Final Review Report and Regulatory Decision

Australian Pesticides & Veterinary Medicines Authority

The Reconsideration of Registrations of Products Containing Methyl Bromide and their Associated Approved Labels

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Manager Pesticides Review
Australian Pesticides and Veterinary Medicines Authority
PO Box E240
KINGSTON ACT 2604
AUSTRALIA

Telephone: 61 2 6210 4765
Facsimile: 61 2 6210 4776
Email: chemrev@apvma.gov.au
APVMA web site: www.apvma.gov.au

FOREWORD

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is an independent statutory authority with responsibility for the regulation of agricultural and veterinary chemicals in Australia. Its statutory powers are provided in the Agvet Code scheduled to the *Agricultural and Veterinary Chemicals Code Act, 1994*.

The APVMA can reconsider the approval of an active constituent, the registration of a chemical product or the approval of a label for a container for a chemical product at any time. This is outlined in Part 2, Division 4 of the Agvet Code.

The specific basis for this reconsideration is whether the APVMA is satisfied that continued use of methyl bromide and products containing methyl bromide, in accordance with the label instructions and warning statements for their use:

- would not be likely to have an effect that is harmful to human beings
- would not be likely have an unintended effect that is harmful to animals, plants or things or to the environment.

The requirements for continued approval of a label for containers for a chemical product are that the label contains adequate instructions. Such instructions include:

- the circumstances in which the product should be used
- how the product should be used
- times when the product should be used
- frequency of the use of the product
- the withholding period after the use of the product
- disposal of the product and its container
- safe handling of the product.

A reconsideration may be initiated when new research or evidence has raised concerns about the use or safety of a particular chemical, a product when used according to the instructions on its label.

The process for reconsideration includes a call for information from a variety of sources, a review of that information and, following public consultation, a decision about the future use of the chemical or product.

In undertaking reviews, the APVMA works in close cooperation with advisory agencies including the Office of Chemical Safety (OCS), the Department of the Environment and Water Resources (DEW[1]), and State Departments of Agriculture, as well as other expert advisors, as appropriate.

[1] Formerly the Department of the Environment and Heritage (DEH)

The APVMA has a policy of encouraging openness and transparency in its activities and community involvement in decision-making. The publication of review reports is a part of that process.

The APVMA also makes these reports available to the regulatory agencies of other countries as part of bilateral agreements.

Under this program the APVMA recommends that countries receiving these reports will not utilise them for registration purposes, unless they are also provided with the raw data from the relevant applicant.

This document on '*The reconsideration of registrations of products containing methyl bromide and their associated label, Final Review Report and Regulatory Decision*' relates to all products containing methyl bromide that have been nominated for review by the APVMA. The review's findings and regulatory decision are based on information collected from a variety of sources. The information and technical data required by the APVMA to review the safety of both new and existing chemical products must be derived according to accepted scientific principles, as must the methods of assessment undertaken.

The *Final Review Report and Regulatory Decision*' containing the APVMA's assessments (The APVMA Review of Methyl Bromide), is available from the APVMA website: http://www.apvma.gov.au/chemrev/chemrev.shtml.

ACRONYMS AND ABBREVIATIONS

AERP	Adverse Experience Reporting Program
APVMA	Australian Pesticides and Veterinary Medicines Authority
AQIS	Australian Quarantine and Inspection Service
CSIRO	Commonwealth Scientific and Industrial Research Organisation
CUEs	Critical Use Exemptions
DAFF	Department of Agriculture, Fisheries and Forestry
DEW[2]	Department of the Environment and Water Resources
DFU	Directions for Use
MBTOC	Methyl Bromide Technical Options Committee
OCS	Office of Chemical Safety (within the Department of Health and Ageing)
OHS	Occupational Health and Safety
PRF	Preliminary Review Findings
QPS	Quarantine and Pre-Shipment

[2] Formerly the Department of the Environment and Heritage (DEH)

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OVERVIEW OF REVIEW FINDINGS AND REGULATORY DECISION

Review Findings

- Methyl bromide is a potent and toxic biocide with insecticidal, fungicidal and herbicidal properties, and is present in 16 Australian-registered products.
- Methyl bromide is being reconsidered because current labels contain uses that may pose an unacceptable risk to the environment. It is the most potent ozone depleting substance still in use in Australia today.
- The international Montreal Protocol recognises that the emission of certain substances (including methyl bromide) can significantly deplete or modify the ozone layer, in a manner that is likely to result in adverse effects on the environment.
- In accordance with the *Montreal Protocol on Substances that Deplete the Ozone Layer* (the Montreal Protocol), the total phase-out of methyl bromide was to be completed by 1 January 2005.
- Many uses on Australian methyl bromide labels are no longer permitted under the Montreal Protocol.
- Uses of methyl bromide used for Quarantine and Pre-Shipment (QPS) and as an industrial feedstock are currently exempt from phase out under the Montreal Protocol.
- In recognition that some industries are having difficulty in finding alternatives to methyl bromide, the Montreal Protocol permits some Critical Use Exemptions (CUEs) where no technical or economically feasible alternative exists. The regulations for CUEs are administered by the Department of the Environment and Water Resources (DEW), and enable DEW to track methyl bromide imported into Australia, to ensure that none is diverted into illegal uses.
- In 2005, Australia used 400 t of methyl bromide for QPS and 147 t for non-QPS uses (i.e. CUEs).
- The review has focussed on:
  - the warnings and instructions on product labels, particularly with respect to known environmental concerns with methyl bromide
  - Australia's obligations under the Montreal Protocol.
- This has involved consultation with the Department of Environment and Water Resources (DEW), the Department of Agriculture, Fisheries and Forestry (DAFF) and the Australian Quarantine and Inspection Service (AQIS).
- No technical assessments were required in the areas of toxicology, Occupational Health and Safety, or residues.
- The review proposes to find that the APVMA is not satisfied that continued use of methyl bromide products, in accordance with existing label instructions, would not be likely to have an unintended effect that is harmful to the environment, specifically damage to the ozone layer.

- However, the APVMA is satisfied that the labels of **all** registered methyl bromide products can be varied in such a way that continued use of the products, in accordance with the varied labels, would not be likely to have an unintended effect that is harmful to the environment. The labels can be varied to restrict all uses to QPS[3] and approved CUE[4]s, on the relevant labels. DEW has advised that the QPS and CUE-related label instructions are acceptable to them.

Responses to issues arising from public consultations

- The PRF had recommended cancellation of methyl bromide products with only in-field horticultural-crop soil fumigation uses on their label, with approved CUE uses that require them to be allowed by APVMA permit. One public consultation suggestion argued for the continued registration of such products.
- The APVMA has assessed this proposal, and agreed that continued registration (albeit very restricted), together with controls imposed by the Montreal Protocol and DEW, poses no greater risk than APVMA permits, and is more practical.
- Hence this was included as a recommendation to the Board and accepted by the Board.
- Whilst considering the option of varying the concentration of methyl bromide and the duration of treatment during QPS fumigations is beyond the scope of the review, the APVMA will continue to:
  - liaise with relevant parties to investigate whether flexible fumigation protocols are acceptable to AQIS
  - explore subsequent assessment by flexible treatment protocols for possible inclusion on methyl bromide labels.
- For economic and logistical reasons, recapture technology is not yet mature enough for mandatory implementation within the Australian fumigation industry. **Note that the Montreal Protocol does not expect adoption of technologies for methyl bromide reduction, if there are no available options or the cost of options is not economical.**
- However, for future consideration, the APVMA will continue to monitor developments in recapture technology, in the event that it becomes economically and logistically feasible. The APVMA will also monitor changes in methyl bromide TLV, as it may have implications for implementation of mandatory recapture.

[3] QPS -= Quarantine and Pre-Shipment. Under the Montreal Protocol, use of methyl bromide in developed countries was to be phased out by 1 January 2005, except for use for QPS and use as chemical feed-stock.

[4] CUE = Critical Use Exemption. These are specific, non-QPS exemptions granted by the Parties to the Montreal Protocol and are reviewed yearly e.g. soil fumigation for certified strawberry runner production.

Regulatory Decision

- The general fumigation part of methyl bromide labels has been amended to allow such fumigation for QPS and approved CUE situations **only**.
- The in-field plant-bed/turf soil fumigation and stored soil/compost/hay fumigation part of the methyl bromide labels have been amended to allow such use for QPS and approved CUE situations **only.**
- The in-field horticultural-crop soil fumigation uses part of methyl bromide labels has been amended to allow such use for QPS and approved CUE situations **only.**
- All labels must carry a comment that recapture is recommended, where feasible.
- The registrations of all 14[5] registered methyl bromide products (see Table 1 on pages 42 and 43) will be affirmed once labels have been varied as above and formally approved by the APVMA Board.
- Previous labels for all 14 methyl bromide products will be cancelled (see Table 2 on page 44).

[5] There were 16 registered methyl bromide products at the commencement of the review. Two products were voluntarily cancelled when the review findings were released in 2007, and so do no longer form part of the review.

EXECUTIVE SUMMARY

Introduction

Methyl bromide is a potent and toxic biocide with insecticidal, fungicidal and herbicidal properties, and is present in 16 Australian-registered products.

It belongs to the chemical group called the halogenated hydrocarbons. At room temperature and pressure, methyl bromide is a colourless gas that is heavier than air. Except at high concentrations, it is also an odourless gas. Methyl bromide is commercially available as a liquefied gas (under pressure) and is stored/transported in steel cylinders/cans. The formulations also may contain 2% chloropicrin [tear gas] or amyl acetate [banana oil, pear oil] as warning agents (i.e. they provide an odour).

