

Guidance for manufacturers and suppliers of 1080 pest animal baits

[1080 is a derivative of FLUOROACETIC ACID and is the common name for sodium fluoroacetate and sodium monofluoroacetate]

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Purpose of the document

The purpose of this document is to:

- Provide advice to applicants on the Department of Health (DH) licensing requirements for 1080 pest animal baits, which are Schedule 7 poisons; and
- Inform applicants of issues DH will consider before issuing a licence to manufacture and supply, or supply 1080 pest animal baits.

This guidance complements but does not supersede information provided in the *Victorian Code of Practice for the Manufacture of Perishable 1080 Pest Animal Baits* (Code of Practice). It will be a DH licence condition for manufacturers of perishable 1080 pest animal baits produced under APVMA permit, that they act in accordance with the Code of Practice.

From 1 January 2008, 1080 pest animal baits will be able to be legally sold by retail in Victoria. This system will replace the current system whereby the Department of Primary Industries (DPI) is the only permitted outlet for 1080 pest animal baits for end users. This includes distribution of commercial products registered by the Australian Pesticides and Veterinary Medicines Authority (APVMA) and perishable (fresh) 1080 pest animal baits.

Under new regulatory arrangements, DPI will no longer be involved in the distribution of 1080 pest animal bait products. The types of bait available and local sources will be determined by market forces.

Under the new system, manufacturers of 1080 pest animal baits may supply the baits to others such as wholesalers, retailers or end users, depending on the type of DH licence held. There will be legal controls on those activities.

Relevant information for applicants to DH for licences to manufacture and supply or supply

Currently, all 1080 substances in Victoria are classed as Listed Regulated Schedule 7 poisons and are not available from commercial retail outlets. Under the new regulatory framework, 1080 pest

animal baits registered with the APVMA or perishable 1080 pest animal baits prepared under APVMA permit, will transfer to the status of Schedule 7 poisons. All other 1080 preparations will remain Listed Regulated Schedule 7 poisons and cannot be legally sold or supplied by retail in Victoria.

Manufacturers and suppliers or suppliers of 1080 pest animal baits will need a licence from DH **before** they can legally (a) purchase 1080 poison or (b) engage in manufacture and sale or supply, or sale or supply, of 1080 pest animal baits.

Those manufacturers who intend to manufacture 1080 pest animal baits and either use those baits themselves or supply those baits directly to the end users, namely to the landholders or contractors who will lay those baits, may apply for a **licence to manufacture and sell or supply by retail** a Schedule 7 poison. This means that the manufacturer will supply 1080 pest animal baits directly from the site of manufacture.

All other manufacturers will need to apply for a licence **to manufacture and sell or supply by wholesale**.

Wholesalers will need a licence **to sell or supply by wholesale**, in order to supply 1080 pest animal baits to others to on-supply.

Requirements for licences to manufacture and sell or supply 1080 pest animal baits vary depending on whether or not you are an existing licence holder, or are seeking a licence to manufacture and/or sell or supply perishable 1080 pest animal baits under APVMA permit or APVMA-registered 1080 pest animal baits.

Applications for a licence comprise the application form, form to nominate a responsible person, a completed poisons control plan and the application fee. The forms and instructions are on the Drugs and Poisons website http://www.health.vic.gov.au/dpu/1080_poison.htm. All forms contain sufficient instruction to enable you to fill them in correctly.

For applications to manufacture 1080 pest animal baits under APVMA permit, the Responsible Person(s) will need to be one of the persons listed on the Commercial Operator Licence.

Fees

The 2009-2010 application fee a **licence to manufacture and sell or supply by retail** a Schedule 7 poison is \$576.30, with an annual renewal fee.

The 2009-2010 application fee a licence **to manufacture and sell or supply by wholesale** is \$665.20, with an annual renewal fee.

The 2009-2010 application fee **to sell or supply by wholesale** is \$665.20 with an annual renewal fee.

