Medicines and Poisons (Poisons and Prohibited Substances) Amendment Regulation 2023

Explanatory notes for SL 2023 No. 162

made under the

Medicines and Poisons Act 2019

General Outline

Short title

Medicines and Poisons (Poisons and Prohibited Substances) Amendment Regulation 2023

Authorising law

Sections 7, 54, 233 and 240 of the *Medicines and Poisons Act 2019.*

Policy objectives and the reasons for them

The *Medicines and Poisons Act 2019* was enacted in September 2019 and introduced a new regulatory framework for medicines and poisons in Queensland. A key objective of the Medicines and Poisons Act is to ensure medicines, poisons, prohibited substances, pesticides and fumigants are used safely and effectively and do not cause harm to human health.

Medicines and poisons are scheduled by the Therapeutic Goods Administration in the Commonwealth Standard for the Uniform Scheduling of Medicines and Poisons (Poisons Standard). The Medicines and Poisons 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 (APVMA).

The *Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021* (Poisons Regulation) regulates poisons and prohibited substances and gives effect to the Medicines and Poisons 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; and
- improving security controls in the use and storage of poisons to prevent diversion for unlawful purposes.

The *Medicines and Poisons (Poisons and Prohibited Substances) Amendment Regulation 2023* (Amendment Regulation) amends the Poisons Regulation to:

- amend the definition of portable testing device;
- clarify that a purchase order must include the name, form, strength and amount of a high-risk poison;
- clarify that a supplier invoice must include the name, form, strength and amount of a high-risk poison;
- amalgamate the dealings authorised by biosecurity officers and nature conservation officers in relation to a low-risk fluoroacetic acid bait;
- exempt biosecurity officers and nature conservation officers from the requirement to obtain a manufacturing licence for the preparation of baits;
- exempt low-risk fluoroacetic acid baits manufactured for immediate use from the requirement to keep batch records;
- amend the definition of an authorised supervisor of the disposal of a schedule 2 (S2), schedule 3 (S3) and schedule 4 (S4) poison or schedule 7 (S7) substance;
- clarify that only an approved person can fumigate burrowing invasive animals;
- update a reference to the Departmental Standard - *Competency requirements for authority holders dealing with poisons* to reflect version 2 of the Competency Standard;
- provide that the chief executive of the Department is authorised to approve training substantially equivalent to a competency in the Competency Standard;
- remove references to the Departmental Standard - *Dealing with restricted S7 poisons for invasive animal control*; and
- update references to the revised Poisons Standard.

Definition of portable testing devices

Portable testing devices provide a near real-time analysis of substances without the need to wait on laboratory analysis. These devices may be used by law enforcement officers to identify suspected illegal drugs, by occupational health and safety professionals to identify unknown hazardous poisons and by environmental scientists to identify land contaminated with hazardous poisons.

Section 7 of the Medicines and Poisons Act provides that a low-risk activity may be exempt from the operation of the Medicines and Poisons Act if it is prescribed by regulation. Section 13 of the Poisons Regulation exempts the use of reference material to calibrate a portable testing device when testing breath or bodily fluid from the requirements of the Medicines and Poisons Act. This exempts users such as law enforcement officers who use portable testing devices to test breath and bodily fluid.

Users of portable testing devices testing substances, other than breath or bodily fluid, must obtain a substance authority under section 30 of the Medicines and Poisons Act if they use reference materials to calibrate the portable testing device. This captures users such as occupational health and safety officers when analysing liquid at a workplace to determine if it is cyanide solution or pure water. Prior to analysing the liquid, the occupational health and safety officer would need to apply for a substance authority to buy and possess the reference material used to calibrate the portable testing device.

The process of obtaining a substance authority causes delays and imposes storage and recordkeeping requirements, which creates an unnecessary regulatory burden for these users. The possession and use of reference materials when calibrating portable testing devices has a negligible risk to public health, as it only amounts to 0.5 grams or less of a regulated poison. Amendments are necessary to provide that the use of a reference material to calibrate a portable testing device when testing or providing immediate analysis of a regulated substance is exempt from the requirements of the Medicines and Poisons Act.

Information requirements for purchase orders

Section 48(1)(e) of the Poisons Regulation requires suppliers of regulated poisons (S7 substances), a medicine treated as a poison (S2, S3, S4 or schedule 8 (S8) poison) and prohibited substances (schedule 9 (S9) and schedule 10 (S10) substances) to include the following information on a purchase order:

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

High-risk poisons are defined in section 7 of the Poisons Regulation as an S8 poison or a prohibited substance, other than a prohibited substance used, or intended to be used, for a therapeutic use. For these high-risk poisons, detailed purchase orders that include the name, form, strength and amount of the poison are necessary to maintain the high-risk poison register and ensure traceability of the poisons to minimise risks of theft or diversion.

For S2, S3, S4 poisons and S7 substances, only the name and amount of poison is useful, as the risk of theft or diversion is low. Capturing details about form and strength provides no additional public safety benefit and is considered an unnecessary administrative and financial burden on those are required to keep records of purchase orders.

