poisons Regulation commences.

If the chief executive certified an alternative way of labelling a package for a poison under section 11(3) of the Health (Drugs and Poisons) Regulation and the certification was in effect immediately before the commencement of the Poisons Regulation, then the certification is taken to be an alternative way of labelling a package for the poison under section 82 of the Poisons Regulation. The certification expires on the day stated in the certification. For example, if a certificate of approval for an alternative labelling for a poison issued by the chief executive expired on 2 February 2022 under the Health (Drugs and Poisons) Regulation, then this certificate of approval is valid until the 2 February 2022 under the Poisons Regulation.

Consistency with policy objectives of authorising law

The regulation is consistent with the policy objectives of the Act.

Inconsistency with policy objectives of other legislation

No inconsistencies with the policy objectives of other legislation have been identified.

Alternative ways of achieving policy objectives

The regulation is the only effective means of achieving the policy objectives.

Benefits and costs of implementation

The cost of implementing the new regulatory framework will be met within existing budget allocations, and the resources used to manage the existing regulatory framework will continue to be used to administer the new framework.

There are no new or increased fees under the proposed legislation. The Queensland Treasury Principles for Fees and Charges (January 2018) require agencies to set fees and charges to accurately reflect the full cost of providing their services. Agencies are also required to have processes in place to ensure the fees and charges maintain their value over time. Therefore, the proposed fees will be subject to annual indexation in line with the Government indexation policy as advised by Queensland Treasury.

The new regime introduces a more streamlined outcome-focused regulatory approach and improves clarity and consistency, and reduces administrative costs for Queensland Health. Further, the option for multi-site licence options for licence or approval holders and entities, rather than individual based authorities, has a high potential to reduce Queensland Health's operating costs, resulting in a more revenue-neutral outcome.

Consistency with fundamental legislative principles

The Poisons Regulation is generally consistent with fundamental legislative principles. Potential breaches of fundamental legislative principles are addressed below.

Rights and liberties of individuals

Does the legislation make rights and liberties, or obligations, dependent on administrative power only if the power is sufficiently defined and subject to appropriate review?

Section 4(3)(a) of the *Legislative Standards Act 1992* states that whether legislation has sufficient regard to the rights and liberties of individuals depends on whether the legislation makes rights and liberties, or obligations, dependent on administrative power only if the power is sufficiently defined and subject to appropriate review.

Section 93 (Requirements for substance management plan) of the Act imposes obligations on the responsible person for a regulated place to make a substance management plan for the place before any dealing happens in relation to a regulated substance and that the plan is to be reviewed at the time prescribed by regulation. A substance management plan is a document setting out known and foreseeable risks associated with dealing with a regulated substance to be managed at the regulated place. Clause 68 (Review of plan—Act, s 93) of the Poisons Regulation provides that a substance management plan must be reviewed as soon as practicable after a review incident happens or at least every five years after the day the substance management plan starts, or the plan is reviewed following a review incident.

Substance management plans are an important component in the management of foreseeable risks associated with dealing with regulated substances when undertaking a regulated activity. Examples of foreseeable risks that need to be mitigated may include diversion or theft of prohibited substances, accidental exposure or spillage of dangerous poisons, or environmental contamination. It is accepted industry practice that similar types of plans are reviewed at least every five years, or in response to an incident of loss or exposure. The entity is best placed to review their plan as they have the knowledge and expertise based on their operating procedures and industry practices. The timeframe of five years reflects workplace health and safety practice. Section 274 of the *Work Health and Safety Act 2011* provides that a code of practice expires five years after it is approved.

Institution of Parliament

Does the subordinate legislation allow for the subdelegation to appropriate persons or in appropriate cases?

Section 4(5)(e) of the Legislative Standards Act states that whether legislation has sufficient regard to the institution of Parliament depends on whether the subordinate legislation allows the subdelegation of a power delegated by an Act, only in appropriate case and to appropriate persons, and if authorised by an Act.

Departmental standards

Section 233 (Making departmental standards) of the Act empowers the chief executive to make standards about carrying out regulated activities with regulated substances and other matters relating to purposes and administration of the Act.

A standard may include procedures for carrying out regulated activities, procedures for keeping, storing and managing regulated substances, training and competency requirements for persons carrying out regulated activities with regulated substances, procedures to ensure products containing regulated substances are safe and suitable for the intended use of the products and requirements for tracing the movement of a regulated substance from its manufacture to final disposal, including requirements about documentation and electronic transmission.

Schedule 3 (Departmental standards) of the Poisons Regulation prescribes the names of approved departmental standards and their version number. The standards are outcome focused and list options to achieve the desired outcomes, which would not be suitable for inclusion in a prescriptive requirement in a regulation. For example, the departmental standard titled *Substance management plans for regulated poisons* provides alternative security measures for ensuring regulated poisons are stored securely.

Prescribing requirements by reference to an external document may be seen to breach section 4(5)(e) of the Legislative Standards Act. 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. The standards will be monitored and updated when necessary, align with industry best practice and are published on the Queensland Health website (www.health.qld.gov.au). When making or amending a standard, relevant individuals and organisations with expertise in, or experience of, the matters under consideration will be consulted.

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.

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.

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.

<u>Poisons Standard</u>

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 made under section 52D of the *Therapeutic Goods Act 1989* (Cwlth).

Clause 54 (Labels and containers to comply with Poisons Standard or approved alternatives) 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.

Clause 69 (Compliance with Poisons Standard or approved alternatives) 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.

These provisions may be seen to breach the principle that subordinate legislation should allow the subdelegation of a power delegated by an Act only in appropriate cases and to appropriate persons and if authorised by an Act (section 4(5)(e) of the Legislative Standards Act). 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. There are representatives from each State on the scheduling committee to ensure the Poisons Standard is applicable in all jurisdictions. Additionally, the committee meets three times each year to discuss updates to be made to the Poisons Standard.

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. In addition, the new legislation will enable regulations to be made so that short-term gaps in the scheduling of a medicine or poison at the national level is addressed by the Queensland legislation if they arise in the future.

External Standards and Guidelines

In some cases, it is necessary to adopt or require compliance with standards that have been developed by relevant industry bodies (such as Australian Standards or standards made by Safe Work Australia).

Clause 70 (Retail sale and storage of S6 poisons) provides that a person does not commit an offence if selling an S6 poison by retail if the poison is stored or sold in child-resistant packaging or it is not stored or sold within the reach of children under four years or 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.

Prescribing an external guideline that is not subject to parliamentary scrutiny may breach section 4(5)(e) of the Legislative Standards Act.

S6 poisons are substances with a moderate potential for causing harm, the extent of which can be reduced through the use of distinctive packaging with strong warnings and safety directions on the label.

The *National guideline for retail storage of Schedule 6 and Schedule 7 poisons* is published under the authority of the Australian Health Minister's Advisory Council and is to be read in conjunction with the relevant provisions of the Poisons Standard and each jurisdiction's drugs/medicines and poisons legislation.

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.

Section 7 of the Act provides that a regulation may prescribe an activity with a substance to be exempt from the operation of the Act if the activity is reasonably expected to pose no health risk or a negligible health risk. Clause 13 (Exemption for reference material—Act, s 7) prescribes that applying or using reference material at an analytical or chemical laboratory or in a portable device is exempt as it is considered low-risk. This allows analytical laboratories to purchase up to 1g of regulated poisons and organisations using portable testing devices to purchase and use up to 0.5g of regulated poisons without an approval. For example, drug testing at workplaces.

Reference material means a substance used to calibrate analytical equipment, or validate an analytical measurement process, that has been manufactured by an accredited laboratory complying with:

- 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).

While the standards are more relevant to manufacturers of reference materials, analytical laboratories and workplaces are able to access the standards from Standards Australia for a fee.

Fundamental legislative principles not contained in Legislative Standards Act

Offences

The offences and penalty amounts contained in the Poisons Regulation are generally consistent with similar offences and penalty amounts contained in the Health (Drugs and Poisons) Regulation and Health Regulation.

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.

Clauses 69(1) and (2) (Compliance with Poisons Standard or approved alternatives) provides it is an offence for a person to supply an S5 or S6 poison unless the poison is labelled or complies with the requirements in part 2 of the Poisons Standard or an alternative way approved by the chief executive. The offences carry a maximum penalty of 40 penalty units.

Part 2 of the Poisons Standard contains nationally agreed requirements for labels, containers, storage, disposal, record keeping and sale, supply, possession or use of poisons. The maximum penalty of 40 penalty units is equivalent to the penalty for offences in the Health (Drugs and Poisons) Regulation, including section 291 (Labels and containers), section 296 (Samples of poisons) and section 300 (Use of food or drink container for poisons prohibited).

