



**Australian Pesticides &
Veterinary Medicines Authority**

**The Reconsideration of Registrations and Label Approvals
Relating to Methyl Bromide**

**METHYL BROMIDE
SCOPE DOCUMENT**

SEPTEMBER 2005

**Australian Pesticides &
Veterinary Medicines Authority**

**Canberra
Australia**

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Methyl Bromide Review

Scope Document

SUMMARY

The APVMA has initiated its reconsideration of the registration of products containing methyl bromide and the approvals of associated labels. This document defines the scope of the matters of concern to the APVMA and outlines the kinds of information the APVMA requires to conduct a comprehensive scientific assessment of methyl bromide.

Methyl bromide is a potent biocide with insecticidal, fungicidal and herbicidal properties contained in 16 registered products. Products containing methyl bromide have been registered in Australia since the second world war. Methyl bromide is used as a soil fumigant in horticultural industries, as a pest control treatment on dry commodities such as stored grain or dried fruit, as well as quarantine and pre-shipment (QPS) treatments for imports, exports and certain commodities transported interstate.

In accordance with the Montreal Protocol for ozone depleting substances the total phase-out of methyl bromide use in Australia, except for Critical Use Exemptions (CUEs) and Quarantine and Pre-shipment (QPS) uses, was to be completed by January 2005. Legislation to ensure that methyl bromide imported into Australia is only used for CUEs and QPS purposes is now in place and administered by the Department of the Environment and Heritage (DEH). This enables DEH to track methyl bromide imported into Australia to ensure that none is diverted into other uses.

Methyl bromide is being reconsidered because current labels contain uses that may no longer be permitted under the Montreal Protocol but are currently controlled by prohibitions under the DEH regulations. As the potential for adverse environmental effects of methyl bromide are well understood, the APVMA is not intending to conduct a new scientific review of available data. The review will focus on Australia's responsibilities under the Montreal Protocol and the compliance of product registrations and label approvals with the Montreal Protocol requirements.

A final decision on methyl bromide will be made after the APVMA assesses available information.

The public is invited to make submissions to the APVMA regarding any of the matters raised in the scope document (see Section 10).

1. INTRODUCTION

Section 31 of the Agvet Codes, authorises the APVMA to reconsider:

- (a) the approval of an active constituent for a proposed or existing chemical product;
- (b) the registration of a chemical product; and
- (c) the approval of a label for containers for a chemical product.

The APVMA has decided to reconsider the registrations of products containing methyl bromide and the approvals of associated labels, on the basis of environmental concerns and adequacy of labels.

2 REGULATORY STATUS AND USE OF METHYL BROMIDE IN AUSTRALIA

2.1 Registered Products

At the commencement of the review, there were 16 registered products containing the active constituent methyl bromide (Attachment 1) all of which are subject to this review. All label approvals for these products are also subject to review. It should be noted that any product registration or label approval that occurs after the commencement of the review would be subject to the outcomes of the review.

2.2 Product formulation

All methyl bromide products used in Australia are formulated as gases. The concentration of methyl bromide in these registered products varies from 300 g/kg to 1000 g/kg. The products are available in a range of pack sizes (12kg, 35kg, 50kg, 66kg, 100kg, 132kg).

2.3 Use patterns

Methyl bromide (IUPAC name bromomethane), is classified as an alkyl bromide. It is a colourless and odourless gas at normal temperatures and pressures, but the liquefied gas can be handled as a liquid under moderate pressure.

Methyl Bromide is a highly effective, broad-spectrum fumigant registered for use to control a number of pests including insects, rodents, weeds and disease causing organisms in a wide range of agricultural and horticultural crops. Its primary uses are for soil fumigation, post harvest protection and quarantine treatments.