Information requirements for supplier invoices

Section 55(1)(e) of the Poisons Regulation requires suppliers of regulated poisons (S7 substances, a medicine treated as a poison (S2, S3, S4 and S8 poisons) and prohibited substances (S9 and S10 substances)) to give the buyer an invoice for the supply of the poison.

The Poisons Regulation requires the invoice to include:

- 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.

For high-risk poisons defined in section 7 of the Poisons Regulation, detailed invoices that include the name, form, strength and amount of the poison are necessary to maintain the high-risk poison register and ensure traceability of the poisons to minimise risks of theft or diversion.

For other regulated poisons, only the name and amount of poison is useful, as the risk of theft or diversion is low. Capturing details about form and strength provides no additional public safety benefit and is considered an unnecessary administrative and financial burden on suppliers required to keep records of invoices.

Supply of low-risk fluoroacetic acid baits to landholders

Chapter 3, part 3, division 2 of the Poisons Regulation relates to the supply of a low-risk fluoroacetic acid bait to a landholder by a biosecurity officer or a nature conservation officer. Schedule 2, part 3 outlines the dealings authorised by these officers, which includes the possession, supply, application and disposal of a low-risk fluoroacetic acid bait.

As the obligations related to the supply of low-risk fluoroacetic acid bait are outlined in chapter 3, part 3, division 2 and schedule 2, part 3 of the Poisons Regulation, there is confusion in the industry about the obligations and responsibilities of persons dealing with low-risk fluoroacetic acid baits. To improve clarity, it is necessary to amalgamate the dealings authorised by biosecurity officers and nature conservation officers in relation to a low-risk fluoroacetic acid bait.

Exempting biosecurity officers and nature conversation officers from the requirement to obtain a manufacturing licence for the preparation of baits

Chapter 2, part 2, division 1 of the Poisons Regulation relates to a manufacturing licence authorising the manufacture of a regulated poison and outlines the obligations and responsibilities when manufacturing a regulated poison. Section 21 of the Medicines and Poisons Act defines *manufacture* to include any process or step undertaken to produce the regulated substance or to prepare the regulated substance for supply to the public or a person, including for administration to an animal.

Biosecurity officers and nature conservation officers can prepare baits by applying a poison to meat, fruit, vegetable or grain, and supply the bait to landholders either for free or on a cost recovery basis. The preparation of baits by biosecurity officers or nature conservation officers are an incidental part of their employment and occurs a few times per year.

As these officers are preparing and supplying a regulated substance to the public, this activity could be interpreted as 'manufacturing' a regulated poison. This has the unintended consequence of applying the requirements under chapter 2, part 2, division 1 of the Poisons Regulation, to these officers.

To achieve the policy intent, amendments are necessary to exempt biosecurity officers and nature conservation officers from the requirement to obtain a manufacturing licence for preparing and supplying low-risk fluoroacetic acid baits for immediate use.

This will not pose a risk to public health and safety, as these officers are authorised officers under the *Biosecurity Act 2014* and *Nature Conservation Act 1992* and are considered suitably qualified to safely prepare and supply restricted S7 poisons. Biosecurity officers and nature conservation officers will continue to be required to meet the minimum qualification requirements outlined in the Departmental Standard - *Competency requirements for authority holders dealing with poisons for manufacturing low-risk fluoroacetic baits*. This will ensure these officers have undertaken the necessary training and education to safely carry out this work.

Exempting low-risk fluoroacetic acid baits manufactured for immediate use from the requirement to keep batch records

Section 20 of the Poisons Regulation states that the holder of a manufacturing licence must keep a record for each batch of regulated poison manufactured under the licence. The section prescribes the information required to be recorded, which includes:

- 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 processing the batch; and
- if a stability study is carried out to test the shelf life and appropriate storage conditions of the batch – details of the study.

The policy intent of the batch record requirement is for traceability purposes, to enable recall of the product if there are quality and safety concerns. As the manufacturing of low-risk fluoroacetic acid baits typically occurs on the same day the baits are intended to be used, it is not practicable or possible to recall these products.[1] Due to the difficulty and impracticality of keeping batch records for low-risk fluoroacetic acid baits manufactured for immediate use, amendments are necessary to exempt keeping batch records in those circumstances. As low-risk fluoroacetic acid baits manufactured for immediate use must be prepared in accordance with section 10 of the Poisons Regulation, this amendment does not increase risks to public health and safety.

Definition of an authorised supervisor of the disposal of a S2, S3, S4 poison or S7 substance

Section 38 of the Poisons Regulation defines an authorised supervisor of the disposal of an S2, S3, or S4 poison or S7 substance as a person stated in the substance authority as being authorised to supervise the destruction of the poison or substance. This definition creates

[1] Fresh low-risk fluoroacetic baits are manufactured primarily for local government coordinated baiting programs, usually involving a small numbers of landholders. Landholders participating in coordinated baiting programs are known to biosecurity/nature conservation officers. These officers will have the contact details of all landholders receiving baits in the event of an incident.

impracticalities, as it requires the substance authority to be updated every time the person authorised to supervise the destruction of the poison or substance changes.