Products containing methyl bromide have been registered in Australia since 1945. 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, and as an industrial feedstock ingredient (or pre-cursor) in the production of other chemicals.

Methyl bromide is the most potent ozone depleting substance still in use in Australia today. The Montreal Protocol recognises that the emission of certain substances (including methyl bromide) can significantly deplete or modify the ozone layer, in a manner that is likely to result in adverse effects on the environment. In accordance with the Montreal Protocol on Substances that Deplete the Ozone Layer (Montreal Protocol), the total phase-out of methyl bromide was to be completed by 1 January 2005. Methyl bromide used for QPS uses and industrial feedstock uses are currently exempt from phase-out under the Montreal Protocol.

In recognition that some industries are having difficulty in finding alternatives to methyl bromide, the Montreal Protocol permits some Critical Use Exemptions (CUEs) where no technical or economically feasible alternative exists.

To meet the requirements of the Montreal Protocol, legislation was enacted (the *Ozone Protection and Synthetic Greenhouse Gas Management Act 1989 and Regulations*) to ensure that methyl bromide imported into Australia is only used for CUEs, QPS purposes and industrial feedstock uses. The regulations are administered by the Department of the Environment and Water Resources (DEW), and enable DEW to track methyl bromide imported into Australia, to ensure that none is diverted into illegal uses.

Methyl bromide is being reconsidered because current labels contain uses that may pose an unacceptable risk to the environment. Many uses are also no longer permitted under the Montreal Protocol, and are currently controlled in Australia by prohibitions under the regulations administered by DEW (e.g. CUEs). As the potential for adverse environmental effects of methyl bromide are well understood, the APVMA is not intending to conduct a scientific review of available data.

This review has focussed on:

- the compliance of product registrations and label approvals with the requirements of the AgVet Codes taking into account contemporary scientific knowledge about the effects methyl bromide; and
- Australia's responsibilities under the Montreal Protocol.

A scope document for the methyl bromide review was released publicly in October 2005, and public submissions invited regarding any of the matters raised in it. Four submissions were received and all have been considered in the recommendations and comments included in this report.

A Preliminary Review findings (PRF) document for the methyl bromide review was released publicly in April 2006 and public submissions invited regarding any of the matters raised in Ten submissions were received and all ten were considered in formulating the comments and recommendations included in Final Review report.

Assessments

The scope of the review has focussed on the warnings and instructions on product labels, particularly with respect to known environmental concerns with methyl bromide, and Australia's obligations under the Montreal Protocol. This has involved consultation with the Department of Environment and Water Resources (DEW[6]), the Department of Agriculture, Fisheries and Forestry (DAFF) and the Australian Quarantine and Inspection Service (AQIS).

No technical assessments were required in the areas of toxicology, Occupational Health and Safety, or residues.

Level of methyl bromide usage in Australia

In the Montreal Protocol, the base-line year for methyl bromide usage, is 1991. In that year Australia consumed approximately 700 t of methyl bromide for non-QPS uses and approximately 200 t for QPS uses. The latter use varied between 200 t and 400 t during the 1990's, in line with droughts and export volumes.

In 2005, the first year of methyl bromide phase-out under the Montreal Protocol, Australia's consumption of methyl bromide was approximately 147 t for non-QPS usages (as CUEs), approximately 400 t for QPS use and approximately 5 t as a feedstock for chemical synthesis. For 2007, CUE use was 48.55 t.

There are no recent, reliable figures for the volume of methyl bromide used on individual QPS uses (e.g. export grain, imported flowers etc) or the split between export versus import uses. In 2000 though, it was estimated that 75% of QPS methyl bromide usage was for Australian exports and 25% for imports.

[6] Formerly the Department of the Environment and Heritage (DEH)

Public submissions on the Scope Document

Public submissions from AQIS, the Commonwealth Scientific and Industrial Research Organisation (CSIRO) Entomology Division, BOC Limited[7] and GrainCorp Operations Limited, provided comments as follows:

Quarantine/pre-shipment (QPS) uses

- Methyl bromide is very important for effective QPS treatments as it is toxic to a wide range of insects, has good penetration, and acts rapidly.
- A best-fumigation practice should be documented and adopted for methyl bromide use in QPS. An example of such a standard is the AQIS Methyl Bromide Standard.
- The advantages of such a standard include minimisation of the impact of methyl bromide on the environment and on OHS, maximising efficacy (100% insect mortality required in QPS situations) and minimisation or elimination of re-treatment.
- Technology should be adopted that recaptures the methyl bromide at the end of the treatment, and either destroys or recycles it.
- The product label should allow flexible dosages and times (called 'flexible CT products[8]'), as the critical factor in efficacy is 'concentration x time' for any one temperature, not merely concentration (dosage) alone.
- Flexible dosages allow reductions in total fumigation time, which is important in keeping pace with increasing pressure for efficacy and timeliness of QPS treatment facilities.

Critical Use Exemption (CUE) uses

- It should be a mandatory requirement for all fumigation treatments performed with methyl bromide under the CUE rule in Australia to:
  - carry out such treatments under:
    - ◊ virtually impermeable film (VIF) in the case of soil treatments
    - ◊ plastic sheets that meet the requirement of the AQIS fumigation standard for impermeability in the case of commodity treatments.
  - adopt and use methyl bromide recapture technology during the ventilation/de-gassing procedure.

Methyl bromide fumigation in general

- Recapture technology can significantly reduce OHS and environmental exposure. Tasmania already makes methyl bromide recapture mandatory for quarantine treatments. This technology is being developed in Australia, is readily available and becoming more cost competitive (as at December 2005, there were 9 systems currently in use in Australia and another 22 in process of manufacture/installation).

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[7] BOC is a company that supplies industrial gases

[8] Note that the word 'product' refers to the mathematical term 'multiply', not a chemical product.

- The Australian standard for fumigation (AS 2476-1981) should be updated. It has not been amended since 1981 and does not reflect current environmental, OHS and licensing concerns and issues.
- If the APVMA implements any significant label changes for methyl bromide products, then these should be communicated to the state/territory authorities responsible for relevant fumigation-competency training (e.g. the nationally endorsed course PRMPM-11B: Conduct Fumigation).

Public submissions on the Preliminary Review Findings

Public submissions on the PRF were received from S.A. Rural Agencies Pty Ltd, the Department of Conservation and Environment NSW, DEW, GrainCorp Operations Limited, Sun Rice (Ricegrowers Ltd), the Department of Primary Industries (Victoria), Nufarm Australia Ltd, the Commonwealth Scientific and Industrial Research Organisation's (CSIRO) Entomology Division and Nordiko Quarantine Systems Pty Ltd (two submissions). The major comments provided are as follows:

Quarantine/pre-shipment (QPS) uses

- Some submissions were concerned that flexible dosing regimes (i.e. variable Concentration [C] and Time [T] options [called 'flexible CT product']), using higher than label doses of methyl bromide (to reduce fumigation time), would run counter to Australia's international obligation to phase out ozone depleting substances.
- However, other submissions pointed out that flexible CT product using increased dosages with shorter treatment times, could reduce emissions if it were allowed in conjunction with recapture technology (currently the Montreal Protocol does not allow this).
- A number of submissions emphasised that flexible dosing regimes can give reductions in total methyl bromide used, as well as fumigation time.
    - However, users cannot reduce the label fumigation time as both the label and compulsory AQIS Standards mandate it, even when an acceptable CT product is achieved in a shorter time frame.
    - Flexible dosing would also allow more effective use of methyl bromide allocations as well as more flexibility in fumigation practices and the time fumigation takes. In particular, it would enable improved efficiency in exporting Australian grain.
    - Hence it was suggested that more thought should be given to this methodology before it is decided not to assess it within the review.
- It was also suggested that if non-QPS uses were to remain on the label, they should be linked to a reference to the regulations under the *Ozone Protection and Synthetic Greenhouse Gas Management Act 1989*. This would make it clear that the products are to be used for quarantine purposes **or** in line with regulations that grant non-QPS use on an exception basis.

Critical Use Exemption (CUE) uses

- If products with horticultural, soil-only fumigation uses on the label were cancelled, this could cause significant disruption, as there would then be no registered products for some approved CUEs. Hence it was suggested that registration of these products be continued and their labels amended to allow use for CUE- approved horticultural soil fumigation only.
- In contrast, one submission argued that due to the limited life of CUEs, their use of methyl bromide should not be reflected on the label, but licensing of use should be implemented by DEW.

Comments on methyl bromide fumigation in general

- Without a mandatory requirement for recapture, increased dosages under a flexible CT product protocol, would increase the risks of exposure and degradation of the ozone layer to an even higher level than currently exists.
- It should be encouraged, or mandatory, for all fumigations to be carried out under VIF, plastic sheets or in sealed enclosures (to prevent losses to the atmosphere during a fumigation) and for recapture equipment to be used. It was acknowledged that there are some technical barriers to use of VIF.
- The 'flexible dosage x time' concept was supported by several respondents. This manipulation of CT product would enable successful fumigations to be performed, because it takes into account different sorption properties of produce and packaging.
- Best-practice fumigation should be encouraged if not mandatory, including monitoring of gas levels to ensure an effective CT product is achieved at all locations within the fumigation chamber.
- Several respondents endorsed recapture and destruction of methyl bromide in order to reduce methyl bromide emissions to the atmosphere.
- A study on the spread of released fumigant at a workplace that was not recapturing the fumigant, showed that methyl bromide does not rapidly dissipate of its own accord to the upper atmosphere. It can spread and remain at lower levels in the workplace, particularly during cold and still weather. This has potential ramifications for worker and bystander OHS.
- Australian Customs experience has been that up to about 30% of containers opened were found to have gas levels exceeding the OHS Threshold Limit Value (TLV). Forced fan recapture was seen as important in reducing exposure to unpacking staff.
- Australian experience is that the cost of recapture has added of the order of 25% to 50% to the cost of fumigations.