More specifically, product labels permit the use of methyl bromide on:

- Flowers, bulbs, nursery and horticultural crops – control of *fusarium* and *verticillium* wilts, *rhizoctonia*, *pythium*, nematodes, weeds, weed seeds;
- Plant beds, turf, local areas, well rotted compost, manure and topsoil, mulching straw or hay – control of nematodes, insects, weed seeds, nutgrass;
- Plant beds and other local areas, decomposed compost and manure – control of damping off fungi such as species of *pythium*, *rhizoctonia* and *fusarium*, soil borne fungi such as *sclerotinia* and *verticillium*;
- Buildings and other structures – rodents;
- Cereal grain, cereal products, dried fruits, pulse and pulse products (including field peas), timber and cane products, buildings and other structures, living plant material, nuts, chocolate products – control of stored product insect pests.

Other uses of methyl bromide include:

- fumigation before export—commodities such as wheat, rice, cut flowers and some fruit and vegetables are treated with methyl bromide before export in order to meet phytosanitary (pest-free) requirements of importing countries; and
- quarantine—methyl bromide is the recommended fumigant for a significant number of commodities imported into Australia including fruits, vegetables, flowers, plant products, timber, bamboo and cane products, machinery, tyres, food processing equipment.

Tables 1 and 2 summarise the use patterns that appear on labels.

It is important to note that the use of methyl bromide in Australia is already tightly regulated under DEH regulations and that many uses contained on product labels in their current form are already prohibited under DEH regulations.

When used as a soil fumigant, methyl bromide gas is usually injected into the soil before a crop is planted. This effectively sterilises the soil, killing the vast majority of soil organisms including soil-borne fungi, nematodes, bacteria and weed seeds. Immediately after the methyl bromide is injected, the soil is covered with plastic tarps, which slow the movement of methyl bromide from the soil to the atmosphere. Its use in soil underpins approximately \$300 million worth of Australian horticulture. Horticultural uses of methyl bromide accounted for approximately 80% of Australia's methyl bromide use in 1991. It provides a broad spectrum of control under a wide range of soil and climatic conditions. Pre-plant soil fumigation accounts for approximately 80% of world use of methyl bromide.

When used as a commodity treatment, methyl bromide gas is injected into a chamber or under a tarp containing the commodities. Commodities which use this material as part of a post-harvest pest control regime include grapes, raisins, cherries, nuts, and imported materials. Some commodities are treated multiple times during both storage and shipment. Commodities may be treated with methyl bromide as part of a quarantine or phytosanitary requirement of an importing country (these uses are exempt from the phase out).

Structural pest control treatment with methyl bromide gas involves the fumigation of buildings and other structures for stored product insect pests and rodents.

2.4 Previous Regulatory Action

There has been no previous regulatory action on methyl bromide by the APVMA. The APVMA has received one adverse experience report on methyl bromide since the establishment of the Adverse Experience Reporting Program (AERP). There had been reported damage to flowers planted in an area adjacent to where methyl bromide had been used. A causal link to methyl bromide could not be firmly established and so no further action was taken.

Table 1 – Methyl bromide for soil fumigation

Crop	Pest	Rate	Minimum exposure time	Aeration time before planting	Critical comments
Flowers, bulbs, nursery and horticultural crops	Fusarium and verticillium wilts, rhizoctonia, pythium, nematodes	500 g/kg (50 g per sq metre)	24 hours	At least 14 days (Increase time if weather becomes wet or cold) (21-28 days 59240)	Thoroughly cultivate the soil and ensure it is kept in a moist condition 5-7 days prior to treatment. Methyl bromide is applied to the soil by means of a sealed pressure injection unit with tyne spacing of 30cm and at a depth of 15-20cm. To seal in fumigant, cover immediately behind tynes with plastic sheet and seal edges.
Plant beds, turf and other local areas	nematodes, insects, weed seeds, nutgrass	50 g per 1 square metre	24 hours	48 hours	
Well-rotted compost, manure and top soil		300 g per 1 cubic metre	24 hours	72 hours	
Mulching straw or hay		120 g per 1 bale	48 hours	24 hours	
Plant beds and other local areas	damping off fungi such as species of <i>pythium</i> ,	100 g per 1 square metre	24 hours	72 hours or longer	
Decomposed compost and manure	<i>rhizoctonia</i> and <i>fusarium</i> , soil borne fungi such as <i>sclerotinia</i> and <i>verticillium</i>	600 g per 1 square metre	24 hours	72 hours or longer	