Amendments are necessary to clarify that an authorised supervisor also includes an appropriately qualified person, approved by the holder of the authority, to supervise the destruction of an S2, S3, S4 poison or S7 substance.

This amendment has no public health risk implications, as it still requires an authorised supervisor to supervise the destruction of an S2, S3, S4 poison or S7 substance. It will offer administrative flexibility for industry and the Department.

Approved persons authorised to fumigate burrowing invasive animals

The definition of *pest* in schedule 1 of the Medicines and Poisons Act enables a regulation to prescribe a biological entity to be, or not be, a pest. Section 6 of the *Medicines and Poisons (Pest Management Activities) Regulation 2021* (Pest Management Regulation) prescribes the definition of a *pest*, which provides that an invasive animal is not a pest. As schedule 7 of the Poisons Regulation defines a European fox or European rabbit as an invasive animal, European foxes and European rabbits are not captured within the definition of a *pest* under section 6 of the Pest Management Regulation and schedule 1 of the Medicines and Poisons Act.

An APVMA approved substance is a fumigant if, when the substance becomes gaseous, it is used to kill a pest. Fumigants are used in fox dens and rabbit burrows to manage these animals. However, as these animals are not defined as pests under the Medicines and Poisons Act and Pest Management Regulation, the fumigation of these animals is not regulated, which may pose a risk to public health and safety.

This is contrary to the policy intent of requiring anyone, other than a primary producer, to undertake the training and education necessary to fumigate fox dens and rabbit burrows safely.[2]

Departmental Standard - Competency requirements for authority holders dealing with poisons

Section 233 of the Medicines and Poisons Act empowers the chief executive to make standards relevant to the objectives and administration of the regulatory framework. Schedule 3 of the Poisons Regulation lists the approved departmental standards by name and version number. When a new version of the departmental standard is made by the chief executive or their delegate, the Poisons Regulation requires an amendment to reflect the new version so it can take effect. The Medicines and Poisons Act provides that the departmental standard does not take effect until it is approved by the Poisons Regulation, or a date stated in the departmental standard.

The Departmental Standard - *Competency requirements for authority holders dealing with poisons* (Competency Standard) establishes the minimum competency requirements for persons seeking to carry out regulated activities with poisons. Compliance with the Competency Standard assists in ensuring that persons who are authorised to carry out regulated activities using regulated substances have the necessary competencies to carry out the activities

[2] Primary producers are exempt from the training requirement, as these persons commercially produce agricultural or horticultural products and are appropriately qualified to carry out pest control activity in the authorised way.

safely. The Competency Standard must be followed where it is referenced by the Medicines and Poisons Act or the Poisons Regulation, or when it is required as a condition of an authority.

Version 2 of the Competency Standard updates the competency requirements to prescribe additional competency requirements for persons, other than primary producers, using a gaseous poison to fumigate burrowing invasive animals. This reflects the additional education and training that should be undertaken to safely carry out those activities. Persons who successfully complete the competency requirements to control burrowing invasive animals will be eligible to receive a burrowing invasive animal competency certificate to undertake those activities.

Chief executive's approval of training substantially equivalent to a competency in the Competency Standard

Version 1 of the Competency Standard provided that a holder of a general approval was required to satisfy and continue to satisfy either the competency requirements stated in the Competency Standard that relate to the type of approval held, or a competency requirement approved by the chief executive that is substantially equivalent to the competencies stated in the Competency Standard.

As these are key requirements and powers under the poisons and prohibited substances regulatory framework, it is appropriate for these requirements and powers to be specified in the Poisons Regulation, rather than the Competency Standard. This will provide clarity, improve transparency in decision-making, and ensure key requirements are specified in the Poisons Regulation.

To reflect the transfer of these requirements from version 1 of the Competency Standard to the Poisons Regulation, version 2 of the Competency Standard does not specify these requirements.

Departmental Standard - Dealing with restricted S7 poisons for invasive animal control

On 27 September 2021, the Departmental Standard - *Dealing with restricted S7 poisons for invasive animal control* (Departmental Standard) was made. Section 23 of the Poisons Regulation 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 Departmental Standard.

The Departmental Standard duplicates many of the APVMA approved label instructions and requirements under the *Chemical Usage (Agricultural and Veterinary) Control Act 1988* administered by the Department of Agriculture and Fisheries for restricted S7 poisons. This duplication has led to confusion about the roles and responsibilities of Queensland Health and the Department of Agriculture and Fisheries in enforcing the regulatory requirements under the Chemical Usage (Agricultural and Veterinary) Control Act and the Medicines and Poisons Act. The duplication also creates the potential for inconsistencies if there are discrepancies in the requirements provided for under different legislation.

As the requirements outlined in the Departmental Standard are largely provided for under the APVMA approved label instructions and Chemical Usage (Agricultural and Veterinary) Control Act, the Departmental Standard is not considered necessary. Queensland Health has published guidelines related to the storage and disposal of poisons and prohibited substances to address any gaps caused by the removal of the Departmental Standard.