Amendment (variation) of labels and product registrations

The key recommendations of the PRF were supported by a number of submissions viz. all general fumigation uses on labels be allowed for QPS uses only, deletion of all soil fumigation uses from all labels (causing cancellation of some products), cancellation of all prior label approvals and inclusion of a recommendation that recapture technology be used.

Some submissions also recommended that the key recommendations be implemented as soon as possible.

However, as noted above, one submission did point out that if products with horticultural-crop[9] soil fumigation only on their label were cancelled, this could cause significant disruption, as there would be no registered products for some approved CUEs (see above).

Meeting with stakeholders *re* recapture of methyl bromide

The APVMA convened a meeting between major industry and State/Federal agency stakeholders in September 2006 to explore the applicability of recapture of methyl bromide in the Australian situation.

Mechanics of recapture

The alternative systems available, the most successful system to date and the mechanics of recapture were discussed. The detail on these subjects is in the body of the report.

Note that these systems are used for two distinct but related purposes:

- gas recapture immediately after fumigation (termed "the available gas", with a concentration between 5,000 and 15,000 ppm in the fumigation vehicle [e.g. a shipping container])
- de-gassing of residual gas that remains after insufficient ventilation or from desorption (gas concentration at a comparatively low level [e.g. 20 to 50 ppm]).

The aim in both cases is to reduce gas level below 5 ppm (the OHS Threshold Limit Value [TLV]).

The Australian Nordiko systems can be used for fumigations under a sheet, or in fumigation tents or containers. Field experience shows these recapture systems are both effective and portable in that environment.

Currently no work has been done on recapture of methyl bromide from fumigated silos or ships' holds. These present a particular challenge, given the huge volume of gas that must be

[9] These products are a mixture with chloropicrin (for better fungal control) and contain 300, 500 or 700 g/kg of methyl bromide only [the rest of the product is chloropicrin]. Currently the only CUE to use these products is strawberry runner production.

These products are distinctly different to methyl bromide products used for other soil-related fumigation (e.g. turf, stored soil/compost/hay), which contain 980–1000 g/kg methyl bromide. The other two current Australian CUEs (flower production under cover and rice disinfestation) use the latter products.

The two product types are not necessarily interchangeable

recaptured i.e. some hundreds of kilograms. The rule of thumb is that 10 g of charcoal are required to absorb 1 g of methyl bromide, so at this stage some tonnes of charcoal would be required.

Issues surrounding adoption of recapture in Australia

Concentrating on sheet, tent and container fumigation, the methyl bromide fumigation companies support the concept of recapture, provided that:

- it is mandatory so there is a level playing field for fumigators
- there is sufficient time to prepare for adoption of the technology, including accumulation of field experience that takes into account the difference between Tasmanian and mainland fumigation logistics (see below).

The main differences between Tasmanian and mainland fumigation situations are:

- The large volume of shipping containers that must be handled, and cleared, in limited space (on the mainland there are more than ten times the number in Tasmania) and often within extremely short time periods (just-in-time systems are common).
- The large distance between container depots on the mainland (some hundreds of kilometres in many cases, which means the fumigator must transport all equipment to the depots, or have multiple recapture-units/filters at each depot).

Hence the logistical operation and costs of sufficient recapture systems to handle peaks (in particular), transportation of recapture systems between depots (or multiple stores of recapture systems at key locations) and the replacement of recapture filters, all need to be clarified at a practical level.

Specific costs of recapture

The APVMA noted that some fumigators had calculated that the lease and filter costs for recapture systems for them, plus extra work hours to mount, monitor and operate recapture systems, could be in the order of $500,000 to $750,000 pa (as at September 2006),

This cost could be markedly reduced, with a higher uptake rate and mass production of units, but was still considered very significant. There was a very real concern that increased costs of fumigation (with recapture) could drive fumigation offshore to cheaper countries (with concomitant concerns then of validating effectiveness of the fumigations).

Note that the Montreal Protocol does not expect adoption of technologies for methyl bromide reduction, if there are no available options or the cost of options is not economical. This is the philosophy underpinning provision of CUEs.

Conclusions of the recapture meeting

- The meeting concluded:
- it was good practice to recommend recapture wherever possible
- whilst the technology was not yet mature enough for universal adoption, it would be useful to work towards recapture, to further protect human health and the environment.

Developments since the September 2006 meeting

- The APVMA is monitoring new developments in this area. Belgium and Rotterdam are moving to mandatory recapture of 80% of the available gas, from ~1/7/07. Note that these two European fumigation situations are very concentrated and central, compared to Australia's more widely dispersed and distributed fumigation situations.
  - Nordiko R & D in Belgium has generated lower cost options and Nordiko R & D in Australia has also trebled the volume of successful, large-volume fumigation-tent recapture to 500 m^3 (cf. a 40-foot shipping container has a volume of 76 m^3).

Public Consultation: major recommendations and discussion

The reconsideration (review) provisions within the Agvet Codes require the APVMA to assess current registration and approval conditions.

Continued registration of products that are for horticultural-crop soil fumigation only

As noted above, a submission did point out that if products with horticultural-crop[10] soil-fumigation on their labels were cancelled, as proposed in the PRF, this would cause significant disruption.

There would then be no registered products for some approved CUEs.

The APVMA has assessed this proposal, and agreed that continued registration (albeit very restricted), together with controls imposed by the Montreal Protocol and DEW, poses no greater risk than APVMA permits, and is more practical.

Hence this has been included as a recommendation to the Board: viz. registration of these products be continued and their labels amended to allow use for CUE- approved horticultural soil fumigation only.

This would keep such products registered, limit their use to CUE approved horticultural-crop soil fumigation, and effectively proscribe unauthorised use.

Fumigation using flexible dosage x time (Flexible CT product)

There were valuable suggestions from AQIS, CSIRO Entomology and GrainCorp Operations Limited, to amend the labels to allow flexible dosage/time x temperature, for different situations (including lower doses and reduced times, as well as potentially higher doses for much reduced treatment time).

This review examined the environmental risk from methyl bromide and whether approved uses on current labels are consistent with the Montreal Protocol. The APVMA has concluded that the environmental risk from methyl bromide is acceptable with current label rates, if use is restricted to QPS and approved CUE uses, as per the Montreal Protocol. In this sense

[10] See footnote 9 above.

flexible CT product is beyond the scope of the review. As well, it would significantly delay the review's conclusion (namely, the implementation of necessary label amendments).

Nonetheless, it is a valuable suggestion. Hence a project has been commenced for APVMA Registration to liaise with AQIS and CSIRO Entomology, in order to explore lower-dose, flexible CT product protocols, and possible AQIS and APVMA approval of them.

Recapture of methyl bromide

Recapture was recommended by some respondents, and a few suggested it be made mandatory. However, it was clear from the stakeholder meeting in September 2006 (see above), that there are serious economic and logistical issues to resolve before this could be considered.

- Therefore the APVMA proposes to keeps a watching brief on recapture technology developments and their implications for Australian adoption.

Review Findings

Of the 16[11] registered methyl bromide products:

- one product is used for general fumigation only (a 1,000 g/kg product)
- nine are used for both general fumigation and in-field plant-bed/turf soil fumigation and stored soil/compost/hay fumigation (all ~ 1,000 g/kg products)
- one is used for in-field plant-bed/turf soil fumigation and stored soil/compost/hay fumigation only (a 700 g/kg product formulated with 300 g/kg chloropicrin)
- five are used for in-field horticultural-crop soil fumigation only [e.g. for strawberry production]. These contain 300 g/kg, 500 g/kg or 700 g/kg of methyl bromide; the rest of the formulation is chloropicrin.

As briefly noted above, soil fumigation uses can be in-field for horticultural-crops (e.g. beds for strawberry runner production) or for plant-beds/turf (e.g. flower production under cover). It also refers to fumigation of stock-piled soil, compost or straw/hay (e.g. in a nursery). These uses are now permitted under CUEs only, or for QPS situations (e.g. import of soil or export of hay).

General fumigation uses can be both QPS uses (e.g. fumigation of imported wood and of exported grain) and non-QPS uses. Examples of non-QPS uses are fumigation of domestic buildings for rodents and post-harvest fumigation of rice (note that the latter use is covered by a CUE in Australia).

Under the terms of the Montreal Protocol, QPS uses are currently exempt from phase-out. DEW has indicated, and the APVMA accepts, that methyl bromide may continue to be used for QPS uses because:

[11] At the time of the release of the review findings, there were 16 registered methyl bromide products. Since then, two products have been voluntarily cancelled. This leaves 14 products subject to the regulatory decisions of the review.

- there is a significantly lower consumption of methyl bromide for QPS uses (compared to non-QPS uses)
- international treaties mandate methyl bromide treatment of trade products (for phyto-sanitary reasons)
- the environmental risk of exotic pests, weeds, diseases etc. from not using methyl bromide in QPS situations is considered to be greater than the environmental risk (ozone-depletion) from QPS uses of methyl bromide.