Table 2 – Methyl bromide for general fumigation

Situation	Pests controlled	Dosage g/m3	Temperature	Exposure time	Critical comments
Cereal grain, cereal products, dried fruits, pulse and pulse products (including field peas), timber and cane products, buildings and other structures, living plant material, nuts, chocolate products	Stored product insect pests	24-32	> 15	24 hours	Under atmospheric pressure
		32-40	10-15	24 hours	
		32-40	> 15	3 hours	Under sustained vacuum (10-16.7kPa absolute pressure)
		40-48	10-15	3 hours	
Buildings and similar structures	Rodents	4	> 4	5 hours	

Other instructions that appear on labels include:

- Do not use when soil temperature is less than 10°C;
- Do not fumigate when very cold, very wet or very dry;
- Do not fumigate within 50cm of roots of desirable vegetation;
- Do not plant or sow for at least 14 days after removal of plastic;
- Do not fumigate more than once as commodity is likely to become unfit for use.

3 BACKGROUND INFORMATION – MONTREAL PROTOCOL

Methyl bromide is considered to be a significant ozone depleting substance. In order to minimise further damage to the ozone layer, The *Montreal Protocol on Substances that Deplete the Ozone Layer* (Montreal Protocol), finalised in September 1987, requires that reduction steps be taken to reduce the use of ozone depleting substances such as methyl bromide. It has been signed by over 180 countries, including Australia and sets out a mandatory timetable for the phase out of such compounds.

The Department of the Environment and Heritage (DEH) is the Commonwealth Government agency responsible for co-ordinating national ozone protection measures and administering the Ozone Protection and Synthetic Greenhouse Gas Management Act 1989. DEH manages the importation and use of methyl bromide via supply chain restrictions that include import permits/quotas, record keeping and reporting requirements and undertake enforcement action when breaches occur.

In 1995 imports of methyl bromide for soil fumigation uses were frozen at 1991 levels and at the Protocol meeting in September 1997, the following phase-out timetable was agreed to for developed countries.

Target	Year
25% reduction from 1991 levels	1999
50% reduction from 1991 levels	2001
75% reduction from 1991 levels	2003
Total phase out	2005

Australia, being a signatory to the Montreal Protocol, is fully committed to the above phase out timetable. Accordingly, since 1999 there have been corresponding reductions in the tonnage of methyl bromide imported.

Critical Use Exemptions (CUE's)

It has been recognised that transitional access to methyl bromide after the 1 January 2005 deadline may be justified in some circumstances. In 1997 a formal decision was made to allow limited "critical use exemptions" in some rare cases. Such exemptions are only granted when several strict criteria are met:

- The failure to provide access would result in a significant market disruption;
- There are no technically and economically feasible alternatives available to an exemption applicant that are acceptable from environmental and human health standpoints;
- The applicant has taken all feasible steps to minimise their use of methyl bromide and the associated emissions; and
- Appropriate efforts are being made to evaluate, commercialise and register alternatives to methyl bromide for use by the applicant.

The decision to approve CUEs is not made by the Australian Government, but by the Parties to the Montreal Protocol. These are granted on a yearly basis, allowing the use of an allocated amount of methyl bromide by specific individuals.

Six specific CUE exemptions were granted to Australian producers/producer associations for 2005. These are for:

- Strawberries Australia for use in strawberry production.
- Strawberry Runner Growers for use in strawberry runner production.
- Queensland Flower Growers Association: for use cut-flower production in Queensland for open and protected cropping.
- Flowers Victoria: for use in cut flower production in protected cropping only
- For use by a specific business producing Almonds.
- Rice Growers Cooperative Ltd. for post harvest disinfestations of rice.