Updating references to the Standard for the Uniform Scheduling of Medicines and Poisons

The Poisons Standard classifies medicines and poisons into 'schedules' of substances from S2 to S10. A substance is categorised into a schedule based on the level of regulatory control required to deal with the public health and safety risks associated with the substance. It provides a uniform approach to control the availability and accessibility of substances that can be used as ingredients in medicines, cosmetics, agricultural chemicals, and industrial and domestic chemicals. The Poisons Standard also includes provisions about containers and labels with a view to promoting uniform labelling and packaging requirements throughout Australia. In Queensland, the Poisons Standard is referenced under the Medicines and Poisons Act.

The Therapeutic Goods Association published the updated Poisons Standard dated 23 June 2023. The revised Poisons Standard makes structural, formatting and readability improvements.

Sections 54 and 69 of the Poisons Regulation reference the Poisons Standard. Although section 14H of the *Acts Interpretation Act 1954* provides that a reference to a law includes an amendment to the law, it is important for the Poisons Regulation to reference the updated Poisons Standard. This will provide clarity for persons interacting with the Poisons Regulation and ensure stakeholders are aware of their obligations.

Achievement of policy objectives

Definition of portable testing devices

The Amendment Regulation amends the definition of portable testing device in section 13(2) to mean a portable device designed to test for the presence of, or provide immediate analysis of, a regulated substance.

The amended definition achieves the policy intent of exempting users of portable testing devices, such as occupational health and safety officers and environmental scientists, from the operation of section 30 of the Medicines and Poisons Act. By capturing the activity undertaken by these users within the definition of portable testing device, these users will no longer be required to apply for a substance authority under section 30 of the Medicines and Poisons Act. This will reduce the administrative burden and expediate the process of testing for the presence of, or providing immediate analysis of, a regulated substance.

Information requirements for purchase orders

The Amendment Regulation updates section 48 to clarify that a purchase order for regulated poison that is not a high-risk poison defined under section 7, is only required to state the name and amount of the poison. As the risk of theft or diversion of regulated poisons and substances that are not high-risk poisons is low, this amendment will achieve the policy aim of reducing the administrative and financial burden on purchasers and suppliers.

A purchase order relating to the supply of a high-risk poison will continue to maintain the requirement to state the unique identifying number, supply date, details of the buyer and the name, form, strength, and amount of the poison. This will ensure details about high-risk poisons are recorded to maintain the high-risk poison register and ensure traceability of the high-risk poisons to minimise risks of theft or diversion.

Information requirements for supplier invoices

The Amendment Regulation updates section 55 to clarify that an invoice for the supply of a regulated poison that is not a high-risk poison defined under section 7, is only required to state the name and amount of the poison. As the risk of theft or diversion of regulated poisons and substances that are not high-risk poisons is low, this amendment will achieve the policy aim of reducing the administrative and financial burden on suppliers.

An invoice relating to the supply of a high-risk poison will maintain the requirement to state the unique identifying number, supply date, details of the buyer and the name, form, strength, and amount of the poison. This will ensure details about high-risk poisons are recorded to maintain the high-risk poison register and ensure traceability of high-risk poisons to minimise risks of theft or diversion.

Supply of low-risk fluoroacetic acid baits to landholders

The Amendment Regulation removes chapter 3, part 3, division 2, and amalgamates the authorised dealings previously under chapter 3, part 3, division 2 in schedule 2 of the Poisons Regulation. Updated schedule 2 clarifies that a biosecurity officer and a nature conversation officer are authorised to 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; and
- the officer is satisfied the health risk to a person or an animal, other than an invasive animal to be controlled, in relation to the application of the poison supplied is likely to be low or negligible.

This achieves the policy intent of ensuring the authorised dealings relating to the supply of a low-risk fluoroacetic acid bait is captured in schedule 2 of the Poisons Regulation.

Exempting biosecurity officers and nature conservation officers from the requirement to obtain a manufacturing licence for the preparation of baits

The Amendment Regulation amends schedule 2 by clarifying that a low-risk fluoroacetic acid bait that is manufactured in accordance with the approved label and for the immediate use by another person to control an invasive animal on the person's land or premises, is a dealing authorised by biosecurity officers and nature conservation officers.

The Amendment Regulation amends schedule 7, by inserting a definition of *immediate use* to mean a low-risk fluoroacetic acid bait manufactured for supply and use on the same date as the bait is manufactured. The Amendment Regulation also amends schedule 6 to ensure that the manufacture of low-risk fluoroacetic acid baits for immediate use continues to be captured within the fee schedule.

These amendments achieve the policy intent of exempting biosecurity officers and nature conservation officers from the requirement to obtain a manufacturing licence for preparing low-risk fluoroacetic acid baits in those circumstances.

Exempting low-risk fluoroacetic acid baits manufactured for immediate use from the requirement to keep batch records

The Amendment Regulation amends section 20 to exempt low-risk fluoroacetic acid baits manufactured for immediate use from the requirement to keep batch manufacturing records. This addresses the difficulties and impracticalities of keeping batch records for each batch of low-risk fluoroacetic acid bait manufactured for immediate use. As the manufacture of low-risk fluoroacetic acid bait for immediate use must follow the prescribed requirements in the Poisons Regulation, this amendment does not pose additional risks to public health and safety.