The APVMA has had regard to the preamble of the Montreal Protocol and contemporary scientific knowledge about the effects methyl bromide.

Note that there are two changes to the PRF findings:

- In the PRF it was proposed that methyl bromide products with only horticultural-crop soil-fumigation uses be cancelled. As discussed above, it is now proposed to vary their labels to cover use with approved CUEs in general (tightly linked to DEW regulations and their public list of approved CUE users [see Attachment 10]).
    - Since the release of the PRF, it has also been established that there are occasions (albeit rare) where these products could be used for quarantine use (e.g. field fumigation against an exotic weed). Hence it is now proposed also that the varied labels for these products include use for QPS situations.
- It was also proposed in the PRF that product labels with other soil-related fumigation uses (e.g. for turf, stored soil/compost/hay etc) should have these uses deleted from the label. It has been since been established that these uses can also be applied to QPS situations (e.g. fumigation of export hay or imported soil, or field fumigation where exotic weeds have established).
    - This other type of soil fumigation also relates to some CUEs. Originally it was planned to authorise these via APVMA off label permits, once such uses were deleted. It is a better solution to place them on the label, particularly as these uses would remain for QPS use.

The review proposes to find that the APVMA is not satisfied that continued use or the product in accordance with existing label instructions would not be likely to have unintended effect that is harmful to the environment, specifically damage to the ozone layer.

However, the APVMA is satisfied that the labels of all methyl bromide products can be varied in such a way that continued use of the products, in accordance with the varied labels, would not be likely to have an unintended effect that is harmful to the environment.

The labels can be varied to restrict all uses to QPS and approved CUEs in general, on the relevant labels. As mentioned above, the APVMA has assessed that inclusion of CUEs on the labels, together with controls imposed by the Montreal Protocol and DEW, poses no greater risk than APVMA permits, and is more practical.

DEW has advised that the QPS and CUE-related label instructions are acceptable to them.

Recapture

In response to submissions from the public consultation processes, the APVMA convened a meeting between major industry and State/Federal agency stakeholders in September 2006, to explore the applicability of recapture of methyl bromide in the Australian situation.

The conclusions from this meeting, and subsequent developments, were included in the Final Review Report and its recommendations to the APVMA Board.

The APVMA proposes to keep a watching brief on developments in recapture technology and liaise with the peak fumigators group, regarding developments in the economics and logistics of its possible implementation.

Allied to this, the APVMA proposes to monitor any changes in Australian TLV for methyl bromide, and any implications this may have on mandatory degassing and/or recapture immediately after fumigation.

Low dose flexible CT product

Also in response to submissions from the public consultation processes, the APVMA explored the feasibility of placing "flexible CT product" protocols onto methyl bromide labels, for the use of methyl bromide in general fumigation (especially of export grains).

The APVMA found this was outside the scope of the review, but intends to continue its project with CSIRO and AQIS. This project is to determine if low dose flexible CT is feasible and acceptable to AQIS, and whether there is sufficient data (etc) for assessment of these protocols onto methyl bromide labels.

Review Outcomes and Regulatory Decisions

Product registration and label approvals

Based on the review assessment and the comments above, the review found that use of methyl bromide products in accordance with current label instructions may have an unintended effect that is harmful to the environment.

However, the review also found that the APVMA was satisfied that that the labels of all 16 methyl bromide products could be varied in such a way that continued use of the products, in accordance with the varied labels, would not be likely to have an unintended effect that is harmful to the environment.

The review found that this could be achieved if labels were varied to restrict all uses to only QPS uses and approved CUE situations, providing the user also has a CUE allowing that use in the year of fumigation.

The APVMA Board accepted all these recommendations and the following actions have been be taken:

Recommended actions	Comments
1.Vary product labels	• **Product label with general fumigation uses only:** label has been varied to allow uses only for QPS uses (e.g. fumigation of imported timber, fumigation of export grain) and approved CUE situations, providing the user also has a CUE allowing that use in the year of fumigation (e.g. disinfestation of domestic rice [a current CUE]). The one product affected is listed in Table 1 (page 42/43). • **Product labels that have both general fumigation and in-field, plant-bed/turf soil fumigation and stored soil/compost/hay fumigation uses:** the general fumigation part of the label has been varied to allow uses only for QPS and approved-CUE situations [as for dot point above]. The in-field, plant-bed/turf soil fumigation and stored soil/compost/hay fumigation part of the label have been varied, to allow such use only for approved QPS uses (e.g. fumigation of export hay or imported soil) and approved CUE situations, providing the user also has a CUE allowing that use in the year of fumigation (e.g. soil fumigation of protected, cut-flower cropping areas, a current CUE). The nine products affected are listed in Table 1 (page 42/43). • **Product label that has only in-field, plant-bed/turf soil fumigation and stored soil/compost/hay fumigation use:** label has been varied to allow such uses only for QPS situations (e.g. fumigation of export hay) and approved CUE situations, provided the user also has a CUE allowing that use in the year of fumigation. The one product affected is listed in Table 1 (page 42/43). • **Product labels that only have only in-field, horticultural-crop soil fumigation use:** labels have been varied to allow in-field soil fumigation only for QPS uses (e.g. field fumigation to eradicate exotic weeds) and approved CUE situations, provided the user also has a CUE allowing that use in the year of fumigation (e.g. for strawberry runner production, a current CUE). The five products affected are listed in Table 1 (page 42/43). • All labels carry a comment that recapture is recommended wherever feasible.
2. Affirm Registrations	• With these label variations, the registrations of the 14 methyl bromide products[12] (above) can be affirmed.
3. Cancel Labels	• Any previous labels of the products, as presented in Table 2 (page 44) have been cancelled.

Labels excerpts that represent the result of all these variations above are presented in Attachments 5, 6 and 7.

[12] At the time of the release of the review findings, there were 16 registered methyl bromide products. Since then, two products have been voluntarily cancelled. This leaves 14 products subject to the regulatory decisions of the review.

Low dose flexible CT product

The APVMA intends to continue its project with CSIRO and AQIS to see if low dose flexible CT is feasible and acceptable to AQIS.

The APVMA also proposes to liaise with a registrant willing to submit an application for flexible CT products to be assessed for approval onto the methyl bromide label.

Recapture

The APVMA proposes to keep a watching brief on developments in recapture technology and liaise with the peak fumigators group, regarding developments in the economics and logistics of its possible implementation.

Allied to this, the APVMA proposes to monitor any changes in Australian TLV for methyl bromide, and any implications this may have on mandatory degassing and/or recapture immediately after fumigation.

1 INTRODUCTION

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

- the approval of an active constituent for a proposed or existing chemical product
- the registration of a chemical product
- the approval of a label for containers for a chemical product.

The APVMA has reviewed registered products containing methyl bromide and the associated label approvals. This review is based on environmental concerns and adequacy of labels with respect to the Agvet Code taking into account contemporary scientific knowledge about the effects of methyl bromide and Australia's obligations under the Montreal Protocol.

The purpose of this document is to provide a summary of the proposed regulatory decisions, resulting from this review of methyl bromide.

1.1 Background information on methyl bromide

Methyl bromide belongs to the chemical group called the halogenated hydrocarbons and is quite toxic to humans. Common synonyms for methyl bromide are CH_3Br, bromomethane, monobromomethane and MBX. The Chemical Abstract System (CAS) number for methyl bromide is 74-83-9.

The boiling point of methyl bromide is ca. 3.5 °C. Consequently, at room temperature and pressure, it is a gas. This gas is odourless (except at high concentrations), colourless and heavier than air.

It is commercially available as a liquefied gas and is stored/transported in steel cylinders/cans. The product formulations also may contain 2% chloropicrin [tear gas] or amyl acetate [banana oil, pear oil] as warning agents (i.e. they provide an odour).

Methyl bromide is a potent biocide with insecticidal, fungicidal and herbicidal properties. Products containing methyl bromide have been registered in Australia since 1945. In Australia, methyl bromide is used as:

- a soil fumigant in horticultural industries
- a pest control treatment on dry commodities such as stored grain or dried fruit
- QPS treatments for
  - imports
  - exports
  - certain commodities transported interstate.
- an industrial feedstock (an intermediate substance that is used to make other chemicals).

1.2 Regulatory status of methyl bromide in Australia

1.2.1 Registered products

At the commencement of the review (September 2005), 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 are also subject to the outcomes of this review. However, as at 23 April 2007, there were no new registered products containing methyl bromide. Hence Attachment 1 also reflects the current status (April 2007) for registered products. There were also no methyl bromide products awaiting registration as at 23 April 2007.

Products for which registration has not been renewed (stopped[13] products) have been listed in Attachment 2. Legally, these products are not directly subject to the outcomes of this review. However, they will face the same assessment and outcomes through the registration process (rather than the review process), once the review outcomes are published.

1.2.2 Product formulation

All methyl bromide products used in Australia are formulated as liquefied gases (under pressure). The concentration of methyl bromide in these registered products varies from 300 g/kg to 1,000 g/kg. The products are available in a range of pack sizes (12 kg, 35 kg, 50 kg, 100 kg).