Clause 70 (Retail sale and storage of S6 poisons) provides that a person selling an S6 poison by retail must ensure the poison is stored or sold in child-resistant packaging or is not stored within reach of children under four years old. The offence carries a maximum penalty of 40 penalty units.

The person does not commit an offence if the person stores the S6 poison in accordance with the *National guideline for retail storage of Schedule 6 and Schedule 7 poisons*, made by the Australian Health Ministers' Advisory Council.

S6 poisons are substances with a moderate potential for causing harm, the extent of which can be reduced through the use of distinctive packaging with strong warnings and safety directions on the label.

The maximum penalty of 40 penalty units is equivalent to the penalty for offences in the Health (Drugs and Poisons) Regulation, including section 291 (Labels and containers), section 296 (Samples of poisons) and section 300 (Use of food or drink container for poisons prohibited).

Clause 71 (Supplying unsolicited S5 and S6 poison samples) provides that a person must not supply a sample of an S5 or S6 poison from place to place, unless the person has a reasonable excuse. The offence carries a maximum penalty of 40 penalty units.

The person does not commit an offence if the person supplies the sample by handing it directly to someone who has an opportunity to refuse to take it. For example, a sample may be handed to a person at a gardening show. The maximum penalty of 40 penalty units, is equivalent to the penalty for offences in the Health (Drugs and Poisons) Regulation including section 291 (Labels and containers), section 296 (Samples of poisons) and section 300 (Use of food or drink container for poisons prohibited).

Clause 73 (Interfering with labelling) provides it is an offence for a person to change, cover, deface or remove an approved label on a compliant container of an S5 or S6 poison. The offence carries a maximum penalty of 40 penalty units.

Labels on regulated substances are an important control measure for minimising public health risk and informing users of any precautions they need to take when using the substance. Alteration of the label increases the risk of misuse and potential harm to the user, including death in some cases, for example cyanide and hydrofluoric acid. The penalty is equivalent to the penalty for the corresponding provision in the Health (Drugs and Poisons) Regulation (section 291).

Clause 74 (Decanting poisons) provides that a person must not decant an S5 or S6 poison from a compliant container into a new container, unless the new container is labelled with the approved name of the poison and the signal word for the poison in capital letters. The signal word for an S5 poison is ‘caution’ and for an S6 substance is ‘poison’. The offence carries a maximum penalty of 40 penalty units.

Clause 75 (Cracked and damaged packaging) provides it is an offence if a person becomes aware that a container of an S5 or S6 poison is cracked or damaged, and the person does not immediately empty the poison into another container labelled with the approved name of the poison and the signal word for poison in capital letters or otherwise dispose of the contents lawfully. The offence carries a maximum penalty of 40 penalty units. Measures in clauses 74 and 75 account for the risks associated with the use of decanted S5 or S6 poison in an unlabelled or inappropriate container. For example, decanting S6 drain cleaner into an unlabelled soft drink bottle which may be readily accessed by a small child.

Poisons leaking from a cracked or damaged container pose a serious risk of harm to people, particularly to young children, for example acid burns or pesticide poisoning. The penalty is equivalent the corresponding provision in the Health (Drugs and Poisons) Regulation (section 291(2)).
Storing poisons in a cracked or damaged container poses a serious risk of harm to people which can be mitigated by transferring the contents to another suitable container which is correctly labelled, or by disposing of the poison in an appropriate way. The appropriate way to dispose of a poison for an S5 or S6 poison is by complying with the disposal instructions on the label. The penalty is equivalent to the penalty for the corresponding provision in the Health (Drugs and Poisons) Regulation (section 291(3)).

Clauses 76(1) and (2) (Contaminating food or drink containers) provides it is an offence for a person to use a food or drink container, or cause a food or drink container to be used, to contain an S5 or S6 poison, or for a person to soak, wash or otherwise treat a poison container in a receptacle used to soak, wash or treat a food or drink container of a type commonly used to hold human or animal food or drink. The offences carry a maximum penalty of 40 penalty units. Measures in clause 76(1) and (2) account for the risks associated with the storage of an S5 or S6 poison in food or drink container. For example, the risk of storing S6 rat baits in a lunchbox that could easily be accessed by a small child.

A poison container means a container that is used, or is of a type commonly used, to hold a poison, or has a brand, mark or label on it stating that the container has been used to hold a poison. Washing poisons containers in a receptacle used to clean food containers poses a serious risk of harm to people, due to the possibility that poison residues may contaminate the food containers. The penalty is equivalent to the penalty for the corresponding provision in the Health (Drugs and Poisons) Regulation (section 291(4)).

Clause 77 (Safe disposal of waste) provides that a person must not dispose of waste from an S5 or S6 poison in a way that affects, or is likely to affect, the health or safety of another person or domestic animal. The offence carries a maximum penalty of 40 penalty units. This measure relates to the inappropriate disposal of S5 or S6 poison, for example disposal of pool chlorine in a council park creating a public health risk for the park users.

The maximum penalty of 40 penalty units, is equivalent to the penalty for offences in the Health (Drugs and Poisons) Regulation including section 291 (Labels and containers), section 296 (Samples of poisons) and section 300 (Use of food or drink container for poisons prohibited).

Clause 78 (Unlawful advertising of prohibited substances) and clause 79 (Unlawful advertising of hazardous poisons) provides it an offence for a person to advertise, or cause a person to advertise, a prohibited substance or a hazardous poison. Both offences carry a maximum penalty of 80 penalty units.

Clause 78(2) does not apply to a person who refers to *Cannabis sativa* in an advertisement in connection with an activity authorised under sections 47 or 48(1) of the *Drugs Misuse Act 1986*. Sections 47 and 48 allow for the lawful possession, growing, production and supply of industrial cannabis plants and seeds for particular licensable activities including growing, export and research. For example, it is legal to provide advertising material to a researcher who has a licence under the *Narcotic Drugs Act 1967* (Cwlth) to possess industrial cannabis plants. Clause 79(2) does not apply to an advertisement of a hazardous poison in a journal, a price list or other promotional material intended for circulation only to persons applying the poison in a workplace. It is inappropriate for these poisons to be in the possession of, or used by, the general community due to high-risk illicit use or diversion risk. The promotion or advertising of these poisons should be limited to legitimate users. It does not apply to S5 and S6 poisons which are used in domestic setting.

Clause 80 (Recording information) provides that if a person records information in writing to comply with a requirement of the Poisons Regulation, it is an offence if a person fails to ensure the information is written in English and if recorded in hard copy, is marked legibly in ink on the document. The offence carries a maximum penalty of 20 penalty units. The person does not commit an offence if they also write in a language other than English if it ensures another person understands an instruction or the person signs their name on the document.

Record keeping is an important control measure for minimising public health risk as it provides information regarding the supply of regulated substances and details of activities undertaken with poisons. To be effective, the records must be written in English so they can be understood. Clause 80(3) allows the information to be written in a language other than English if it is necessary for the information to be understood by non-English speaking people. The penalty is equivalent to the penalty for the corresponding provision in the Health (Drugs and Poisons) Regulation (section 305).

Clause 81(2) (Keeping information) provides it is an offence if a person responsible for recording and keeping of information fails to ensure the information is readily retrievable, can not be altered, obliterated, deleted or removed without detection and fails to ensure it is kept for five years after the day it is recorded. The offence carries a maximum penalty of 20 penalty units.

Records are an important control measure for minimising public health risk as they provide information regarding dealings with regulated substances. The value of the records is reduced if they can be changed without an indication of the change and the person responsible. Records are often kept electronically, and as electronic data technology advances some older records may not be retrievable unless the records are transferred to newer software and hardware. Clause 81 requires any records must be retrievable over the retention period. The penalty is equivalent to the corresponding provision in the Health (Drugs and Poisons) Regulation (section 302).

Consultation

A wide range of stakeholders were invited to comment on the Poisons Regulation, including:

- Accord (peak national association for hygiene, personal care products manufacturer and marketers);
- AgForce Queensland;
- Chemistry Australia;
- GrowCom;
- analytical laboratories;
- Local Government Association of Queensland;
- local governments;
- poison manufacturers, wholesalers and retailers;
- Queensland Farmers' Federation;
- logistics industry; and
- universities.

Fifteen written submissions were received, including from local governments, agricultural sector representatives and peak bodies.