Definition of an authorised supervisor of the disposal of a S2, S3, S4 poison or S7 substance

The Amendment Regulation updates the definition of *authorised supervisor* in section 38. The updated definition clarifies that an authorised supervisor also includes an appropriately qualified person, approved by the holder of the authority, to supervise the destruction of an S2, S3, S4 poison or S7 substance. This reduces the administrative burden of requiring the 'authorised supervisor' on a substance authority to be updated every time the supervisor changes.

Definition of burrowing invasive animal

The Amendment Regulation updates the Poisons Regulation by amending:

- schedule 2 by creating two new classes of approved person, which authorises:
  - primary producers to use a gaseous poison to treat burrowing invasive animals; and
  - a person who has a burrowing invasive animal competency certificate to use a gaseous poison to treat burrowing invasive animals.
- schedule 7 to insert definitions of:
  - *burrowing invasive animal* that includes a European fox or European rabbit;
  - *burrowing invasive animal competency certificate*; and
  - *gaseous poison*.

This ensures that the fumigation of burrowing invasive animals is appropriately regulated, by only authorising a primary producer or a person who has a burrowing invasive animal competency certificate to use a gaseous poison to treat these animals.

Departmental Standard - Competency requirements for authority holders dealing with poisons

The Amendment Regulation updates schedule 3 of the Poisons Regulation to reflect version 2 of the Competency Standard. A copy of the updated Competency Standard will be tabled in Parliament as extrinsic material, to reflect the revised standard. The Medicines and Poisons Act provides that the Competency Standard does not take effect until it is approved by the regulation.
The new version of the Competency Standard makes the following changes:

- adds the CPPUPM3011 competency unit, which will be required for a person to obtain a burrowing invasive animal competency certificate;
- removes the ability for the chief executive of Queensland Health to approve substantially equivalent competencies as the Amendment Regulation specifies this power in Clause 6;

- adds a definition for 'burrowing invasive animal', which includes a European fox or a European rabbit;
- adds a definition for 'gaseous poison'; and
- adds additional competencies in Appendix 1 that are equivalent to the primary competencies.

Prescribing version 2 of the Competency Standard in the Poisons Regulation achieves the policy intent of promoting public health and safety. The amendment ensures persons, other than a primary producer, who use a gaseous poison to control burrowing invasive animals undertakes the training and education necessary to safely carry out this activity. Primary producers are exempt from the requirement to obtain the CPPUPM3011 competency unit, as they commercially produce agricultural or horticultural products, and are appropriately qualified to control burrowing invasive animals.

Chief executive's approval of training substantially equivalent to a competency in the Competency Standard

The Amendment Regulation amends section 22 of the Poisons Regulation to clarify that a holder of a general approval must satisfy and continue to satisfy, either:

- the competency requirements stated in the Competency Standard that relate to the type of approval held; or
- a competency requirement, approved by the chief executive, that is substantially equivalent to the competencies stated in the Competency Standard.

This will achieve the policy intent of ensuring key requirements for holders of a general approval are specified in the Poisons Regulation, rather than in extrinsic materials.

Departmental standard - Dealing with restricted S7 poisons for invasive animal control

The Amendment Regulation removes reference to the Departmental Standard from the Poisons Regulation.

The obligations outlined in the Departmental Standard will instead be covered by:

- the APVMA labelling requirements;
- section 13 of the Chemical Usage (Agriculture and Veterinary) Control Act;
- a Queensland Health storage guideline titled '*Regulated poisons storage requirements*'; and
- a Queensland Health disposal guideline titled '*Regulated poisons disposal requirements'*.

This will align with other agricultural chemical products authorised under the Medicines and Poisons Act. Queensland Health has published the requirements on the Queensland Health website (www.health.qld.gov.au) to address the gap resulting from removing the Departmental Standard. The requirements will be included in the conditions of any substance authorities issued.

Updating references to the Poisons Standard

The Amendment Regulation updates the references to the Poisons Standard to align with the revised Poisons Standard published by the Therapeutic Goods Administration on 22 September 2023.

Consistency with policy objectives of authorising law

The regulation is consistent with the policy objectives of the authorising 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 Amendment Regulation is the only effective means of achieving the policy objectives.

Benefits and costs of implementation

The amendments will make regulatory requirements clearer and easier for industry and the community to comply with, thereby supporting the effectiveness of the Poisons and Prohibited Substances framework.

The amendments will also streamline existing requirements and reduce the regulatory burden on some businesses and the government without increasing risks to public health and safety.

There are no resource or financial implications associated with the proposed amendments. Implementation costs associated with the amendments will be met within existing budget allocations of Queensland Health.