A number of methyl bromide products also include chloropicrin, at concentrations between 20 g/L (2%) and 700 g/L (70%). The 2% products include chloropicrin in the formulation as a warning agent. The methyl bromide products with 300 g/L, 500 g/L and 700 g/L of chloropicrin, include it in the formulation to enhance the effect of the methyl bromide. Such mixtures are preferred by some users, as US research has shown that there is a synergistic effect between these two compounds. It appears that chloropicrin offers superior control of fungal pests, whereas methyl bromide is a better broad spectrum fumigant with efficacy against a wide range of pathogens, including weeds and nematodes.

1.2.3 Use patterns

Methyl bromide is a colourless and odourless gas at normal temperatures and pressures. However, the liquefied gas can be handled as a liquid under moderate pressure.

It 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. In Australia, its primary uses are for soil fumigation, post harvest protection and quarantine treatments.

[13] Stopped products can no longer be manufactured, but existing product can be sold at retail outlets. Such purchased product and product already on farms (etc) can be used (as per the label) for a further period as determined by the APVMA. The period in this case ends on 30/6/2007.

More specifically, product labels currently permit the use of methyl bromide (with or without chloropicrin) for one or more of the following:

- Flowers, bulbs, nursery and horticultural crops for the control of *Fusarium* and *Verticillium* wilts, *Sclerotinia*, *Rhizoctonia*, *Pythium*, nematodes, weeds, weed seeds, insects and rodents.
- Plant beds, turf, local areas, well-rotted compost, manure and topsoil, mulching straw or hay for the control of nematodes, insects, weed seeds, nutgrass (double dosage) and rodents[14].
- Plant beds, turf and other local areas, decomposed compost and manure for the 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 for the control of 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 for the 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 phyto-sanitary (pest-free) requirements of importing countries.
- 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.
- Industrial feedstock: methyl bromide is used as an ingredient in the production of high value chemicals, including pharmaceuticals. Feedstock uses break down the methyl bromide during the production of the final chemical product.

Note that some of the pre-export and quarantine uses are not on the labels of any methyl bromide products, and so are made available via APVMA off-label permits. Permits are not included in the review, as the legislation relating to reconsiderations of Agvet chemical products does not include them.

The use patterns that appear on methyl bromide labels are summarised in tabular form, in Attachment 3 (Soil Fumigation) and Attachment 4 (General Fumigation).

It is important to emphasise that the use of methyl bromide in Australia is already tightly regulated under DEW regulations. Therefore many uses present on product labels in their current form are already prohibited under DEW regulations (see Background information: the Montreal Protocol below).

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

[14] Only one product claims rodent control in this situation.

bromide is injected, the soil is covered with plastic tarpaulins, 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 (the base year for national consumption, within the Montreal Protocol).

It provides a broad spectrum of control under a wide range of soil and climatic conditions. Pre-plant soil fumigation accounts for approximately 70% of world use of methyl bromide.

When used as a commodity treatment, methyl bromide gas is injected into a chamber, or under a tarpaulin 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 only be treated with methyl bromide as part of a quarantine or phyto-sanitary requirement of an importing country; these uses are currently exempt from the phase-out imposed by the Montreal Protocol.

Lastly, there is also structural pest control treatment with methyl bromide gas. This involves the fumigation of buildings and other structures for stored product insect pests and rodents.

1.2.4 Previous regulatory action

There has been no previous regulatory action on methyl bromide by the APVMA, since its use in Australia has been tightly regulated under DEW regulations since 1996. 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.

1.3 Reasons for methyl bromide review

1.3.1 Background information: the Montreal Protocol

Methyl bromide is the most potent ozone depleting substance still in widespread use in Australia today. In order to minimise further damage to the ozone layer, The *Montreal Protocol on Substances that Deplete the Ozone Layer* (Montreal Protocol), was adopted by 25 countries in September 1987.

It came into force on 1 January 1989, when it was ratified by 29 countries and the EEC. Australia signed the Montreal Protocol on 8 June 1988. It requires that reduction steps be taken to reduce the use of ozone depleting substances such as methyl bromide. Since 1987, over 180 countries have signed the Montreal Protocol, which sets out a mandatory timetable for the phase out of such compounds.

The preamble to the Montreal Protocol recognizes that:

- world-wide emissions of methyl bromide 'can significantly deplete and otherwise modify the ozone layer in a manner that is likely to result in adverse effects on human health and the environment'
- methyl bromide emissions have 'potential climatic effects'
- 'measures taken to protect the ozone layer from depletion should be based on relevant scientific knowledge, taking into account technical and economic considerations'
- countries should 'protect the ozone layer by taking precautionary measures to control equitably total global emissions of substances that deplete it, with the ultimate objective of their elimination on the basis of developments in scientific knowledge, taking into account technical and economic considerations and bearing in mind the developmental needs of developing countries'
- it has to consider 'the importance of promoting international co-operation in the research, development and transfer of alternative technologies relating to the control and reduction of emissions of substances that deplete the ozone layer, bearing in mind in particular the needs of developing countries'.

DEW is the Australian Government agency responsible for co-ordinating national ozone protection measures. DEW is also responsible for administering the Ozone Protection and Synthetic Greenhouse Gas Management Act 1989 and its associated regulations.

Consequently DEW manages the importation and use of methyl bromide. This is achieved via supply chain restrictions that include import permits/quotas, record keeping and reporting requirements and DEW undertakes enforcement action when breaches occur.

The APVMA regulates methyl bromide uses in agriculture and related industries (including structural treatments for pests), by registering products and approving uses, under the Agvet Codes. Registration or approval is done after risk-assessments (including risk-management) in the areas of chemistry/manufacture, toxicology, OH&S, residues, trade, efficacy, crop-safety and environment, providing the risk in these areas is acceptable. Following APVMA registration and approval of uses, each State and Territory polices methyl bromide use via their individual Control of Use legislation. Hence the States/Territories have their own requirements on who may handle methyl bromide and conduct fumigations.

In 1995, imports of methyl bromide for soil fumigation uses were frozen at 1991 levels and at the Montreal Protocol meeting in September 1997, the following phase-out timetable was agreed to for developed[15] countries:

Target	Year
25% reduction from 1991 levels	1999
50% reduction from 1991 levels	2001

[15] There are approximately 34 developed countries, which include Australia. There is a separate phase-out timetable for developing countries viz. a freeze in 2002 at average 1995–1998 levels, with a 20% reduction by 2005 and phase-out by 2015.

70% reduction from 1991 levels	2003
Total phase out[16]	1/1/2005

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

1.3.2 Critical Use Exemptions (CUEs)

In recognition that some industries are having difficulty in finding methyl bromide alternatives the Montreal Protocol allows some critical uses of methyl bromide where no technical or economically feasible alternative exists. In 1997 a formal decision was made to allow limited CUEs 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
- 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 were for:

- Strawberries Australia Inc. for use in strawberry production
- strawberry runner growers for use in strawberry-runner production
- Queensland Flower Growers Association: for use in cut-flower production, for open and protected cropping (Queensland only)
- Flowers Victoria: for use in cut flower production in protected cropping only
- for use by specific businesses producing almonds
- Rice Growers Cooperative Ltd for post-harvest disinfestation of rice.

The use on strawberry production was the largest amount of methyl bromide approved for 2005 (67 tonnes).

[16] Except for Critical Use Exemptions (CUEs), Quarantine/Pre-shipment (QPS) uses and industrial feedstock uses [see next section].

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

The 2007 and 2008 CUEs have been further reduced to just three: strawberry runner production, cut flowers in Victoria only and post-harvest disinfestation of rice.

1.3.3 Quarantine and pre-shipment (QPS) uses

QPS uses of methyl bromide are currently exempt from the phase out plan. The *Ozone Protection and Synthetic Greenhouse Gas Management Regulations 1995* set out what are QPS uses.

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

- official control is that performed by, or authorised by, a national plant, animal or environmental protection or health authority
- 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 currently exempt from phase out under the Montreal Protocol, it is expected that international pressure to reduce reliance on methyl bromide will move towards the eventual, total phase-out of methyl bromide in the future.

1.3.4 Label Amendments

Methyl bromide product labels in their current form contain uses that are not consistent with the Montreal Protocol. These uses are currently controlled by prohibitions under legislation administered by DEW. 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 has focussed on Australia's responsibilities under the Montreal Protocol, and the compliance of product registrations and label approvals with the Montreal Protocol requirements.

1.4 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

- the way in which it is approved for use in Australia.

On the basis of the concerns outlined above (see under Reasons for Review above), 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.

Therefore the APVMA review has focussed on the warnings and instructions on product labels, particularly in respect of known environmental concerns with methyl bromide, and Australia's obligations under the Montreal Protocol. This has involved consultation with DEW, DAFF and AQIS.

1.5 Regulatory Options

The basis for a reconsideration of the registration and approvals for a chemical, is whether the APVMA is satisfied that the requirements prescribed by the Agvet Codes for continued registration and approval are being met.

In the case of methyl bromide, these requirements are that the use of the product as per its instructions for use, would not be likely to have an unintended effect that is harmful to the environment. This reconsideration has been influenced by the terms of the Montreal Protocol.

There can be three possible outcomes of the reconsideration of the registration of products containing methyl bromide and their labels. Based on the information reviewed, the APVMA may be:

- satisfied that the products and their labels continue to meet the prescribed requirements for registration and approval and therefore confirms the registrations and approvals
- satisfied that the conditions to which the registration or approval is currently subject can be varied in such a way that the requirements for continued registration and approval will be complied with and therefore varies the conditions of registration or approval (which can include a label variation)
- not satisfied that the requirements for continued registration and approval continue to be met and suspends or cancels the registration and/or approval.

