

Factsheet – Do I need a Substance Management Plan

Who is this factsheet for?

This factsheet describes circumstances when the chief executive may require a person to have a Substance Management Plan (SMP).

This information applies to all persons who hold a substance authority for poisons under the *Medicines and Poisons Act 2019* (the MPA).

When is an SMP needed?

An SMP is a tool that identifies, and addresses known and foreseeable risks to public health and safety when dealing with regulated substances. Specifically, an SMP describes the risk management measures an organisation will implement to prevent or mitigate risks. The MPA has prescribed that the following substance authority holders must have an SMP:

- Holders of a manufacturing licence;
- Holders of a wholesale licence; and
- Holders of a general approval that deals with high-risk poisons.

The MPA also requires the authority holder to have an SMP if it is required as a condition of the authority.

SMP as a condition of substance authority

The chief executive may require an SMP to be implemented when additional risk management is required to ensure safety and security in dealing with the regulated substances.

Large and complex organisations will require robust governance and procedural arrangements to ensure regulated activities are undertaken in a manner that mitigates public health risk. For example, regulated activities involving several people dealing with regulated substances across many sites with strong inter-relationships and dependencies (e.g. purchasing or transfer of regulated substances between sites) in the management of sites under a single authority. Alternatively, an entity may be operating at a single site, but has a complex organisational arrangement with a large number of employees and other persons dealing with regulated substances such as in a university setting.

Strong governance and risk management may also be required when undertaking high-risk activities involving restricted S7 (RS7) poisons, where safety and/or security are of concern. Examples of high-risk activities include dealing with concentrates or large quantities of poisons (liquid fluoroacetic acid) concentrate for the manufacture of baits or large

quantities of cyanide (for processing of metals) or using heroin or ketamine (high-risk poisons) in an analytical laboratory.

Rural landholders undertaking invasive animal control with RS7 poisons will not require an SMP.

The flowchart in Appendix 1 provides details about when the chief executive may require authority holders to have an SMP as a condition of authority due to complex organisational arrangements. The flowchart in Appendix 2 provides details about when the chief executive may require authority holders to have an SMP as a condition of authority due to high-risk activities.

If an SMP is required, then authority holders must have the SMP prior to commencing any regulated activity with a regulated substance. The only exception is during the transitional period where substance authority holders will have until 26 September 2022 to finalise their SMP. Please see the factsheet '*Transitional arrangements*' for more information.

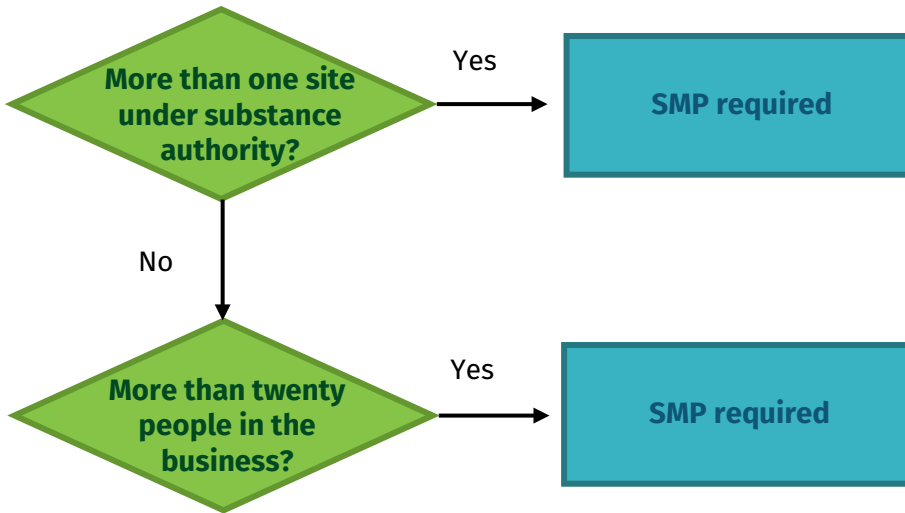
SMPs will be required to comply with the requirements outlined in the Departmental Standard, '*Substance management plans for regulated poisons – version 1*'.

The chief executive may determine whether an authority holder needs an SMP as a condition of their authority on a case-by-case basis. This means that the holder of an authority may be required to have an SMP as a condition of their authority, even if the scenarios in Appendix 1 and Appendix 2 do not apply to them.

Definitions

Term	Meaning
High-risk poison	A Schedule 8, Schedule 9 or Schedule 10 poison under the Poisons Standard.
Restricted Schedule 7 poison	A substance listed in schedule 1 of the Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021.
RS7 poisons for invasive animal control	Fluoroacetic acid, para-aminopropiophenone (PAPP) and strychnine.
Rural landholder	Includes landowner or lessees

Appendix 1: Scenario 1



Appendix 2: Scenario 2