Consistency with fundamental legislative principles

The Amendment Regulation is generally consistent with the fundamental legislative principles in section 4 of the *Legislative Standards Act 1992*. Potential breaches of the fundamental legislative principles are outlined below:

Institution of Parliament

Reference to external documents

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 cases and to appropriate persons, as authorised by an Act (section 4(5)(e) of the Legislative Standards Act).

The Amendment Regulation includes references to a range of external documents. In certain circumstances, prescribing requirements by reference to an external document may be seen to breach section 4(5)(e) of the Legislative Standards Act.

Competency Standard

Section 233 of the Medicines and Poisons Act empowers the chief executive to make standards about carrying out regulated activities with regulated substances and other matters relating to the purpose and administration of the Medicines and Poisons Act. A departmental standard may cover a range of matters, including competency requirements for persons carrying out regulated activities with regulated substances, and may adopt all or part of another entity's code, guideline, protocol or standard.

The Competency Standard is outcomes focused. It provides minimum criteria and acceptable actions to achieve the required outcomes, including multiple options in situations where a range of vocational courses or qualifications are acceptable to achieve the outcomes. These outcomes-based requirements would not be suitable for inclusion in a regulation, which is inherently a more prescriptive instrument.

The Poisons Regulation will be amended to reflect the updated version number each time a new version of the Competency Standard is made. A copy of the updated Competency Standard will be tabled as extrinsic material each time the regulation is amended, to reflect the changed Competency 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 industry best practice and the detailed nature of the documents justifies the references to external documents. For these reasons, prescribing requirements by reference to the Competency Standard does not breach fundamental legislative principles.

Chief Executive approvals

The Amendment Regulation provides that a licensed technician must satisfy and continue to satisfy the relevant competency standards stated in the Competency Standard, or a competency approved by the chief executive that is substantially equivalent to the relevant competency in the Competency Standard. Allowing the chief executive of Queensland Health to approve a competency that is substantially equivalent to a competency in the Competency Standard may be seen to breach section 4(5)(e) of the Legislative Standards Act.

The power of the chief executive to approve a competency that is substantially equivalent to a competency in the Competency Standard was previously prescribed in version 1 of the Competency Standard. The Amendment Regulation prescribes this requirement in the Poisons Regulation itself to improve clarity and transparency of decision-making.

Allowing the chief executive to approve substantially equivalent competencies is necessary to avoid the duplication of education and training requirements. The chief executive of Queensland Health, who is empowered under the Medicines and Poisons Act to make the Competency Standard, is the appropriate person to make these decisions. As such, the powers of delegation do not breach fundamental legislative principles, as it permits delegation only in appropriate cases and to appropriate persons.

Poisons Standard

Clause 10 and 16 of the Amendment Regulation make reference to the Poisons Standard. The purpose of the Poisons Standard is to provide a nationally uniform schedule of substances, which can be applied in the legislation of all Australian jurisdictions, usually by reference in each jurisdiction's medicines and poisons legislation. The intention of classifying medicines and poisons into schedules allows for the setting of different levels of control for the availability of substances included in each schedule.

There are two advisory committees to advise the Commonwealth decision-maker, the Secretary of the Commonwealth Department of Health. Each state and territory is entitled to nominate a member with relevant knowledge, expertise and experience, on each of the committees. The advisory committees advise and make recommendations on the level of access that should apply to each substance, that is, the schedule in which the substance should be included. It is appropriate to rely on the scheduling decisions reflected in the Poisons Standard because it utilises the combined knowledge of national experts in a committee setting.

The Poisons Standard is regularly reviewed and updated approximately three times per year following extensive committee meetings and decision-making processes. The Medicines and Poisons legislative framework would not keep pace with changes to the Poisons Standard if the legislation required amendment each time the Poisons Standard changed. The Poisons Standard provides for national uniformity and consistency, which creates certainty for industry, particularly for those that work across jurisdictions. As a Commonwealth legislative instrument, the latest version of the Poisons Standard is always available on the Federal Register of Legislation (https://www.legislation.gov.au/).

Reference to the Poisons Standard in the Amendment Regulation is considered justified noting the detailed, technical and clinical nature of the matters contained in the Poisons Standard, and the flexibility this provides to remain up to date with current practices and requirements. If the matters referenced in the Poisons Standard were contained in the Poisons Regulation, they would regularly be out-of-date and not reflect changing practices, substances, and activities. For these reasons, the powers of delegation do not breach fundamental legislative principles, as delegation is permitted only in appropriate cases and to appropriate persons.

Consultation

AgForce Queensland, Agricultural Poison Retail Representatives (Elders and Nutrien Ag Solutions), Darling Downs-Moreton Rabbit Board, and Local Government Association of Queensland were consulted on amendments relevant to their industry. These stakeholders support the amendments consulted on.

The Office of Best Practice Regulation was consulted when developing the Impact Analysis Statement for the amendments contained in the Amendment Regulation. Queensland Health has assessed the amendments in accordance with the *Queensland Government Better Regulation Policy* as being unlikely to result in significant adverse impacts. The Minister for Health, Mental Health and Ambulance Services and Minister for Women, and the Director-General of Queensland Health are satisfied that the regulatory review requirements have been met and have approved the Impact Analysis Statement for publication.