Scenarios for licences

The scenarios below apply during the transition period into the new regulatory framework. During the transition period, DH intends to inspect all premises applying for new licences or amended licences to enable the manufacture and sale or supply, or sale or supply by wholesale, of 1080 pest animal baits.

Check the scenarios below to choose the one that fits your requirements.

Applicant does not currently hold a DH licence to manufacture and sell or supply, or a DH licence to sell or supply, a Schedule 7 poison by wholesale

Scenario 1 To obtain a licence to manufacture and sell or supply perishable **1080 pest animal baits prepared under APVMA permit** you will need to complete the forms specially designed for a:

- a) Licence to Manufacture and Sell or Supply 1080 Perishable Baits by Wholesale; or
- b) Licence to Manufacture and Sell or Supply 1080 Perishable Baits by Retail, and:
 - o Complete the 1080 Application Form* (Wholesale or Retail).
 - o Complete 1080 Responsible Person Form*.
 - o Complete and maintain 1080 Poisons Control Plan*.
 - o Pay the application fee (cheque payable to DH).

and submit these to DH.

* A special set of 1080 Forms is to be used for application to manufacture and sell or supply perishable 1080 pest animal baits manufactured under APVMA permit.

DH inspection of premises will be required.

Scenario 2 To obtain a licence to manufacture and sell or supply [APVMA-registered 1080 pest animal baits](#) you will need to complete the forms for a Licence to Manufacture and Sell or Supply by Wholesale and

- Complete an application form for the licence.
- Complete an application to nominate a responsible person.
- Complete and maintain a Poisons Control Plan.
- Pay the application fee (cheque payable to DH).

and submit these to DH.

DH inspection of premises will be required.

Scenario 3 To obtain a licence to sell or supply by wholesale [APVMA-registered 1080 pest animal baits](#) and/or perishable [1080 pest animal baits prepared under APVMA permit](#) you will need to complete the forms for a Licence to Sell or Supply by Wholesale and

- Complete an application form for the licence.
- Complete an application to nominate a responsible person.
- Complete and maintain a Poisons Control Plan.
- Pay the application fee (cheque payable to DH).

and submit these to DH.

DH inspection of wholesaling premises will be required.

Scenario 4 Applicants in scenarios (1) or (7) for a licence to manufacture and sell or supply perishable [1080 pest animal baits prepared under APVMA permit](#) who also wish to commence wholesale supply of [APVMA-registered 1080 pest animal baits](#), will need to incorporate descriptions of this activity within the relevant sections of the 1080 Poisons Control Plan submitted in the application.

Applicant currently holds a DH licence to manufacture and sell or supply, or a DH licence to sell or supply a Schedule 7 poison by wholesale.

As an inspection will be required, the fee payable is the equivalent of a fee for a new application.

Scenario 5 Existing licence holders who have a licence to manufacture and sell or supply by wholesale [APVMA-registered 1080 pest animal baits](#), who wish to manufacture and sell or supply perishable [1080 pest animal baits prepared under APVMA permit](#), will need to:

- complete the 1080 Application Form* (Wholesale or Retail)
- Complete 1080 Responsible Person Form*.

- Complete and maintain 1080 Poisons Control Plan*.
- Pay the amendment fee where inspection is required (cheque payable to DH).

and submit these to DH.

* A special set of 1080 Forms is to be used for application to manufacture and sell or supply perishable **1080 pest animal baits prepared under APVMA permit**.

DH inspection of premises will be required before the 1080 Poisons Control Plan is approved and the licence amended.

Scenario 6 Existing licence holders who have a licence to manufacture and sell or supply Schedule 7 poisons by wholesale who wish to commence manufacture and sale or supply of **APVMA-registered 1080 pest animal baits**, will need to consider if the existing Responsible Person and Poisons Control Plan are adequate and if not:

- complete a new application to nominate a responsible person
- Revise the existing Poisons Control Plan.
- Pay the amendment fee where inspection is required (cheque payable to DH).

and submit these to DH.