Some stakeholders provided feedback on drafting matters. This feedback was incorporated into the Poisons Regulation where appropriate. Information sheets provided during consultation have also been updated to provide additional clarification.

Engagement and ongoing communication with external stakeholders continued after the conclusion of the consultation period with follow-up meetings, sharing of information and discussions occurring during the process of finalising the Poisons Regulation.

Submissions received from stakeholders indicated support for the regulatory measures in the Poisons Regulation. Stakeholders, including AgForce and universities, commended the years of continuous engagement with stakeholders which has resulted in comprehensive and reasonably practical regulatory provisions for public safety. These include provisions relating to 'approved persons', entity-level general approvals and licensing requirements and the use of departmental standards in the scheme. Stakeholders acknowledged that the new regime would reduce regulatory burden and improve compliance practices.

A number of recommendations on drafting matters were received from stakeholders to enhance the clarity of the Regulation. These were mainly associated with administrative matters; consistency, clarity and improvements to definitions; compliance measures outlined in the departmental standards; broadening the list of 'approved persons' in the Regulation; and clarification regarding some of the transitional arrangements from the Health (Drugs and Poisons) Regulation to the new scheme.

Where appropriate, these were incorporated into the Poisons Regulation. Information sheets provided during consultation have also been updated to provide additional clarification.

The updated factsheets and other resources will be provided to stakeholders to support the implementation of the new regulatory scheme.

In their submissions, local governments provided a number of recommendations to support stronger regulatory controls for a safe and effective delivery of invasive animal control programs in Queensland. Local governments sought tightening of the definition of the terms 'approved person', 'substance authority', and 'authorised person' in relation to supply of low-risk fluoroacetic acid baits. They also advocated for the development of additional regulatory measures to support compliance monitoring of landholders using regulated poisons for invasive animal control, for example, a centralised database of land holders accessing regulated poisons for invasive animal control. Other policy related matters were also raised specifically relating to clarifying roles and responsibilities of state agencies and local governments which will be considered during the implementation of the new regulatory scheme.

The Office of Best Practice Regulation assessed the entire medicines and poisons regulatory framework, in accordance with *The Queensland Government Guide to Better Regulation* and advised that no further regulatory impact analysis was required on the basis that the proposal is unlikely to lead to significant adverse impacts and should reduce overall regulatory requirements.

Notes on provisions

Chapter 1 Introduction

Part 1 Preliminary

Short title

Clause 1 states that the short title of the regulation will be the *Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021*.

Commencement

Clause 2 states that this regulation commences on 27 September 2021.

Definitions

Clause 3 provides that the dictionary in schedule 7 defines particular words used in this regulation.

Application of regulation

Clause 4 provides that this regulation applies in relation to a regulated activity that is dealing with a poison or prohibited substance.

Clause 4(2) provides that this regulation does not apply in relation to carrying out any of the following regulated activities:

- a dealing with an S7 poison authorised under section 60 (Authorisation of persons subject to work health and safety laws) of the *Medicines and Poisons Act 2019*;
- a pest management activity, or asking or directing another person to carry out a pest management activity;
- disposing of waste from a fumigant or pesticide.

Part 2 Categories of poisons and prohibited substances

Regulated poisons

Clause 5 provides that a ***regulated poison*** is a hazardous poison or a prohibited substance, other than a prohibited substance used, or intended to be used, for a therapeutic use.

A hazardous poison is defined in section 16 (Meaning of *hazardous poison*) of the Medicines and Poisons Act as a schedule 7 (S7) substance, or a schedule 2 (S2), schedule 3 (S3), schedule 4 (S4) or schedule 8 (S8) medicine, which is treated as a poison if the medicine is not used, or is not intended to be used, for a therapeutic purpose.

A prohibited substance is defined in section 13 (Meaning of *prohibited substance*) of the Medicines and Poisons Act as a substance to which schedule 9 (S9) or schedule 10 (S10) of the Poisons Standard applies. A regulation may also prescribe another substance to be an S9 or S10 prohibited substance.

A *therapeutic use* is defined in part 1 of the Poisons Standard. Poisons Standard means the current Poisons Standard within the meaning of section 52A(1) of the *Therapeutic Goods Act 1989* (Cwlth). See the *Medicines and Poisons (Pest Management Activities) Regulation 2021* in relation to pest management activities carried out using pesticides and fumigants.

S2, S3, S4 and S8 poisons

Clause 6 provides that an S2, S3, S4 or S8 poison is an S2, S3, S4 or S8 medicine treated as a poison under section 12(2) (Meaning of poison) of the Medicines and Poisons Act.

A poison is defined in section 12 (Meaning of *poison*) of the Medicines and Poisons Act as a substance to which schedules 5, 6 or 7 of the Poisons Standard applies, other than a fumigant or pesticide. A medicine is treated as a poison under the Act if the medicine is not used, or is not intended to be used, for a therapeutic use.

High-risk poisons

Clause 7 provides that a ***high-risk poison*** is an S8 poison or a prohibited substance, other than a prohibited substance used, or intended to be used, for a therapeutic use.

Restricted S7 poisons

Clause 8 provides that a ***restricted S7 poison*** is an S7 poison stated in schedule 1.

Non-restricted S7 substances

Clause 9 provides that a ***non-restricted S7 substance*** is an S7 substance that is not a restricted S7 poison.

Low-risk fluoroacetic acid bait

Clause 10 provides that a ***low-risk fluoroacetic acid bait*** is a poison that is fluoroacetic acid in the form of a bait containing the acid in a concentration of not more than 0.5 grams for each kilogram of the bait.

Part 3 Authorisations and approval of departmental standards

Approved persons—Act, s 54

Clause 11 provides that for section 54(1) (Authorisation of prescribed classes of persons) of the Medicines and Poisons Act, a class of persons stated in schedule 2 is prescribed for the dealing with the regulated poison stated in the table for the class of persons to the extent the dealing is carried out by a person acting as a member of the class of persons and within the scope for the dealing, if any.

Clause 11(2) provides for this section a definition of *scope*.

Departmental standards—Act, s 233

Clause 12 provides that for section 233(4) (Making departmental standards) of the Medicines and Poisons Act, each departmental standard mentioned in schedule 3 is approved. Under section 233(4) of the Medicines and Poisons Act, a departmental standard takes effect on the day it is approved by regulation, or a later day staged in the standard.

Clause 12(2) provides that a reference in this regulation to a departmental standard by its name is a reference to the standard stated in schedule 3 with that name and with the version number mentioned opposite that name.

Part 4 Exemptions and exclusions

Exemption for reference material—Act, s 7

Clause 13 provides that the following activities, with the following substances, are prescribed for section 7(1) (Exemption for low-risk activities) of the Medicines and Poisons Act:

- applying or using a reference material containing 1 gram or less of a regulated poison at an analytical or chemical laboratory;
- applying or using a reference material containing 0.5 grams or less of a regulated poison in a portable testing device;
- buying or possessing reference material for an activity mentioned in paragraphs (a) or (b).

Clause 13(2) provides for this section definitions of *accredited laboratory*, *portable testing device* and *reference material*.

Excluded places—Act, s 60

Clause 14 provides that for the definition of *excluded place* in section 60(3)(b) (Authorisation for persons subject to work health and safety laws) of the Medicines and Poisons Act, a place used for the sole or main purpose of carrying out or providing one or more activities or services stated in schedule 4 is prescribed to be an excluded place.

Excluded S7 poisons—Act, s 60

Clause 15 provides that for the definition of *excluded S7 poison* in section 60(3) (Authorisation for persons subject to work health and safety laws) of the Medicines and Poisons Act, a restricted S7 poison is prescribed to be an excluded S7 poison.

Chapter 2 Standard conditions for substance authorities

Part 1 Preliminary

Application of chapter—Act, s 70

Clause 16 provides that for section 70(1)(a) (Conditions) of the Medicines and Poisons Act, this chapter prescribes standard conditions applying in relation to substance authorities authorising dealings with regulated poisons.

Part 2 Conditions for particular types of substance authorities

Division 1 Manufacturing licences

Application of division

Clause 17 provides that this division applies in relation to a manufacturing licence authorising the manufacture of a regulated poison.

Manufacturing supervisors

Clause 18 provides that the holder of a manufacturing licence must appoint an appropriately qualified person to supervise manufacturing under the licence.

Clause 18(2) provides that the holder must take all reasonable steps to ensure the person mentioned in subsection (1) satisfies, and continues to satisfy, the competency requirements stated in the *Competency requirements for authority holders dealing with poisons* departmental standard that relate to the supervision of manufacturing for the type of licence held and the manufacture of a regulated poison under the licence is carried out under the supervision of the person.