Notes on provisions

Short title

Clause 1 states the short title is the *Medicines and Poisons (Poisons and Prohibited Substances) Amendment Regulation 2023*.

Commencement

Clause 2 provides for the commencement of the regulation on 1 December 2023.

Regulation amended

Clause 3 provides that the regulation amends the *Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021* (Poisons Regulation).

Amendment of s 13 (Exemption for reference material—Act, s 7)

Clause 4 amends the definition of *portable testing device* to mean a portable device designed to test for the presence of, or provide immediate analysis of, a regulated substance. This ensures that the use of any regulated substance as reference material to calibrate a portable testing device is exempt from the operation of the Medicines and Poisons Act. Reference material amounts to 0.5 grams or less of a regulated poison.

Amendment of s 20 (Batch manufacturing records)

Clause 5 inserts new subsection (2) into section 20. New subsection (2) states that the requirement to keep a batch record provided for under subsection (1) does not apply in relation to a batch of regulated poison that is a low-risk fluoroacetic acid bait, if the bait manufactured for immediate use.

Amendment of s 22 (Competency for dealings)

Clause 6 inserts new subsection 22(2A). New subsection (2A) provides that a person satisfies a requirement to have a competency stated in the Departmental Standard - *Competency requirements for authority holders dealing with poisons,* if the person has a statement of attainment stating the person has successfully completed the competency or has successfully completed training, approved by the chief executive, that is substantially equivalent to the competency.

Clause 6(2) renumbers sections 22(2A) and (3) as sections 22(3) and (4).

Omission of s 23 (Compliance with departmental standard for restricted S7 poisons)

Clause 7 omits section 23 to remove the operation of the Departmental Standard - *Dealing with restricted S7 poisons for invasive animal control*. This ensures there is no duplication in the requirements under the Medicines and Poisons regulatory scheme, and requirements provided under the APVMA approved label instructions and Chemical Usage (Agricultural and Veterinary) Control Act.

Amendment of s 38 (Disposal of S2, S3 or S4 poison or S7 substance)

Clause 8 updates the definition of an authorised supervisor for a substance authority to mean:

- a person stated in the authority as being authorised to supervise the destruction of an S2, S3 or S4 poison or an S7 substance under the authority; or
- an appropriately qualified person, approved by the holder of the authority, to supervise the destruction of an S2, S3 or S4 poison or S7 substance.

This provides holders of a substance authority with the option of either stating the authorised supervisor in the authority, or ensuring an appropriately qualified person is present when an S2, S3, or S4 poison or S7 substance is being destroyed.

Amendment of s 48 (Purchase order requirements)

Clause 9 omits section 48(1)(e) and replaces it with new sections 48(1)(e) and (ea).

New section 48(1)(e) provides that a purchase order for a regulated poison other than a high-risk poison must specify the name and amount of the poison.

New section 48(1)(ea) provides that a purchase order for a high-risk poison must state the name, form, strength and amount of the poison.

Clause 9(2) renumbers the provisions in section 48(1) to reflect the amendments made to section 48 by clause 9(1).

Amendment of s 54 (Labels and containers to comply with Poisons Standard or approved alternatives)

Clause 10 updates the references in section 54 to align with the revised Poisons Standard published on 23 June 2023.

Clause 10(1) amends section 54(1)(a) by replacing ‘part 2, section 1’ with ‘part 2, division 2’.

Clause 10(2) amends section 54(2)(a) by replacing ‘part 2, section 2’ with ‘part 2, division 3’.

Amendment of s 55 (Supplier must give invoice)

Clause 11 omits section 55(e) and replaces it with new sections 55(1)(e) and (f).

New section 55(1)(e) provides that a supplier supplying a regulated poison other than a high-risk poison must provide an invoice stating the name and amount of the poison.

New section 55(1)(f) provides that a supplier providing a high-risk poison, must provide an invoice stating the name, form, strength and amount of the poison.

Omission of ch 3, pt 3, div 2 (Supply of low-risk fluoroacetic acid baits)

Clause 12 omits chapter 3, part 3, division 2 because authorised dealings in relation to the supply of low-risk fluoroacetic acid baits by biosecurity officers and nature conservation officers is now provided for in schedule 2, section 12 of the Poisons Regulation (see clause 17).

Amendment of s 62 (Applying regulated poisons safely)

Clause 13 omits section 62(b) because the Departmental Standard - *Dealing with restricted S7 poisons for invasive animal control* has been repealed. This ensures there is no duplication in the requirements under the Medicines and Poisons regulatory scheme, and requirements provided under the APVMA approved label instructions and Chemical Usage (Agricultural and Veterinary) Control Act.

Clause 13(2) renumbers section 62(c) as 62(b).

Omission of s 63 (Possessing low-risk fluoroacetic acid baits)

Clause 14 omits section 63 because the Departmental Standard - *Dealing with restricted S7 poisons for invasive animal control* has been repealed. This ensures there is no duplication in the requirements under the Medicines and Poisons regulatory scheme, and requirements provided under the APVMA approved label instructions and Chemical Usage (Agricultural and Veterinary) Control Act.