The specific proposed action/s from this review are covered in Section 5 and below.

2 ENVIRONMENTAL ISSUES

The environmental impacts of methyl bromide have been studied and are well known. Methyl bromide has been classified as a powerful ozone-depleting substance. The bromines it contains are fifty times more destructive to ozone than chlorine (e.g. 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 enviroment (global warming), and will have downstream impacts on agriculture.

As mentioned above, the potential for the adverse environmental effects of methyl bromide are well understood, and the APVMA has not conducted a new scientific review of available data. The review has focussed on whether continued use of methyl bromide products in accordance with existing label instructions would not be likely to have an unintended effect that is harmful to the environment.

3 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.

3.1 Methyl bromide usage pre 2005 and post 2005

3.1.1 Global use in the developed countries

For example, in 1991 the 34 developed (industrialised) countries within the Montreal Protocol used ca. 56,000 t of methyl bromide (some 80% of it in the USA, the EU and Japan)[17]. By 2001 this had been reduced to ca. 23,500 t and by 2003 to ca. 14,800 t.

In 2005 (the first year for CUEs), there were ca. 16,000 t of CUEs allocated to 16 developed countries (including Australia). For most of these 16 countries, their CUE total for 2005 was in the range of 12% (France, Japan) to 38% (US) of their 1991 usage, with a median value of 25% [Australia 21%].

In 2006, developed country CUE tonnage was set at ca.11,000 t (Australia at 9.4 % of 1991, and the US at 32%).

From 2006 onwards, further reductions in methyl bromide consumption for CUEs are expected, as industries continue to adopt alternatives to the remaining uses of methyl bromide. Preliminary figures for world-wide CUEs in 2007 are ca. 7,500 t (Australia at 6% of 1991 and the US at 27%), though extra uses/tonnage may be granted by the end of 2006.

3.2 Australian use

In the Montreal Protocol, the base-line year for methyl bromide usage is 1991. In that year Australia consumed approximately 700 t of methyl bromide for non-QPS uses and approximately 200 t for QPS uses. The latter use varied between 200 t and 400 t during the 1990s, in line with droughts, export volumes of treated products [etc].

In 2005, the first year of methyl bromide phase-out under the Montreal Protocol, Australia's consumption of methyl bromide was approximately 147 t for non-QPS usages (as CUEs), approximately 400 t for QPS use and approximately 5 t for feedstock. For 2007, CUE use was 48.5 t.

There are no recent, reliable figures for the volume of methyl bromide used on individual QPS uses (e.g. export grain, imported flowers etc) or the split between export versus import uses. In 2000 though, it was estimated that 75% of QPS methyl bromide usage was for Australian exports and 25% for imports.

[17] For developing countries, their peak use (in 1998) was approximately 18,000 t. By 2002/3 this reduced to around 12,000 t, which means their 20% reduction by 2005 had already been achieved.

3.3 Critical uses permitted for 2005–2007

CUEs vary between countries, depending on the sectors that use methyl bromide.

They also vary in tonnage allowed per year, based on the ease of substitution of methyl bromide for the particular sector. However, in general most CUE tonnage is used on field crops.

For example, the USA has some 15 crops or uses that attract CUE status, including:

- field crops (e.g. tomatoes, strawberries, peppers, cucurbits, eggplant) [~ 80% of US CUE tonnage]
- orchard replants [~ 6%]
- mills and processors [~ 6%]
- post-harvest uses [~ 4%]
- nursery stock (including and forestry nurseries) [~ 2%]
- ornamentals [~ 2%]
- turf-grass/strawberry-runners [~ 1%].

Most CUE countries[18] have similar CUEs to the USA and a similar percentage allocation of their CUE tonnage. That is, the majority is used on field crops. In general, since CUEs commenced in 2005, either the number of CUEs have decreased per country per year, and/or the tonnage per CUE decreased, in line with the overall reduction in total CUE tonnage.

Developments in Australia reflect this international pattern, with:

- six CUEs in 2005 (using 147 t: 21% of Australia's 1991 non-QPS methyl bromide usage)
- four CUEs in 2006 (65.85 t: 9.4%)
- three CUEs in 2007 (48.55 t: 6.9%)
- three proposed CUEs for 2008 (at least 46.65 t [6.7%], with a further 1.8 t yet to be approved).

[18] For example, the US, Canada, France, Germany, Spain, Italy, the UK, Belgium, Holland, Greece, Poland, Belgium, Switzerland, Japan, Israel, Australia and NZ.

4 SUMMARY OF PUBLIC SUBMISSIONS

4.1 Public submissions to the Scope Document

Four public submissions were received in response to the Scope document.

The first submission (AQIS) acknowledged the impact of methyl bromide as an ozone-depleting substance, but also emphasised the importance of methyl bromide to QPS. The reason for this is that methyl bromide is toxic to a wide range of insects; it has good penetration and acts rapidly. It also suggested adoption of best fumigation practice in QPS, as exemplified by the AQIS Methyl Bromide Standard. This is necessary not just for prevention of gas leaks to minimise the impact of methyl bromide on the environment, but also for minimisation of OHS risks.

It is also necessary to ensure maximum efficacy, as 100% insect mortality is required in QPS situations. The AQIS Standard is a suitable standard and includes practices that ensure gas-tight enclosures, use of VIM (vapour impermeable membrane), use of vaporisers, optimal exposure times, uniform distribution of gas such that the minimum concentration for efficacy occurs at all points and concentration at the end of the treatment is above the minimum effective concentration ('effective end-point concentration').

The other advantage of 100% control from one treatment is that subsequent re-treatments are not necessary, which reduces methyl bromide usage and environmental release.

As well, to minimise further the effect of methyl bromide on the environment, the submission argued that technology should be adopted that recaptures the methyl bromide at the end of the treatment, and either destroys or recycles it.

The point was also made that such practices should be adopted for all methyl bromide uses, not just QPS uses. In this regard, any practice standard should also include protection of users.

Further, it was recommended that the Australian standard for fumigation (AS 2476-1981) be updated. It has not been amended since 1981 and does not reflect current environmental, OHS and licensing concerns and issues. Lastly, should the APVMA implement any significant label changes for methyl bromide products, then these should be communicated to the state/territory authorities responsible for relevant, fumigation-competency training (e.g. the nationally-endorsed course PRMPM-11B : Conduct Fumigation).

The second submission (CSIRO Entomology) made similar points to the first submission about QPS uses of methyl bromide (see above). Flexibility in the label, to allow different concentrations by time, for specific temperatures and insects was emphasised.

It was also recommended that the label include the following requirements for QPS uses:

- ventilation of the treatment volume should ensure that remaining concentration of methyl bromide in the enclosure meet OHS requirements for safe entry; and
- ensuring that any methyl bromide sorbed into the fumigated product has desorbed (degassed) sufficiently to meet OHS requirements for safe handling.

CUEs were dealt with separately. It was recommended that it be a mandatory requirement for all fumigation treatments performed with methyl bromide, under the CUE rule in Australia, to:

- carry out such treatments under
  - virtually impermeable film (VIF) in the case of soil treatments
  - plastic sheets that meet the requirement of the AQIS fumigation standard for impermeability, in the case of commodity treatments.
- adopt and use methyl bromide recapture technology during the ventilation/de-gassing procedure.

With respect to fumigation practice in general, the same points made by the first submission were presented regarding the updating the Australian Standard for fumigation, and communicating label changes to trainers and fumigators.

Hence the second submission recommended that on the basis of extensive past research in fumigants, the methyl bromide label should reflect the following:

- appropriate containment technologies to ensure that insecticidal levels of methyl bromide can be maintained for an adequate exposure period (including monitoring of methyl bromide concentrations during treatment)
- flexible dosages, as the critical factor is 'time x concentration' for any one temperature, not merely concentration alone
- recapture technology should be employed wherever possible to minimise the release of methyl bromide to the atmosphere.

The third submission (BOC) to the Scope document had no issue with modification to methyl bromide labels, to comply with the Montreal Protocol. It also outlined the new fumigants under assessment and the ethyl-formate product registered in March 2005, all of which are alternatives to methyl bromide.

As well, it emphasised the development of recapture technology, and supports it from both OHS and environmental grounds. The submission also noted that the Montreal Protocol parties ratified formal encouragement of such developments for quarantine and CUE uses. It pointed out that Tasmania has regulated the requirement that methyl bromide must be recaptured when used for quarantine purposes. Lastly, that this technology, which is being developed in Australia, is readily available and becoming more cost-competitive. One company (Nordiko) has 9 recapture systems in operation around Australia and another 22 ordered and in the process of manufacture and installation.

The fourth submission (GrainCorp Operations Ltd) made comments similar to those of AQIS and CSIRO Entomology (above).

This submission pointed out that whilst fumigation of grain is an approved use under QPS exemptions of the Montreal Protocol, the Directions for Use (DFU) on the labels do not allow for best fumigation practice.

Best fumigation practice is flexible, allowing management of an appropriate concentration (C) by time (T), to achieve the best CT product for all life stages of stored-product insect pests.

Significant research has been done in this regards by CSIRO Entomology. A critical outcome has been manipulation of dosage/exposure (CT), to achieve a CT product appropriate for the temperature of the commodity being fumigated, whilst still achieving complete control of stored-product insect pests of that commodity.

One other outcome of CSIRO's research is a reduction of total fumigation time. This is essential at pre-shipment fumigation facilities, so they can keep pace with increasing pressure for efficiency and timeliness.