DH inspection of premises will be required before the revised 1080 Poisons Control Plan is approved and the licence amended.

Scenario 7 Existing licence holders who have a licence to manufacture and sell or supply Schedule 7 poisons by wholesale, who wish to commence manufacture and sale or supply of perishable **1080 pest animal baits prepared under APVMA permit**, will need to:

- Complete the 1080 Application Form*.
- Complete 1080 Responsible Person Form*.
- Complete and maintain 1080 Poisons Control Plan*.
- Pay the application fee (cheque payable to DH).

and submit these to DH.

* A special set of forms are to be used for application to manufacture and sell or supply perishable 1080 pest animal baits manufactured under APVMA permit.

DH inspection of premises will be required before issuing an amended licence.

Scenario 8 Existing licence holders who have a wholesale licence to sell or supply Schedule 7 poisons who wish to sell or supply by wholesale **APVMA-registered 1080 pest animal baits** or perishable **1080 pest animal baits prepared under APVMA permit**, will need to consider if the existing Responsible Person and Poisons Control Plan are adequate and if not:

- complete a new application to nominate a responsible person
- Revise the existing Poisons Control Plan.
- Pay the amendment fee where inspection is required (cheque payable to DH).

and submit these to DH.

DH inspection of premises will be required before issuing an amended licence.

What happens after your application is received

When an inspection is required, an officer from the Drugs and Poisons Regulation Group of DH will contact you to arrange a time to visit and inspect your premises. The aim of the inspection is to

ascertain that you are aware of your responsibilities in manufacturing 1080 pest animal baits, that the manufacturing premises, systems and competence of those involved in manufacture will enable the baits to be manufactured in a safe and secure manner and that the information provided in the Poisons Control Plan accurately reflects your business. A licence will only be granted when the premises are determined to be "suitable, sanitary and adequately equipped" for the purpose.

You will only be eligible to apply for a licence to manufacture and sell or supply 1080 pest animal baits:

- If you intend to manufacture APVMA-registered 1080 products, or
- If you intend to manufacture and sell or supply perishable 1080 pest animal baits prepared using APVMA-registered 1080 aqueous solution and supplied in accordance with APVMA Permit Number 8781 and:
 - You have an existing DH licence to manufacture and sell or supply the above APVMA-registered 1080 aqueous concentrate, or
 - You are a person or company that holds Commercial Operator Licences with identified persons who have undertaken 1080 manufacturer training, have a vermin destroyer endorsement and have undertaken Agsafe personnel on-line training.

From the time we receive your application, it will take 4-6 weeks to arrange and conduct the inspection, compile the inspection report and issue the licence. Deficiencies noted at inspection will need to be rectified before the licence is issued. This may increase the elapsed time before the licence can be issued.

The manufacturing premises, equipment, security, systems for keeping records and sale or supply protocols need to be substantially complete and in place before any inspection takes place. The inspection provides the opportunity for you to demonstrate that you are ready to obtain APVMA-registered 1080 aqueous solution to use in bait manufacture and also to clarify any aspects of manufacturing the baits or regulatory requirements in handling 1080 poison and 1080 pest animal baits.

The premises are to be assessed as "suitable, sanitary and adequately equipped for the manufacture, sale supply or use of the poisons or controlled substances to which the licence applies". DH addresses only requirements under the Drugs, Poisons and Controlled Substances Act and Regulations. You should have checked with State and local government authorities and have the requisite approvals for the premises and discharge of 1080 contaminated washings and comply with other relevant legislation for occupational health and safety and dangerous goods.

Sale or supply protocols will be checked to ensure that sale or supply is only to authorised persons and that staff are trained to understand and implement the protocols.