Amendment of s 65 (Disposal of waste from low-risk fluoroacetic acid baits)

Clause 15 amends section 65 by removing the reference to the Departmental Standard - *Dealing with restricted S7 poisons for invasive animal control* and replacing it with 'in a way that prevents a person or an animal accessing the bait and that is otherwise lawful'. This amendment reflects the repeal of the Departmental Standard, while ensuring the requirements in relation to the disposal of waste from low-risk fluoroacetic baits remain.

Clause 15 also provides an example of a way to prevent access to a bait, namely burying the bait in a deep pit.

Amendment of s 69 (Compliance with Poisons Standard or approved alternatives)

Clause 16 updates references in section 69 to align with the revised Poisons Standard published on 23 June 2023.

Clause 16(1) omits from section 69(1)(a) 'part 2, section 1' and replaces with 'part 2, division 2'.

Clause 16(2) omits from section 69(2)(a) 'part 2, section 2' and replaces with 'part 2, division 3'.

Amendment of sch 2 (Approved persons)

Clause 17 amends the dealings authorised for biosecurity officers in schedule 2, section 12 and nature conservation officers in schedule 2, section 14. Clause 17 also inserts the dealings authorised by primary producers in new division 4 and dealings authorised by persons with a burrowing invasive animal competency certificate in new division 5.

Clause 17(1) amends schedule 2, section 12 by inserting new row 1. The amendment enables biosecurity officers to manufacture a low-risk fluoroacetic acid bait, provided the poison is manufactured in accordance with the approved label of the fluoroacetic acid contained in the bait and it was manufactured for immediate use by another person to control an invasive animal on the person's land or premises.

Clause 17(1) amends schedule 2, section 12, row 3. This amendment clarifies the scope of dealing in relation to the supply of a low-risk fluoroacetic acid bait. The amendment adds subsection (b), which provides that a biosecurity officer must be satisfied the health risk to a person or an animal, other than an invasive animal to be controlled, is likely to be low or negligible. This amendment is a consequence of the omission of chapter 3, part 3, division 2 in clause 12.

Clause 17(2) amends schedule 2, section 14 by inserting new row 1. The amendment enables nature conservation officers to manufacture a low-risk fluoroacetic acid bait provided the poison is manufactured in accordance with the approved label of the fluoroacetic acid contained in the bait and it was manufactured for immediate use by another person to control an invasive animal on the person's land or premises.

Clause 17(2) amends schedule 2, section 14, row 3. This amendment clarifies the scope of dealing in relation to the supply of a low-risk fluoroacetic acid bait. The amendment adds subsection (b), which provides that a nature conservation officer must be satisfied the health risk to a person or an animal, other than an invasive animal to be controlled, is likely to be low or negligible. This amendment is a consequence of the omission of chapter 3, part 3, division 2 in clause 12.

Clause 17(3) amends schedule 2, part 3, by inserting new division 4 (Primary producers), comprising sections 18A and 18B, and new division 5 (Persons with particular competencies), comprising sections 18C and 18D. These provisions regulate the use of gaseous poisons to control a burrowing invasive animal, by only authorising a primary producer or person who has a burrowing invasive animal competency certificate to carry out the activity.

New section 18A provides that division 4 applies to a person who commercially produces agricultural or horticultural products (a primary producer).

New section 18B provides that a primary producer can perform the following regulated activities:

- possess a gaseous poison, if the poison is possessed to control a burrowing invasive animal;
- apply a gaseous poison, if the poison is applied to control a burrowing invasive animal; and
- dispose of a gaseous poison.

New section 18C provides that division 5 applies to a person who has a burrowing invasive animal competency certificate.

New section 18D provides that a person who has a burrowing invasive animal competency certificate can perform the following regulated activities:

- possess a gaseous poison, if the poison is possessed to control a burrowing invasive animal;
- apply a gaseous poison, if the poison is applied to control a burrowing invasive animal; and
- dispose of a gaseous poison.

Amendment of sch 3 (Departmental standards)

Clause 18 amends schedule 3, by replacing the reference to 'version 1' with 'version 2' to reflect new version 2 of the Departmental Standard - *Competency requirements for authority holders dealing with poisons* and removes the reference to the Departmental Standard - *Dealing with restricted S7 poisons for invasive animal control*.

Amendment of sch 6 (Fees)

Clause 19 amends schedule 6, items 1(a) and 5(a), by replacing 'for low-risk fluoroacetic acid baits using fresh meat' with 'to manufacture low risk fluoroacetic acid baits for immediate use'. This clarifies that fees are payable for a renewal application for a manufacturing licence or wholesale licence for a hazardous poison if the application is to renew a manufacturing licence to manufacture low-risk fluoroacetic acid baits for immediate use.

Amendment of sch 7 (Dictionary)

Clause 20 amends schedule 7 by inserting definitions for *burrowing invasive animal competency certificate*, *burrowing invasive animal*, *gaseous poison* and *immediate use*.