Clause 18(3) provides for this section a definition of *competency standard*.

Quality control

Clause 19 provides that the holder of a manufacturing licence must take all reasonable steps to ensure a regulated poison manufactured under the licence is fit for its intended use and free from contamination.

Batch manufacturing records

Clause 20 provides that the holder of a manufacturing licence must keep a record of the following information for each batch of regulated poison manufactured under the licence:

- a unique identifier;
- details of materials used in the manufacture;
- the supplier of the materials for manufacture;
- the procedures and controls used in manufacturing;
- details of tests carried out during the processing the batch;
- details of study, if a stability study is carried out to test the shelf life and appropriate storage conditions of the batch.

Division 2 General approvals for controlling invasive animals

Application of division

Clause 21 provides that this division applies in relation to a general approval authorising a dealing with a restricted S7 poison to control an invasive animal.

Competency for dealings

Clause 22 provides that the holder of a general approval must satisfy, and continue to satisfy, the competency requirements stated in the *Competency requirements for authority holders dealing with poisons* departmental standard that relate to the type of approval held.

Clause 22(2) provides that the holder of the general approval must take all reasonable steps to ensure that every person dealing with a restricted S7 poison under the approval satisfies, and continues to satisfy, the relevant competency requirements stated in the *Competency requirements for authority holders dealing with poisons* departmental standard.

Clause 22(3) provides for this section a definition of *competency standard*.

Compliance with departmental standard for restricted S7 poisons

Clause 23 provides that the holder of a general approval must take all reasonable steps to ensure that every person dealing with a restricted S7 poison under the approval complies with the *Dealing with restricted S7 poisons for invasive animal control* departmental standard.

Part 3 Conditions for particular regulated poisons

Division 1 Possession of high-risk poisons

Subdivision 1 Preliminary

Application of division

Clause 24 provides that this division applies in relation to a substance authority authorising the possession of a high-risk poison.

Definitions for division

Clause 25 provides for this division definitions of *high-risk poison register* and *portion*.

Subdivision 2 High-risk poison register

Keeping register

Clause 26 provides that the holder of a substance authority must keep a document (a ***high-risk poison register***) about the total amount of a high-risk poison authorised to be possessed under the authority.

Clause 26(2) provides that the holder must take all reasonable steps to ensure the high-risk poison register states how each portion of the total amount of the high-risk poison is dealt with and how much of the high-risk poison is possessed at any given time at each authorised place for the authority

Information that must be recorded in register

Clause 27 provides that this section applies to each person carrying out a dealing with a portion of a high-risk poison under a substance authority.

Clause 27(2) provides that at the time of the dealing, the person must record the following information in the high-risk poison register for the substance authority:

- date of the dealing;
- name, form, strength and amount of the portion;
- details of the dealing;
- name, position and signature of the person;
- if the dealing is supply, the contact details of the person who supplied the portion and the contact details of the person to whom the portion was supplied;
- if the dealing is disposal, the name and position of the person who witnessed the destruction of the portion and the method of destruction;
- if the dealing is not supply or disposal, the name and position of any other person who is involved in carrying out the dealing under the substance authority.

Corrections to register

Clause 28 provides that a person mentioned in section 27(1) must not amend a high-risk register unless the person is correcting the register in the way mentioned in subsections (2) and (3).

Clause 28(2) provides that the person may correct an entry (an ***original entry***) in the high-risk poison register by making a record of the following information with the entry:

- date the correction is made;
- name and position of the person;
- name and the position of another person who witnessed the person making the correction;
- reason for the correction.

Clause 28(3) provides that the person must not cancel, delete or obliterate the original entry when making the correction.

Electronic register

Clause 29 provides that this section applies if the holder of a substance authority keeps a high-risk poison register in an electronic form.

Clause 29(2) provides that the holder must take all reasonable steps to ensure the following:

- a person can make entries in the register only by using the person's secure system identifier provided by the holder; and
- the person's secure system identifier is automatically recorded with an entry in the register made by the person; and
- the register is set up in a way that allows the information required under sections 27 and 28 to be included in the register; and
- the entries in the register are able to be easily reproduced on paper.

Clause 29(3) provides that the holder must make and keep a record of each person's secure system identifier in a form that can not readily be altered without detection.

Clause 29(4) provides for this section a definition of *secure system identifier*.

Paper register

Clause 30 provides that this section applies if the holder of a substance authority keeps a high-risk poison register in a paper form.

Clause 30(2) provides that the holder of the substance authority must take all reasonable steps to ensure:

- a page can not be removed from the register without detection; and
- the register is set up in a way that allows the information required under sections 27 and 28 to be included in the register.

Reconciling register

Clause 31 provides that the holder of a substance authority must reconcile the remaining portion of a high-risk poison for the authority with how much of the poison is physically possessed at each authorised place for the authority.

Clause 31(2) provides that the reconciliation must be done at least monthly.

Clause 31(3) provides for this section a definition of *remaining portion*.

Reporting lost, stolen or destroyed register

Clause 32 provides that if the holder of a substance authority has a high-risk poison register that is lost, stolen or destroyed (each an ***incident***), the holder of the substance authority must give a notice to the chief executive about the incident.

Clause 32(2) provides that the notice must be given to the chief executive as soon as practicable, and no later than seven days, after the incident.

Subdivision 3 Storage and transportation

Storing and transporting high-risk poison

Clause 33 provides that the holder of a substance authority must take all reasonable steps to ensure the following:

- a high-risk poison possessed under the authority is stored in a secure area; and
- if the high-risk poison is transported in a vehicle, the poison is stored in a secure area of the vehicle.

Clause 33(2) provides that subsection (1) does not prevent the holder taking steps that are reasonably necessary for otherwise dealing with the high-risk poison in the authorised way.

Clause 33(3) provides that subsection (4) applies if the substance authority is a wholesale licence or manufacturing licence.

Clause 33(4) provides that the holder of the licence must also ensure each premises in which the high-risk poison is stored is constantly monitored by an alarm system or person located at the premises.

Division 2 Disposal of high-risk poisons

Application of division

Clause 34 provides that this division applies in relation to a substance authority authorising the disposal of waste from a high-risk poison.

Destroying high-risk poison

Clause 35 provides that the holder of the substance authority must take all reasonable steps to ensure waste from a high-risk poison disposed of under the authority is destroyed under the supervision of an inspector, or another person stated in the authority as being authorised to supervise the destruction of the poison.

Division 3 Possession of particular hazardous poisons

Storage of S2, S3 or S4 poison

Clause 36 provides that this section applies in relation to a substance authority authorising the possession of an S2, S3 or S4 poison.

Clause 36(2) provides that the holder of the substance authority must take all reasonable steps to ensure the S2, S3 or S4 poison is stored in a way that prevents the poison from being accessed by a person who is not authorised to deal with the poison.

Clause 36(3) provides that subsection (2) does not prevent the person taking steps that are reasonably necessary for otherwise dealing with the S2, S3 or S4 poison in the authorised way.

Division 4 Disposal of particular hazardous poisons

Application of division

Clause 37 provides that this division applies in relation to a substance authority authorising the disposal of waste from an S2, S3 or S4 poison or an S7 substance.

Disposal of S2, S3 or S4 poison or S7 substance

Clause 38 provides that the holder of a substance authority must take all reasonable steps to ensure waste from an S2, S3 or S4 poison or S7 substance disposed of under the authority is destroyed under the supervision of an authorised supervisor for the authority.

Clause 38(2) provides for this section a definition of *authorised supervisor*.

Part 4 Notification conditions

Division 1 Conditions for all regulated poisons

Application of division

Clause 39 provides that this division applies in relation to a substance authority authorising a dealing with a regulated poison.

Particular changes to persons or places

Clause 40 provides that the holder of a substance authority must give the chief executive notice if any of the following changes are proposed by the holder:

- a change to an authorised place for the authority;
- a change to a relevant person stated in the authority;
- a change to the person who is appointed to supervise manufacturing under the licence, if the substance authority is a manufacturing licence.

Stopping dealing

Clause 41 provides that this section applies if the holder of a substance authority proposes to stop carrying out a dealing with a regulated poison under the substance authority.

Clause 41(2) provides that the holder must give the chief executive a notice stating the following:

- the day the dealing is proposed to stop;
- the amount of regulated poison that is likely to be unused on the day mentioned in paragraph (a), if any;
- how the person proposes to deal with any unused poison.