In summary, GrainCorp recommends the following changes to existing methyl bromide labels which include fumigation of grain as a use:

- Existing DFU for cereal grain be modified to allow management of both dosing and exposure time, to achieve a Concentration x Time (CT) product which is appropriate for the temperature of the commodity being fumigated.
- To detail a requirement to regularly monitor gas levels during fumigation of cereal grain, to ensure the appropriate CT is achieved at all locations within a fumigation enclosure.

4.2 Public submissions to the Preliminary Review Finding

Ten public submissions on the PRF were received from the following: S.A. Rural Agencies Pty Ltd, the Department of Conservation and Environment NSW, DEW, GrainCorp Operations Limited, Sun Rice (Ricegrowers Ltd), the Department of Primary Industries (Victoria), Nufarm Australia Ltd, the Commonwealth Scientific and Industrial Research Organisation (CSIRO) Entomology Division and Nordiko Quarantine Systems Pty Ltd (two submissions). They provided comments on the following:

4.2.1 Amendment (variation) of labels and product registrations

The key recommendations of the PRF were supported by a number of submissions:

- delete general fumigation uses on labels with exception of QPS uses and include a recommendation that recapture technology be used
- product labels that have both soil fumigation and general fumigation uses should have the soil fumigation uses deleted
- CUEs should be allowed by APVMA off label permits, in concert with DEW's management of the use of methyl bromide
- cancellation of registrations and approvals of methyl bromide products that only have soil fumigation uses
- cancellation of all previous label approvals (including stopped products), prior to the most recent *(review-updated)* label approval.

It was also recommended that the key recommendations be implemented as soon as possible.

One submission however (Nufarm), did point out that if products with only horticultural-crop soil fumigation were cancelled, this could cause significant disruption amongst CUE users. The reason is that there would then be no registered products for such approved CUEs.

Consequently it was suggested that labels with only horticultural-crop soil fumigation be amended to allow use on CUE-approved soil fumigation only. This would keep the product registered, limit their use to CUE-approved soil fumigation uses (if applicable) and effectively proscribe un-authorised use.

4.2.2 Quarantine/pre-shipment uses

- One submission (DEW) emphasised with respect to flexible doses (i.e. variable Concentration [C] by Time [T] options, called 'flexible CT product[19]'), that importance should be placed on reducing the amount of methyl bromide used, rather than the time taken to fumigate i.e. increasing methyl bromide dosage to reduce fumigation time would run counter to Australia's international obligation to phase out ozone depleting substances.
- DEW confirmed that in the latest Methyl Bromide Technical Options Committee (MBTOC) report, QPS use of methyl bromide in 2003 was approximately 11,245 t, which was around 28% of global methyl bromide use. As non-QPS use decreases, then QPS use as a percentage of global use will increase, though the absolute QPS tonnage may remain substantially unchanged.
- DEW agreed with the APVMA's proposed recommendations and suggested that if non-QPS uses were to remain on the label, that they be linked to a reference to the regulations under the Ozone Protection and Synthetic Greenhouse Gas Management Act 1989. This would make it clear that the products are to be used for quarantine purposes, or in line with regulations that grant non-QPS use on an exception basis.
- CSIRO pointed out that flexible dosing regimes can give reductions in total methyl bromide used, not just fumigation time. This can occur via a reduced dosage per se, with a concomitant increase in fumigation time. As well, in some cases an increased fumigation time can allow more methyl bromide to break down on the commodity, within the fumigation chamber. This would also allow more effective use of limited methyl bromide allocations. Hence it was suggested that more thought should be given to this methodology before it is decided to leave it off the label.
    - Equally well, increased dosages with shorter treatment times could reduce emissions, if it were allowed in conjunction with recapture technology. However, CSIRO concedes that it is difficult to include on a label and unclear who could sanction this option, given the current consumption-based algorithm developed for the Montreal Protocol.
- GrainCorp re-iterated its previous comment (in response to the Scope document), which recommended a flexible dosage x time protocol (flexible CT product), on the basis that reduced fumigation periods are achieved. This would enable improved efficiency in exporting Australian grain. The company wished to emphasise that a reduced fumigation time does not necessarily require a higher dosage of methyl bromide.

[19] Note that the word 'product' refers to multiplication, not a chemical product.

- For example, the current label specifies a minimum fumigation period of 24 hours (for a dose range of 24–32 g/m3 and a temperature greater than 15oC). Legally, this 24-hour period cannot be reduced, even when an acceptable CT product is achieve in a shorter time frame. At the lowest existing recommended dosage rate of 24 g/m3, a required CT product can be achieved in significantly less than 24 hours in well-sealed storages structures.
- Attachment 5 of the PRF detailed a proposed QPS methyl bromide label, which includes fumigation of cereal grains. This proposed label describes the same dosage range as the existing label. As a result there is no likelihood of reduction in quantity of methyl bromide used for cereal grain fumigation, which the PRF described as the critical test in reviewing of value of public consultation suggestions.

- These lower dosage rates should be specifically for storages that are tested to meet a sealing standard. It is suggested that a pressure test standard be described on the label, similar to the pressure test standard being considered in the existing APVMA label review for solid aluminium phosphine preparations.
- Hence GrainCorp recommended, as part of the current methyl bromide label review, that technical discussion be entered into between the APVMA, CSIRO Entomology, AQIS, GrainCorp and other interested users to establish a set of recommendations on suitable dosage rates and exposure times.
  - The objective of these recommendations must be to allow for reduced fumigation times, in order to enable efficiencies to be gained in exporting Australian grain, whilst reducing consumption of methyl bromide.
- The Critical Comments on labels, for General Fumigation, should require regular monitoring of gas levels during fumigation of cereal grain, to ensure the appropriate CT product is achieve at all locations within a fumigation enclosure.

4.2.3 Critical Use Exemption uses

- One submission (Nufarm), pointed out that if products with only horticultural-crop soil fumigation on their label were cancelled, this could cause significant disruption amongst CUE users. The reason is that the products used for horticultural-crop CUEs have labels that only specify horticultural-crop soil fumigation use. Consequently it was suggested that such labels be amended to allow use for CUE-approved horticultural-crop soil fumigation only. This would keep such products registered, limit their use to CUE-approved soil fumigation, and effectively proscribe un-authorised use.
- Chemical Standards (Victoria) provided the following comments in relation to use in strawberry runner production:
  - The current methyl bromide product labels with a soil use contain the statement 'DO NOT use when soil temperature at 10-15cm is below 10^{o}C'. It is possible that soil temperatures at the time of fumigation for strawberry runner production at Toolangi is below 10 ^{o}C at 10–15cm depths.
  - The availability of virtually impermeable film (VIF) or low permeability barrier films (LPBF) for strawberry runner growers in Australia is uncertain.
  - The potential of the use of VIF or LPBF to create occupational health and safety issues for farm workers.

- The degree to which VIF or LPBF use reduces the volume of atmospheric emission of methyl bromide is unclear.
- With regards to the permits, it is Chemical Standards' understanding that users will need to obtain either an off-label use permit to use a registered products or a permit to use an unregistered product. The following situation applies in Victoria with regards to these permits, given that methyl bromide is a Schedule 7 compound.
- Off-label use permit: a permit is required under section 25A of the Agricultural and Veterinary Chemicals (Control of Use) Act 1992. Applicants should contact Chemical Standards Branch or obtain a permit application form from the website available at www.dpi.vic.gov.au .
- Use of an unregistered product: a permit from the APVMA would be required. If the APVMA does issue permits for the use of unregistered methyl bromide products in soil for strawberry runner production it is asked that they note the dot points listed above.

- Nordiko commented that due to the limited life of CUEs, their use of methyl bromide should not be reflected on the label, but licensing of CUE use of methyl bromide should be implemented by DEW.

4.2.4 Methyl bromide fumigation in general

- DEW recommended that it be mandatory for all fumigations to be carried out under VIF, plastic sheets and/or use recapture equipment.

  DEW acknowledged that there are some technical barriers to use of VIF, including availability in suitable sizes and quantities (particularly for soil fumigation in the field).
- SunRice supported the 'flexible dosage x time' concept (i.e. flexible CT product). This manipulation of CT product would enable successful fumigations to be performed, because it takes into account different sorption properties of produce and packaging.
- SunRice also supported best-practice fumigation, including monitoring of gas levels to ensure an effective CT product is achieved at all locations within the fumigation chamber.
- Similarly, SunRice supported use of highly impermeable films or enclosures, to increase methyl bromide retention in the fumigation facility. Allied to this, the company endorsed recapture and destruction of methyl bromide, to reduce methyl bromide emissions to the atmosphere.
- CSIRO suggested that changes to the methyl bromide labels be sent to Standards Australia, so that matters relating to practical fumigation technique could be considered and emphasised in the revision of the AS for fumigation (initiated 2006).
- Nordiko indicated that:
  - From an OHS perspective, the release of any fumigant into the workplace, subjects both workers and bystanders to the risk of exposure. When considering occupational exposure Threshold Limit Values (TLV) for fumigants, methyl bromide has a TLV of 5 ppm, while phosphine has a TLV of 0.3 ppm. Note that some years ago, the TLV for methyl bromide was 15 ppm and is currently 0.5 ppm in the EU and 1 ppm in the US. To prevent exposure of humans, animals

and plants, and to protect of the environment, methyl bromide should be used with care and recaptured after use.