The use on flowers is the largest amount of methyl bromide approved for 2005 (6 tonnes).

For 2006, exemptions have been granted for almonds (specific processors), cut flowers in Queensland and Victoria, post harvest disinfestations of rice in consumer packs and strawberry runner producers.

Quarantine and pre-shipment (QPS) uses

QPS uses of methyl bromide are currently exempt from the phase out plan. QPS uses are strictly defined by the Montreal Protocol.

Quarantine applications are treatments to prevent the introduction, establishment and/or spread of quarantine pests (including diseases) or to ensure their official control, where:

- i) Official control is that performed by, or authorised by, a national plant, animal or environmental protection or health authority;
- ii) Quarantine pests are pests of potential importance to the areas endangered thereby and not yet present there, or present but not widely distributed and being officially controlled.

Pre-shipment applications are those non-quarantine applications applied within 21 days prior to export to meet the official requirements of the importing country or existing official requirements of the exporting country. Official requirements are those which are performed by, or authorised by, a national plant, animal, environmental, health or stored product authority.

Although QPS uses are not covered by the Montreal Protocol, it is expected that international pressure to reduce reliance on methyl bromide will move towards the eventual phase-out of methyl bromide for all uses in the future.

4. REASON FOR REVIEW

Methyl bromide product labels in their current form contain uses that are no longer permitted under the Montreal Protocol but are currently controlled by prohibitions under the DEH regulations. They include the control of rodents and general references for application to nursery and horticultural crops.

As the potential for adverse environmental effects of methyl bromide are well understood, the APVMA is not intending to conduct a new scientific review of available data. The review will focus on Australia's responsibilities under the Montreal Protocol and the compliance of product registrations and label approvals with the Montreal Protocol requirements.

5 SCOPE OF THE REVIEW

The scope of the review has been defined taking into consideration the reasons for the nomination of methyl bromide, the information already available on this chemical and the way in which it is approved for use in Australia.

On the basis of the concerns outlined above (Reasons for Review), it is appropriate that the registrations and label approvals of methyl bromide be subject to reconsideration under Part 2, Division 4, of the Agvet Codes.

The APVMA review will therefore focus on the warnings and instructions on product labels particularly in respect of known environmental concerns with methyl bromide. This will involve consultation with DEH, Department of Agriculture, Fisheries and Forestry (DAFF) and the Australian Quarantine and Inspection Service (AQIS). The review would ensure that uses that would remain viable under the Montreal Protocol would not be removed. Alternative arrangements such as permits may be used in situations where labels do not cover QPS or CUE use patterns or where their inclusion onto labels, particularly CUEs may be problematic.

The public is invited to make submissions to the APVMA regarding any of the matters raised in the scope document (see Section 8).

6 ENVIRONMENTAL ISSUES

The environmental impacts of methyl bromide have been well studied. Methyl bromide has been classified as a powerful ozone-depleting substance. The bromines it contains are fifty times more destructive to ozone than chlorine (eg. from CFCs). Concerns about the depletion of the ozone layer exist because the ozone layer reduces the amount of harmful ultraviolet radiation that reaches the Earth's surface. Any significant change to this layer can have far-reaching consequences for human health (skin cancer) and the environment (global warming) and will have downstream impacts on agriculture.

As the potential for the adverse environmental effects of methyl bromide are well understood, the APVMA is not intending to conduct a new scientific review of available data. The review will focus on Australia's responsibilities under the Montreal Protocol and the compliance of product registrations and label approvals with the Montreal Protocol requirements.

7 INTERNATIONAL REGULATORY STATUS OF METHYL BROMIDE

Countries around the world are taking the same action as in Australia with respect to the objectives and measures within the Montreal Protocol. Australia is not unique in this regard.