Division 2 Conditions for restricted S7 or high-risk poisons

Application of division

Clause 42 provides that this division applies in relation to a substance authority authorising a dealing with a restricted S7 poison or high-risk poison.

Loss of, or exposure to, poison

Clause 43 provides that the holder of a substance authority must notify the chief executive, orally or in writing, if either of the following incidents happen:

- an amount of a restricted S7 poison or high-risk poison possessed under the authority is not accounted for;
- a release of a restricted S7 poison or high-risk poison possessed under the authority causes, or is likely to cause, someone to require medical treatment.

Clause 43(2) provides that the notification must be given as soon as practicable after the incident happens and include enough particulars to identify the nature of the incident and its location.

Clause 43(3) provides that if the notification is given orally, the holder must give the chief executive a later written notice within seven days after the incident happens.

Chapter 3 Requirements for dealings

Part 1 Preliminary

Application of chapter—Act, s 91

Clause 44 provides that for section 91(1) (Requirements may be prescribed) of the Medicines and Poisons Act, that this chapter prescribes requirements for a person authorised under sections 54(4) or 62 of the Medicines and Poisons Act to deal with a regulated poison, in relation to carrying out the dealing.

Part 2 Buying regulated poisons by wholesale

Application of part

Clause 45 provides that this part applies to a person (the ***buyer***) who is authorised to buy a regulated poison.

Clause 45(2) provides that this part does not apply in relation to a dealing that is buying a regulated poison from a supplier by retail.

Definition for part

Clause 46 provides for this part a definition of *supplier*.

Buyer must give purchase order

Clause 47 provides that a buyer who buys a regulated poison from a supplier must give a written purchase order for the poison to a supplier before or at the time of supply of the poison.

Purchase order requirements

Clause 48 provides that a buyer must state each of the following matters in a purchase order given under section 47:

- date of the purchase order;
- name and contact details of the buyer;
- the buyer's ABN, if the buyer carries on a business;
- details of the buyer's authorisation under the Medicines and Poisons Act to buy the poison;
- name, form, strength and amount of the poison;
- if the poison is to be delivered to the buyer, the physical address of the buyer for delivery.

Clause 48(2) provides that the purchase order must be prepared and sent to the supplier in a way that is reasonably likely to minimise fraud or tampering, allow the purchase order to be amended only by the buyer or supplier and be signed or marked with a unique identifier for the buyer.

Buyer must give information about authorisation

Clause 49 provides that a buyer who buys a regulated poison from a supplier must give the supplier information demonstrating that the buyer is authorised under the Medicines and Poisons Act to buy the poison.

Buyer to keep invoice

Clause 50 provides that if a buyer receives an invoice from a supplier for the supply of a regulated poison to the buyer, the buyer must keep the invoice.

Part 3 Supplying regulated poisons

Division 1 Supply to buyers

Application of division

Clause 51 provides that this division applies to a person (a ***supplier***) who is authorised to supply a regulated poison.

Definition for division

Clause 52 provides for this division a definition of *buyer*.

Supply to authorised buyer only

Clause 53 provides a supplier must not supply a regulated poison to a buyer unless the supplier reasonably believes that the buyer is a person authorised under the Medicines and Poisons Act, or permitted under a corresponding law or another law, to buy the poison.

Labels and containers to comply with Poisons Standard or approved alternatives

Clause 54 provides that a supplier must not supply a regulated poison to a buyer unless the poison is labelled in accordance with the requirements for labelling the poison stated in part 2, section 1 of the Poisons Standard or if an alternative way for labelling the poison is approved, or taken to be approved, by the chief executive under section 82.

Clause 54(2) provides that a supplier must not supply a regulated poison to a buyer unless the container of the poison complies with the requirements for a container of the poisons stated in part 2, section 2 of the Poisons Standard or if an alternative way for packaging the poison is approved, or taken to be approved, by the chief executive under section 82.

Clause 54(3) provides that the supplier does not contravene subsection (1) or (2) if the schedule of the Poisons Standard in which the regulated poison is listed has changed within six months after the poison was labelled or packaged and the supplier had labelled or packaged the poison in accordance with the schedule of the Poisons Standard in which the poison was listed before the change to the listing happened.

Clause 54(4) provides that to remove any doubt, it is declared that subsections (1)(a) and (2)(a) do not apply to the supplier to the extent an exemption mentioned in the Poisons Standard applies to the labelling or packaging for the regulated poison.

Supplier must give invoice

Clause 55 provides that a supplier who supplies a regulated poison to a buyer must give the buyer a written invoice for the supply that states the following information:

- a unique identifier for the invoice;
- date of the supply;
- name and contact details of the buyer;
- buyer's ABN, if the buyer carries on a business; and
- name, form, strength and amount of the poison.

Clause 55(2) provides that the supplier must keep a copy of the invoice or the information stated in the invoice.

Supplier to ensure buyer confirms receipt of restricted S7 or high-risk poisons

Clause 56 provides that a supplier must not supply a restricted S7 poison or high-risk poison to a buyer unless the buyer signs a document confirming receipt of the poison, or if the poison is to be delivered to the buyer, the supplier arranges for a receipt to be signed by the buyer when the poison is delivered to the buyer.

Clause 56(2) provides that the supplier must give a notice to the chief executive in the approved form if the supplier does not receive a receipt under subsection (1)(b) within seven days after the day the restricted S7 poison or high-risk poison is delivered to the buyer.

Direct delivery

Clause 57 provides that this section applies if a supplier arranges delivery of a regulated poison to a buyer.

Clause 57(2) provides that the supplier must take all reasonable steps to ensure the regulated poison is delivered directly to the physical address of the buyer for delivery stated on the purchase order for the poison.

Division 2 Supply of low-risk fluoroacetic acid baits

Application of division

Clause 58 provides that this division applies to a person authorised to supply a low-risk fluoroacetic acid bait.

Supply to landholders

Clause 59 provides that a person must not supply a low-risk fluoroacetic acid bait to a person mentioned in schedule 2, sections 15 or 17 (a ***landholder***) unless the person reasonably believes the health risk in relation to the application of the bait is likely to be low or negligible.

Clause 59(2) provides that the person must give the landholder a copy of the *Dealing with restricted S7 poisons for invasive animal control* departmental standard when supplying the low-risk fluoroacetic acid bait.

Division 2 Supply of liquid paraquat

Application of division

Clause 60 provides that this division applies to a person authorised to supply an S7 substance that is liquid paraquat.

Treating liquid paraquat

Clause 61 provides that before a person supplies liquid paraquat, the person must ensure the liquid paraquat is coloured to appear blue or green and treated with a sufficient amount of a stenching agent to make the paraquat smell offensive.

Part 4 Other dealings with regulated poisons

Applying regulated poisons safely

Clause 62 provides that a person who is authorised to apply a regulated poison must apply the poison:

- in accordance with the approved label, if the poison has an approved label;
- in the way stated in the *Dealing with restricted S7 poisons for invasive animal control* departmental standard, if the poison is a low-risk fluoroacetic acid bait without an approved label; or
- otherwise, in a way that does not cause, or is not likely to cause, a health risk.

Possessing low-risk fluoroacetic acid baits

Clause 63 provides that a person who is authorised to possesses a low-risk fluoroacetic acid bait must possess the bait in the way stated in the *Dealing with restricted S7 poisons for invasive animal control* departmental standard.

Storing and transporting S7 substances

Clause 64 provides that this section applies to a person authorised to possess an S7 substance, including a restricted S7 poison.

Clause 64(2) provides that the person must take all reasonable steps to ensure the following:

- the S7 substance is stored in a secure area; and
- if the S7 substance is transported in a vehicle, the substance is stored in a secure area of the vehicle.

Clause 64(3) provides that subsection (2) does not prevent the person taking steps that are reasonably necessary for otherwise dealing with the S7 substance in the authorised way.

Disposal of waste from low-risk fluoroacetic acid baits

Clause 65 provides that a person who is authorised to dispose of waste from a low-risk fluoroacetic acid bait must dispose of the waste in the way stated in the *Dealing with restricted S7 poisons for invasive animal control* departmental standard.

Chapter 4 Substance management plans

Regulated places and responsible persons—Act, s 92

Clause 66 provides that for the definition of a *regulated place* in section 92 (Definitions for part) of the Medicines and Poisons Act, each place stated in column 1 of the table in schedule 5 is prescribed to be a regulated place.

Clause 66(2) provides that for the definition of *responsible person* in section 92 (Definitions for part) of the Medicines and Poisons Act, the person stated in column 2 of the table in schedule 5 is prescribed to be the responsible person for the regulated place stated opposite in column 1.