DH inspection of the premises to be used for manufacturing and sale or supply

DH inspection of the premises will be consistent with the requirements of the Code of Practice, with an emphasis on the following:

Security

- Perimeter and premises security.
- Capacity to keep unauthorised personnel outside the manufacturing area.

Access

- Restricted to authorised persons to the facility, APVMA-registered 1080 aqueous solution and treated baits.

Storage

- Secure storage for registered 1080 aqueous solution.
- Secure storage for 1080 pest animal baits.

Records

- Capacity to keep and maintain records of transactions for a period of 3 years; capacity to track batch manufacture, date of manufacture and supply.

Training

- 1080 manufacture training for all manufacturing licensed Commercial Operators is done.
- Standard operating procedures are in place, including for the manufacturing process (volumes and dilutions) and there is a system to keep them up to date.
- Other documents, such as the Poisons Control Plan, Code of Practice, APVMA Permit 8781 and manufacturer training documents, are readily available and are understood.
- Staff are trained in the standard operating procedures.
- Staff have practised dummy runs and are competent in using the manufacturing equipment such as the bait sealing equipment, measuring devices, injecting equipment, bait dyeing and packaging.
- All staff are aware of occupational health and safety requirements and have taken steps to assess and minimise the risks.

Administration area

- Clean area is dedicated to "office administration" activities such as telephone, document storage, e.g. of safety data sheets, procedures and regulations, write up of batch records and other records;
- Clean area is set aside for conducting paperwork with clients, for example examining the Bait User Declaration form and licence details, and recording the name and address of the client and the product details for the purchase.

Manufacture

- Space planning and allocation is sufficient to enable segregation into clean areas and 1080 treatment areas.
- Cleanable surfaces such as bench tops and floors.
- Clean areas are set aside for storage and preparation of equipment and bait substrates prior to treatment with 1080 aqueous solution.
- Segregated area for treatment with 1080 aqueous solution and dye; contained preparation trays or troughs to capture and contain spillage.
- Sufficient space to treat, dry and store baits efficiently.
- Loading technique and facilities are such that the external surfaces of containers will not become contaminated with 1080 poison.
- Personal protective equipment is provided and can be cleaned.

Emergency contacts

- Emergency contact details are prominently displayed; local doctor or hospital is aware of the manufacturing activity.
- First aid measures are in place.

Clean up

- The work area and equipment can be easily cleaned and dried after each manufacturing batch, to reduce the risk of contamination of staff, as well as reducing the risk of contamination of other baits.
- Wash up and draining area for contaminated items.
- Adequate staff washing and change facilities.

Disposal

- Adequate facilities are in place for the disposal of untreated meat and carrot products.
- Adequate facilities are in place for the disposal of 1080 contaminated waste, including meat and carrot waste, other particulate waste, and contaminated washings from wash-up sink, equipment, floors and benches.
- Operating procedures are in place and staff are trained to correctly dispose of contaminated materials
- Any approvals or permits needed from the local council or Environment Protection Agency are in place.

Distribution area

- Site includes a clean spacious and dry area for loading of labelled containers of 1080 pest animal bait.
- The public does not have access to the manufacturing premises, i.e. cannot enter the manufacturing or storage area.

Supply

- Manufacturer understands how to check the Bait User Declaration Form and what to do if he is not satisfied with the validity of the documentation, or that the number and type of baits purchased are not consistent with the risk assessment.
- Manufacturer understands to ask for proof of age if he suspects the client is below the age of 18 years.

Labels

- Manufacturer understands labelling requirements and can show at least a draft or mock up of the product label.

Packaging

- Manufacturer can demonstrate the packaging to be used and show how it meets requirements.

Follow up

- If manufacturing facilities are not assessed as "suitable, sanitary and adequately equipped" DH will request that deficiencies are amended before issuing a licence will be considered. This may add extra delays in the issuing of the licence. Deficiencies noted relating to other agencies will be referred to those agencies.

Audit

- DH may audit licence holders at any time. Generally notice is given to arrange a suitable time.