The U.S. CUE's covers exemptions for 15 crops or uses, including tomatoes, strawberries, peppers, cucurbits, orchard replants, and post-harvest uses.

8 SUBMISSIONS FROM THE PUBLIC INVITED

Interested parties are invited to provide information or data relevant to the issues raised in this scope document. These must reach the APVMA by no later than 23 December 2005. Submissions can be sent either by email to chemrev@apvma.gov.au or by mail to:

Manager Pesticides Review
Australian Pesticides and Veterinary Medicines Authority
PO Box E240
KINGSTON ACT 2604
Telephone: (02) 62723213
Facsimile: (02) 6272 3218

9 DATA ASSESSMENT AND POSSIBLE OUTCOMES

Depending on the findings of the technical assessment, a review can result in one of three broad outcomes:

- The APVMA is satisfied that products containing methyl bromide continue to meet the conditions to which registrations and label approvals are currently subject and affirms the registration and label approvals; or
- The APVMA is satisfied that the conditions to which the registration and label approvals are currently subject can be varied in such a way that the requirements for continued registration and label approval will be complied with, and varies the conditions of approval and registration; or
- The APVMA is not satisfied that the conditions continue to be met and suspends or cancels the registration and approvals.

10 CONSULTATION THROUGHOUT THE REVIEW PROCESS

From initiation of the review through to the implementation of the review outcomes, the APVMA will consult with relevant stakeholders and interested parties. Prior to finalisation of any report, comments from key stakeholders and the public will be sought.

The draft of the review summary along with proposed recommendations is intended to be made available to the stakeholders and public through the APVMA website or direct communication. A period will be allowed for the stakeholders and the public to comment on the draft.

ATTACHMENT 1 – Registered products containing methyl bromide

NCRIS No	Product Name	Registrant	Label Approval Numbers
32106	Agrigas M Methyl Bromide Fumigant	BOC Gases Australia Ltd	32106/01
34060	Agrigas MC Methyl Bromide Fumigant	BOC Gases Australia Ltd	Ψ
34066	Nufarm Methyl Bromide 980 Fumigant	Nufarm Australia Limited	34066/0604 34066/0298 34066/0204
34067	Nufarm Methyl Bromide 1000 Fumigant	Nufarm Australia Limited	34067/0204 34067/0298 34067/0604
41303	SA Rural Methyl Bromide 980 Fumigant	S.A. Rural Agencies Pty Ltd	41303/0802
41390	Dibbs Brom-O-Gas 1000 Fumigant	RA Dibbs & Sons Pty Ltd	41390/0303 41390/1002
41394	Dibbs Brom-O-Gas 980 Fumigant	RA Dibbs & Sons Pty Ltd	41394/0203 41394/1002
41488	Nufarm Bromopic 700:300 Soil Fumigant	Nufarm Australia Limited	41488/0200 41488/0204
51125	Nufarm Fungifume Soil Fumigant	Nufarm Australia Limited	51125/0204 51125/0998
51126	Nufarm Vertafume Soil Fumigant	Nufarm Australia Limited	51126/0504 51126/0998
51208	Rural Soil Fumigant 500-500	S.A. Rural Agencies Pty Ltd	51208/1198 51208/1202
52781	Southern Cross Methyl Bromide 1000 Fumigant	Southern Cross Fumigation Services Pty Ltd	52781/0400 52781/0503 52781/1200
53267	Rural Methyl Bromide 1000 Fumigant	S.A. Rural Agencies Pty Ltd	53267/1000 53267/1202
58001	Southern Cross Methyl Bromide 980 Fumigant	Southern Cross Fumigation Services Pty Ltd	58001/1103
59240	Southern Cross Soil Fumigant 500-500	Southern Cross Fumigation Services Pty Ltd	59240/1004
59241	Southern Cross Soil Fumigant 700-300	Southern Cross Fumigation Services Pty Ltd	59241/1104

Ψ Label approved prior to the commencement of the Agvet Codes