Matters for plan—Act, s 93

Clause 67 provides that for section 93(2)(b) (Requirements for substance management plan) of the Medicines and Poisons Act, the matters stated in the *Substance management plan for regulated poisons* departmental standard are prescribed.

Review of plan—Act, s 93

Clause 68 provides that for section 93(3)(b) (Requirements for substance management plan) of the Medicines and Poisons Act, the following times are prescribed for a substance management plan for a regulated place:

- as soon as practicable after a review incident happens in relation to the regulated place; or
- at least every five years after the day the substance management plan starts or the day the plan was last reviewed, if the plan is reviewed in any five-year period after the plan starts.

Clause 68(2) provides for this section a definition of *review incident*.

Chapter 5 Offences

Part 1 S5 and S6 poisons

Division 1 Supplying S5 and S6 poisons

Compliance with Poisons Standard or approved alternatives

Clause 69 provides it is an offence for a person to supply an S5 or S6 poison unless the poison is labelled in accordance with the requirements for labelling the poison stated in part 2, section 1 of the Poisons Standard or the alternative way, if an alternative way for labelling the poison is approved, or taken to be approved, by the chief executive under section 82. The offence carries a maximum penalty of 40 penalty units.

Clause 69(2) provides it is an offence for a person to supply an S5 or S6 poison unless the container of the poison complies with the requirements for a container of the poison stated in part 2, section 2 of the Poisons Standard or the alternative way, if an alternative way for packaging the poison is approved, or taken to be approved, by the chief executive under section 82. The offence carries a maximum penalty of 40 penalty units.

Clause 69(3) provides that a person does not commit an offence against subsections (1) or (2) if the schedule of the Poisons Standard in which the poison is listed has changed within six months after the poison was labelled or packaged and the person had labelled or packaged the poison in accordance with the schedule of the Poisons Standard in which the poison was listed before the change to the listing happened.

Clause 69(4) provides that to remove any doubt, it is declared that subsections (1)(a) and (2)(a) do not apply to the person to the extent an exemption mentioned in the Poisons Standard applies to the labelling or packaging of the S5 or S6 poison.

Retail sale and storage of S6 substances

Clause 70 provides it is an offence if a person selling an S6 poison by retail fails to take all reasonable steps to ensure the poison is stored or sold in child-resistant packaging or it is not stored or sold within the reach of children under four year of ages. The offence carries a maximum penalty of 40 penalty units.

Clause 70(2) provides that a person does not commit an offence against subsection (1) 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.

Supplying unsolicited S5 and S6 samples

Clause 71 provides that it is an offence for a person to supply a sample of an S5 or S6 poison from place to place, unless the person has a reasonable excuse. For example, leaving a sample of an S5 or S6 poison in a letterbox. The offence carries a maximum penalty of 40 penalty units.

Clause 71(2) provides that subsection (1) does not apply to a person supplying a sample by handing it directly to someone who has an opportunity to refuse to take it. For example, handing out a sample to an attendee at a gardening show.

Division 2 Possessing S5 and S6 poisons

Definitions for division

Clause 72 provides for this division definitions of *compliant container* and *signal word*.

Interfering with labelling

Clause 73 provides it is an offence for a person to change, cover, deface or remove an approved label on a compliant container of an S5 or S6 poison. The offence carries a maximum penalty of 40 penalty units.

Decanting poisons

Clause 74 provides it is an offence for a person to decant an S5 or S6 poison from a compliant container into a new container unless the new container is labelled with the approved name of the poison and the signal word for the poison in capital letters. The offence carries a maximum penalty of 40 penalty units.

Cracked and damaged packaging

Clause 75 provides it is an offence if the person becomes aware that a compliant container of an S5 or S6 poison is cracked or damaged, if the person does not immediately:

- empty the poison into another container and label the other container with the approved name of the poison and the signal word for the poison in capital letters, if the contents are to be applied by the person; or
- otherwise, dispose of the contents lawfully.

The offence carries a maximum penalty of 40 penalty units.

Contaminating food or drinks containers

Clause 76 provides it is an offence for a person to use a food or drink container, or cause a food or drink container to be used, to contain an S5 or S6 poison. The offence carries a maximum penalty of 40 penalty units.

Clause 76(2) provides that it is an offence for a person to soak, wash or otherwise treat a poison container in a receptacle used to soak, wash or treat a food or drink container. The offence carries a maximum penalty of 40 penalty units.

Clause 76(3) provides for this section definition of *food or drink container* and *poison container*.

Division 3 Disposing of waste from S5 and S6 poisons

Safe disposal of waste

Clause 77 provides that it is an offence for a person to dispose of waste from an S5 or S6 poison in a way that affects, or is likely to affect, the health or safety of another person or domestic animal. The offence carries a maximum penalty of 40 penalty units.

Part 2 Advertising

Unlawful advertising of prohibited substances

Clause 78 provides it is an offence for a person to advertise, or cause a person to advertise, a prohibited substance. The offence carries a maximum penalty of 80 penalty units.

Clause 78(2) provides that subsection (1) does not apply in relation to:

- an advertisement of a prohibited substance in a price list intended for circulation only to persons authorised under the Medicines and Poisons Act, or permitted under a corresponding law or another law, to use the substance; or
- an advertisement of *Cannabis sativa* in connection with an activity authorised under sections 47 or 48(1) of the *Drugs Misuse Act 1986*.

Unlawful advertising of hazardous poisons

Clause 79 provides it is an offence for a person to advertise, or cause a person to advertise, a hazardous poison. The offence carries a maximum penalty of 80 penalty units.

Clause 79(2) provides that subsection (1) does not apply in relation to an advertisement of a hazardous poison in a journal, a price list or other promotional material intended for circulation only to:

- persons applying the poison in a workplace; or
- persons authorised under the Medicines and Poisons Act, or permitted under a corresponding law or another law, to supply the poison.

Clause 79(3) provides for this section a definition of *workplace*.

Part 3 Record keeping

Recording information

Clause 80 provides that this section applies if a person records information in writing to comply with a requirement under this regulation.

Clause 80(2) provides it is an offence if a person fails to ensure the information is written in English and marked legibly in ink, if the information is recorded on paper. The offence carries a maximum penalty of 20 penalty units.

Clause 80(3) provides that subsection (2)(a) does not prevent the person also writing the information in another language to help someone understand the information and does not apply in relation to the person's signature.

Keeping information

Clause 81 provides that this section applies if a person is required to record or keep information to comply with a requirement under this regulation.

Clause 81(2) provides it is an offence if the person fails to ensure the information is readily retrievable, can not be altered, obliterated, deleted or removed without detection and is kept for five years after the day it is recorded. The offence carries a maximum penalty of 20 penalty units.

Chapter 6 Administration

Part 1 Administration by chief executive

Chief executive may approve alternative ways of labelling or packaging poisons

Clause 82 provides that the chief executive may approve a way (an ***alternative way***) of labelling or packaging a poison that is different to the Poisons Standard.

Clause 82(2) provides that the chief executive may approve the alternative way only if the chief executive is satisfied it is unlikely to adversely affect public safety.

Clause 82(3) provides that for subsection (2), the chief executive must have regard to the nature of the poison and the purpose for which the poison is commonly used or intended to be used.

Clause 82(4) provides that the chief executive must publish, on the department's website, a notice stating the requirements of the alternative way, the day, no earlier than the day the notice is published, that the approval of the alternative way takes effect and the period, if any, for which the approval of the alternative way has effect.

Clause 82(5) provides that subsection (6) applies if an appropriate authority, for a purpose or in another State, has authorised (whether by approval, exemption or some other way) another way to label or package a poison for the purpose or other State. *Appropriate authority* is defined in part 1 of the Poisons Standard.

Clause 82(6) provides that to the extent authorised by the appropriate authority, the other way is taken to be an alternative way approved under this section, unless the chief executive publishes a notice on the department's website stating the other way is not approved for Queensland.

Replacing lost, stolen or damaged hard copy substance authorities

Clause 83 provides that this section applies if the chief executive has given a person a hard copy document evidencing a substance authority for a dealing with a regulated poison.

Clause 83(2) provides that the person may apply to the chief executive for a replacement of the document if it is lost, stolen or damaged.

Clause 83(3) provides that the application must be in the approved form and be accompanied by the fee stated in schedule 6.

Part 2 Fees

Division 1 General

Definition for part and schedule 6

Clause 84 provides for this part and schedule 6 definitions of *licensing fee* and *site*.

Fees payable generally

Clause 85 provides that the fees payable under the Medicines and Poisons Act in relation to a substance authority for a dealing with a regulated poison are stated in schedule 6.

Clause 85(2) provides that a licensing fee for a substance authority is payable for each site for the authority for each year of the term of the authority.

Clause 85(3) provides that for any part of the term of a substance authority that is not a full year, the licensing fee payable in relation to that part of the term is the proportion of the licensing fee attributable to the number of months, rounded up to whole months, of that year that are in the term.

Division 2 Exemptions

Manufacturing licence for hazardous poisons

Clause 86 provides that no licensing fee is payable for an initial application or renewal application for a manufacturing licence for a hazardous poison (each a ***later application***) if:

- an initial application or renewal application for a manufacturing licence for an S4 medicine (each a ***first application***) has been made, and not withdrawn or refused, under the *Medicines and Poisons (Medicines) Regulation 2021*; and
- the site the subject of the later application is the same as the site the subject of the first application; and
- the term proposed for the later application ends no later than the last month of the term proposed in the first application or, if the chief executive has granted the first application, the term of the substance authority granted on the first application; and
- all fees payable under the Medicines and Poisons Act for the first application have been paid.

Wholesale licence for hazardous poisons

Clause 87 provides that no licensing fee is payable for an initial application or renewal application for a wholesale licence for a hazardous poison (each a ***later application***) if:

- an initial application or renewal application for a manufacturing licence or wholesale licence for an S4 medicine, or a manufacturing licence for an S8 medicine (each a ***first application***) has been made, and not withdrawn or refused under *the Medicines and Poisons (Medicines) Regulation 2021*; and
- the site the subject of the later application is the same as the site the subject of the first application; and
- the term proposed for the later application ends no later than the last month of the term proposed in the first application or, if the chief executive has granted the first application, the term of the substance authority granted on the first application; and
- all fees payable under the Medicines and Poisons Act for the first application have been paid.

Division 3 Refunds

Rejected or withdrawn application

Clause 88 provides that this section applies if an applicant has paid the licensing fee for an application for a substance authority for a hazardous poison and the application is refused by the chief executive or withdrawn by the applicant.

Clause 88(2) provides that the chief executive must refund the applicant the licensing fee for the application.

Authority granted for shorter term

Clause 89 provides that this section applies if an applicant has paid the licensing fee for an application for a substance authority for a hazardous poison for a particular term (the ***proposed term***) and the application is granted for a period (the ***granted term***) that is shorter than the proposed term.

Clause 89(2) provides that the chief executive must refund the applicant the amount that is the proportion of the paid licensing fee attributable to the number of months, rounded up to whole months, that is the difference between the proposed term and granted term.

Clause 89(3) provides that no refund is payable if the amount under subsection (2) is zero or less than zero.

Surrender of authority

Clause 90 provides that this section applies if the holder of a substance authority for a hazardous poison paid the licensing fee for an application for the authority for a particular term (the ***granted term***) and the substance authority is surrendered before the end of the granted term.

Clause 90(2) provides that the chief executive must refund the applicant the amount that is the proportion of the paid licensing fee attributable to the number of months, rounded up to whole months, remaining in the granted term after the surrender.

Clause 90(3) provides that no refund is payable if the amount under subsection (2) is zero or less than zero.

Chapter 7 Savings and transitional provisions

Certified way of packaging

Clause 91 provides that this section applies if the chief executive certified a container for packing a poison under section 10(3) of the repealed *Health (Drugs and Poisons) Regulation 1996* and the certification was in effect immediately before the commencement.

Clause 91(2) provides that the certification is taken to be an alternative way for packaging the poison approved under section 82 until the stated day, if an expiry day is stated in the certification or otherwise, the day that is one year after the commencement.

Certified way of labelling

Clause 92 provides that this section applies if the chief executive certified an alternative way of labelling a package for a poison under section 11(3) of the repealed *Health (Drugs and Poisons) Regulation 1996* and the certification was in effect immediately before the commencement.

Clause 92(2) provides that the certification is taken to be an alternative way of labelling a package for the poison approved under section 82 until the stated day, if an expiry day is stated in the certification or otherwise, the day that is one year after the commencement.

Chapter 8 Amendment of other regulations

Regulations amended

Clause 93 provides that schedule 8 amends the regulations mentioned in it.

Schedule 1 Restricted S7 poisons

Schedule 1 provides for a list of restricted S7 poisons.

Schedule 2 Approved persons

Part 1 Aerial distributors

Division 1 Commercial pilots

Class of person

Clause 1 provides that this division applies to a person (a ***commercial pilot***) who holds a commercial pilot licence issued by CASA that is endorsed with an aerial application rating, has spraysafe accreditation issued by the Aerial Application Association of Australia Limited and is employed to aerially distribute a poison.

Dealing authorised

Clause 2 provides that a commercial pilot to which this division applies, can perform the following regulated activities:

- possess a low-risk fluoroacetic acid bait;
- apply a low-risk fluoroacetic acid bait, if the poison is applied by aerial distribution;
- dispose of waste from a low-risk fluoroacetic acid bait.

Division 2 Pilots of remotely piloted aircraft

Class of person

Clause 3 provides that this division applies to a person (a ***pilot of remotely piloted aircraft***) who holds a remote pilot licence issued by CASA and has a chemical competency certificate or spraysafe accreditation issued by the Aerial Application Association of Australia Limited and is employed to aerially distribute a poison.

Dealing authorised

Clause 4 provides that a pilot of a remotely piloted aircraft to which this division applies, can perform the following regulated activities:

- possess a low-risk fluoroacetic acid bait;
- apply a low-risk fluoroacetic acid bait, if the poison is applied by aerial distribution;
- dispose of waste from a low-risk fluoroacetic acid bait.

Division 3 Aerial operators

Class of person

Clause 5 provides that this division applies to a person (an ***aerial operator***) who holds an air operator's certificate issued by CASA that is endorsed with an aerial application rating and is employed to aerially distribute a poison.

Dealing authorised

Clause 6 provides that an aerial operator to which this division applies, can perform the following regulated activities:

- buy a low-risk fluoroacetic acid bait, if the poison is bought for aerial distribution;
- possess a low-risk fluoroacetic acid bait;
- supply a low-risk fluoroacetic acid bait, if the poison is supplied to a person authorised to apply the poison by aerial distribution;
- dispose of waste from a low-risk fluoroacetic acid bait.

Division 4 Operators of remotely piloted aircraft

Class of person

Clause 7 provides that this division applies to a person (an ***operator of remotely piloted aircraft***) who holds a remotely piloted aircraft operator's certificate issued by CASA and is employed to aerially distribute a poison.

Dealing authorised

Clause 8 provides that an operator of remotely piloted aircraft to which this division applies, can perform the following regulated activities:

- buy a low-risk fluoroacetic acid bait, if the poison is bought for aerial distribution;
- possess a low-risk fluoroacetic acid bait;
- supply a low-risk fluoroacetic acid bait, if the poison is supplied to a person authorised to apply the poison by aerial distribution;
- dispose of waste from a low-risk fluoroacetic acid bait.

Part 2 Carriers

Class of person

Clause 9 provides that this part applies to a person (a ***carrier***) who is engaged to deliver a regulated poison by another person who is authorised under the Medicines and Poisons Act, or permitted under a corresponding law or another law, to supply the poison.

Dealing authorised

Clause 10 provides that a carrier can possess a regulated poison, if the poison is possessed for the purposes of delivering the poison under any conditions applying in relation to the supply of the poison.

Part 3 Invasive animal controllers

Division 1 Biosecurity officers

Class of person

Clause 11 provides that this division applies to an authorised officer (a ***biosecurity officer***) authorised under the *Biosecurity Act 2014* who has a baiting competency certificate.

Dealing authorised

Clause 12 provides that a biosecurity officer to which this division applies, can perform the following regulated activities:

- possess a low-risk fluoroacetic acid bait, if the poison is possessed to control an invasive animal;
- supply a low-risk fluoroacetic acid bait, if the poison is supplied to another person to control an invasive animal on the person's land or premises;
- apply a low-risk fluoroacetic acid bait, if the poison is applied to control an invasive animal;
- dispose of waste from a low-risk fluoroacetic acid bait.

Division 2 Nature conservation officers

Class of person

Clause 13 provides that this division applies to an authorised person (a ***nature conservation officer***) authorised under the *Nature Conservation Act 1992* who has a baiting competency certificate.

Dealing authorised

Clause 14 provides that an authorised nature conservation officer to which this division applies, can perform the following regulated activities:

- possess a low-risk fluoroacetic acid bait, if the poison is possessed to control an invasive animal;
- supply a low-risk fluoroacetic acid bait, if the poison is supplied to another person to control an invasive animal on the person's land or premises;
- apply a low-risk fluoroacetic acid bait, if the poison is applied to control an invasive animal;
- dispose of waste from a low-risk fluoroacetic acid bait.

Division 3 Rural landholders and their adult employees and agents

Subdivision 1 Rural landholders

Class of person

Clause 15 provides that this division applies to a person (a ***rural landholder***) who is the owner or occupier of land or premises in a rural area.

Dealing authorised

Clause 16 provides that a rural landholder to which this division applies, can perform the following regulated activities:

- possess a low-risk fluoroacetic acid bait, if the poison is supplied by an approved person under division 1 or 2 and is possessed to control an invasive animal;
- apply a low-risk fluoroacetic acid bait, if the poison is supplied by an approved person under division 1 or 2 and is applied to control an invasive animal;
- dispose of waste from a low-risk fluoroacetic acid bait.

Subdivision 2 Adult employees and agents

Class of person

Clause 17 provides that this division applies to an adult (the ***landholder***) who is employed by, or acting as an agent for, a person mentioned in section 15 .

Dealing authorised

Clause 18 provides that a landholder to which this division applies, can perform the following regulated activities:

- possess a low-risk fluoroacetic acid bait, if the poison is supplied to the landholder by an approved person under division 1 or 2, and is possessed to control an invasive animal;
- apply a low-risk fluoroacetic acid bait, if the poison is supplied to the landholder by an approved person under division 1 or 2 and is applied to control an invasive animal;
- dispose of waste from a low-risk fluoroacetic acid bait.

Part 4 Local governments and their employees

Division 1 Local government

Class of person

Clause 19 provides that this division applies to a local government or the chief executive of a local government (a ***local government***).

Dealing authorised

Clause 20 provides that a local government to which this division applies, can perform the following regulated activities:

- possess a non-restricted S7 substance;
- supply a non-restricted S7 substance, if the poison is supplied in the course of providing a service to the public or to an owner or occupier of land for managing weeds or vegetation on the land;
- dispose of waste from a non-restricted S7 substance.

Division 2 Local government employee

Class of person

Clause 21 provides that this division applies to a person employed by a local government (a ***local government employee***).

Dealing authorised

Clause 22 provides that a local government employee to which this division applies, can perform the following regulated activities:

- possess a non-restricted S7 substance;
- supply a non-restricted S7 substance, if the poison is supplied in the course of providing a service to the public or to an owner or occupier of land for managing weeds or vegetation on the land;
- dispose of waste from a non-restricted S7 substance.

Part 5 Pest management service providers

Division 1 Business owners

Class of person

Clause 23 provides that this division applies to a business operator under the *Medicines and Poisons (Pest Management Activities) Regulation 2021*.

Dealing authorised

Clause 24 provides that a business owner to which this division applies, can perform the following regulated activities:

- buy an S7 substance, if the poison is bought for the operator's pest management business;
- possess an S7 substance, if the poison is possessed for the operator's pest management business.

Division 2 Qualified persons

Class of person

Clause 25 provides that this division applies to a qualified person under the *Medicines and Poisons (Pest Management Activities) Regulation 2021*.

Dealing authorised

Clause 26 provides that a qualified person to which this division applies, can perform the following regulated activities:

- buy an S7 substance, if the poison is bought for a pest management activity for which the qualified person is authorised under the Medicines and Poisons Act;
- possess an S7 substance, if the poison is possessed for a pest management activity for which the qualified person is authorised under the Medicines and Poisons Act.

Part 6 Pharmaceutical professions

Division 1 Pharmacists

Class of person

Clause 27 provides that this division applies to a pharmacist who owns, or is an employee of, a community pharmacy (a ***pharmacist***).

Dealing authorised

Clause 28 provides that a pharmacist to which this division applies, can perform the following regulated activities:

- buy a non-restricted S7 substance, cyanide or strychnine;
- possess a non-restricted S7 substance, cyanide or strychnine;

- supply a non-restricted S7 substance, cyanide or strychnine;
- dispose of waste from a non-restricted S7 substance, cyanide or strychnine.

Division 2 Other employees at community pharmacies

Class of person

Clause 29 provides that this division applies to a person, other than a pharmacist, who is an employee of a community pharmacy.

Dealing authorised

Clause 30 provides that a person employed at a community pharmacy can perform the following regulated activities:

- possess a non-restricted S7 substance, cyanide or strychnine;
- supply a non-restricted S7 substance, cyanide or strychnine, if the poison is supplied under the supervision of a pharmacist at the premises of the community pharmacy.

Part 7 Suppliers from other jurisdictions

Class of person

Clause 31 provides that this part applies to a person (a ***supplier from other jurisdictions***) who is permitted under a corresponding law to supply a regulated poison, whether by wholesale or retail.

Dealing authorised

Clause 32 provides that a supplier from other jurisdictions can supply a regulated poison, if:

- the poison is supplied in compliance with any conditions of the person's permission under the corresponding law; and
- the person arranges delivery of the poison only to someone within Queensland who is authorised, or for whom it is not unlawful, to buy the poison; and
- the person does not possess the poison by storing it at a place in Queensland or arrange for the poison to be collected from a storage facility located in Queensland; and
- the supply is not otherwise authorised under section 50 of the Medicines and Poisons Act.

Part 8 Veterinary professions

Division 1 Veterinary surgeons

Class of person

Clause 33 provides that this division applies to a veterinary surgeon.

Dealing authorised

Clause 34 provides that a veterinary surgeon can perform the following regulated activities:

- buy a non-restricted S7 substance, if the poison is bought for animal treatment;
- possess a non-restricted S7 substance;
- supply a non-restricted S7 substance, if the poison is supplied for animal treatment;
- apply a non-restricted S7 substance, if the poison is applied for animal treatment;
- dispose of waste from a non-restricted S7 substance.

Division 2 Employees at veterinary premises

Class of person

Clause 35 provides that this division applies to a person who is employed at veterinary premises under the *Veterinary Surgeons Act 1936*.

Dealing authorised

Clause 36 provides that a person employed at veterinary premises can perform the following regulated activities:

- possess a non-restricted S7 substance, if the poison is possessed for animal treatment under the supervision of a veterinary surgeon at the veterinary premises;
- supply a non-restricted S7 substance, if the poison is supplied for animal treatment under the supervision of a veterinary surgeon at the veterinary premises;
- apply a non-restricted S7 substance, if the poison is applied for animal treatment under the supervision of a veterinary surgeon at the veterinary premises;
- dispose of waste from a non-restricted S7 substance, if the waste is disposed of under the supervision of a veterinary surgeon at the veterinary premises.

Schedule 3 Departmental standards

Schedule 3 provides for a list of named and version numbered departmental standards.

Schedule 4 Activities and services for excluded places

Schedule 4 provides for a list of activities and services for excluded places. Section 60(3) (Authorisation for persons subject to work health and safety laws) of the Medicines and Poisons Act provides that the definition of ***excluded place*** includes another place prescribed by regulation to be an excluded place.

Clause 14 of the Poisons Regulation provides that a place used for the sole or main purpose of carrying out or providing one or more activities or services stated in schedule 4 is prescribed to be an excluded place.

Schedule 5 Substance management plans—regulated places and responsible persons

Schedule 5 prescribes regulated places and responsible persons for section 66 of the Poisons Regulation.

The Medicines and Poisons Act defines a *regulated place* in section 92 (Definitions for part) as a place where a dealing happens, or is proposed to happen, with a regulated substance and prescribed by regulation to be a regulated place.

The Medicines and Poisons Act defines a r*esponsible person,* for a regulated place in section 92 (Definitions for part) as the person prescribed by regulation to be the responsible person for the regulation place.

Clause 66 provides that for the definition of a ***regulated place*** in section 92 (Definitions for part) of the Medicines and Poisons Act, the places are stated in schedule 5, column 1. For the definition of ***responsible person*** in section 92 (Definitions for part) of the Medicines and Poisons Act, the person stated in schedule 5, column 2, is the responsible person prescribed for the regulated place.

Schedule 6 Fees

Schedule 6 provides that the fees payable under the Medicines and Poisons Act are stated in the schedule.

Schedule 7 Dictionary

Schedule 7 defines certain words and terms used throughout the regulation.

Schedule 8 Regulations amended

Schedule 8 provides a list of regulations amended.