- Methyl bromide should be used in sealed enclosures, where there is little or no chance of the gas escaping into the workplace or environment. The best way to achieve this is to contain the fumigation in a sealed system, recapture the gas and then destroy it. Such a procedure ensures that at no time during or after the fumigation, is the gas released into the atmosphere or the workplace.
- Without the use of a forced fan recapture system, at least a twenty-four hour withholding/aeration period (with chamber doors open or sheet removed), would be essential to reduce the risk of exposure. Even with the container or chamber doors open for this period, unless the air inside the enclosure is forced to evacuate and replaced by fresh air, there is still the very real chance of isolated pockets of gas being trapped between items of cargo. This would then still present an opportunity for exposure to unpacking staff. Forced fan recapture enables the gas to be evacuated from the container or other enclosure, in one to two hours.
- An essential piece of equipment is a low level monitor. This enables the fumigator to check for leaks. For the OHS reasons above, this unit should be fitted with an alarm set to the relevant TLV/TWA (5 ppm for methyl bromide).
- Whilst Nordiko embraces the concept of flexible dosage and time, the company feels that any increase in dosage (e.g. for high-dose/very-short-duration fumigation) is not supportable. Such action would not comply with the wishes of the Parties to the Montreal Protocol, who are seeking reduced usage of methyl bromide.
- Where possible, a decrease in the dosage should be sought for specific target insect pests, with more specific impact risk assessments being carried out by Biosecurity Australia.
- Without a mandatory requirement for recapture, increased dosages would increase the risks of exposure and degradation of the ozone layer to an even higher level than currently exists.
- Note that at the 2005 Open Ended Working Group meeting of the Parties to the Montreal Protocol, Decision XV111/10 was put up to be passed to the 18th Meeting of the Parties (MOP 18), recommending recapture and destruction of methyl bromide. This was ratified at the MOP18 and requests for data showing efficacy of recapture systems was made. Subsequently forms were made available from DEW, for the reporting of this data for consideration by the MBTOC, with a view to making such systems accredited technology approved by the Parties. After approval of such recapture technology, it will appear in the list of approved recapture and destruction technologies, within the body of the Montreal Protocol.
- An Australian study has been done on the spread of released fumigant post-fumigation, at a workplace that was not recapturing the fumigant. This showed that the popular conception that methyl bromide rapidly dissipates of its own accord to the upper atmosphere is not valid. The fumigant can spread and remain at lower levels in the workplace, particularly during cold and still weather. A methodology that ensures the containment and recapture of methyl bromide is clearly desirable to help ensure the safety of workplaces.

- Australian Customs now employ Nordiko units in almost all of their cargo interception centres, where their experience has been that up to about 30% of containers opened were found to have gas levels exceeding the TLV. Nordiko has also found considerable anecdotal evidence of similar problems in the general business area, where importers have found warehouse staff suffering health problems through suspected fumigant gas exposure. As methyl bromide is most commonly used for Australia, the chances are that methyl bromide gas exposure has been the cause in many of these instances.
- Nordiko's experience working with fumigation companies in Australia is that the cost of recapture has added of the order of 25% to 50% to the cost of fumigations. In Tasmania, where this practice is mandatory, the market has accepted this and the incidence of accidental exposure to gas has dropped dramatically.
- An undergraduate thesis submitted in 2006 to the University of Sydney quantified the health costs and benefits of methyl bromide recapture, and showed the net benefits to society of methyl bromide recapture.
- The adoption of recapture and destruction technology will afford protection to the ozone layer, together with a reduction in risk to humans, animals and plant-life. It will also allow the continued responsible and safe use of methyl bromide where its use is necessary, until a reliable and efficient alternative is found.
- Recapture will also set a basis for the treatment of other fumigant gases for the future. The majority of fumigant gases are toxic and pose a significant risk to all life forms. The Nordiko system has the ability to be used with any fumigant gas.

4.3 Meeting with stakeholders re recapture of methyl bromide

The APVMA convened a meeting between major industry and State/Federal agency stakeholders in September 2006, to explore the applicability of recapture of methyl bromide in Australia

Attendees included major fumigators who use methyl bromide, representatives from State or Federal OHS, public health, control-of-use and quarantine bodies/agencies, CSIRO, Nordiko (the Australian maker of recapture systems) and the APVMA.

There were also two visitors from Mebrom Asia, one of the biggest methyl bromide producing companies in the world. It is based in Belgium, which has been investigating mandatory recapture. The list of invitees is in Attachment 8.

4.3.1 Mechanics of recapture

Nordiko gave a brief presentation on the various systems of fumigant recapture used throughout the world. It was clear that charcoal absorption is the most progressed technology world wide, but that there has been comparatively little adoption and field experience of this outside of Australia. Within Australia, there are a number of sites utilising Nordiko's recapture systems. It was also pointed out that the Nordiko systems can be used for recapture of other fumigant gases, such as phosphine and potential methyl bromide alternatives such as carbonyl sulphide.

Recapture systems can recover and destroy in excess of 99.9% of the methyl bromide that has not leaked or reacted during the fumigation (this is called the available gas). Depending on the fumigation conditions, available gas is generally between 55% and 80% of the initial amount of methyl bromide used in the fumigation. Some 20%–45% of the methyl bromide used in a treatment is lost through leakage and chemical reaction, but it can be as high as 67%. Note that the recapture of the first 80% of the available gas is the quickest, at one to two hours per container.

It is important to note that the recaptured methyl bromide is mixed with other gases and other contaminants and currently there is no cost-effective technology to enable this to be re-used. Hence the recaptured product must be destroyed.

Note that recapture systems are used for two distinct but related purposes:

- gas recapture immediately after fumigation (gas concentration between 5,000 and 15,000 ppm in the fumigation vehicle [e.g. a shipping container])
- degassing of residual gas that remains after insufficient ventilation or from desorption (gas concentration at a comparatively low level [e.g. 20 to 50 ppm]).

The aim in both cases is to reduce gas level to 5 ppm, the OHS Threshold Limit Value [TLV], or less. Note that the level of 20-50 ppm in the latter situation (above) is a potential OHS risk to unloaders, hence the need for active de-gassing.

Nordiko systems can be used for fumigations under sheets, under fumigation tents or within containers. These recapture systems have been actively used in Tasmania by fumigation companies, and this field experience shows they are both effective and portable in that environment.

As at September 2006 there was a been a limit to the size of volumes that could be been treated e.g. to stacks approximately twice the size of a 40 foot shipping container (i.e. approximately 150–200 m^3). Currently no work has been done on recapture of methyl bromide from fumigated silos or ship-holds.

The latter present a particular challenge, given the huge volume of gas that must be recapture i.e. some hundreds of kilograms. The rule of thumb is that 10 g of charcoal are required to absorb 1 g of methyl bromide, so at this stage some tonnes of charcoal would be required.

Concentrating on sheet, tent and container fumigation, the methyl bromide fumigation companies support the concept of recapture, provided that:

- it is mandatory, so that there is a level playing field for fumigators
- there is sufficient time to prepare for implementation, including accumulation of field experience that takes into account the difference between Tasmanian and mainland fumigation logistics (see below).

With respect to container (etc) fumigation on the mainland, very few fumigators work at their own premises. Most work is done on containers (etc) at a container depot owned and operated by a container-transport company. The fumigators must provide their own equipment for the fumigation operation. The depots usually suffer from shortage of space, with containers stacked 3 or 4 high to maximise ground space. They also suffer from tight deadlines for container delivery and also the need to keep moving containers out of the depot very quickly,

because of the space restraint. This has implications for fumigators, with respect to the timeliness of fumigation operations and the extra time that may be needed for recapture operations.

4.3.2 Issues surrounding adoption of recapture in Australia

The main differences between Tasmanian and mainland fumigation situations, are:

- the large volume of shipping containers that must be handled, and cleared, in limited space (on the mainland there are more than ten times the number in Tasmania)
- often within extremely short time periods (just-in-time systems are common)
- the larger distance between container depots on the mainland (some hundreds of kilometres in many cases), which means the fumigator must transport all equipment to the depots, or have multiple recapture units/filters at each depot.

Hence the logistical operation and costs of:

- sufficient recapture systems to handle peaks (in particular)
- transportation of recapture systems between depots (or multiple stores of recapture systems at key locations)
- the replacement of recapture filters.

All these issues need to be clarified at a practical level.

For example, a single depot can handle 600 containers in a single day. If 200 of these need to be fumigated (which takes 24 hours) and transported (6 hours say) to clients within 36 hours of receipt (common with just-in-time systems that operate in ports and businesses), then 100 - 200 recapture units could be required on the one day. In the case of export containers, if fumigation and/or recapture take too long, then the ship may well have left before completion.

A 40-foot shipping container may have 3 kg of methyl bromide injected into it (depending on dose rate), with 1.5 kg to 1 kg of the gas remaining in the container after the 24-hour fumigation period (containers are sealed but are not gas tight). If each recapture unit absorbs 1.5 kg of methyl bromide from a container, then its 200 kg carbon filter would need replacement after 14 containers. This could vary if low dose flexible CT were acceptable (as there would be less gas to be recaptured per container).

As well, power outlets are not always readily available/accessible in all parts of container depots. In such cases, fumigators would need to have a number of generators to power the recapture units, which is an extra cost.

Recapture of 99% of the available methyl bromide from a newly-fumigated container can take between two and four hours (using active, fan-forced aeration), depending on the dose rate, volume of the container, stack tightness and the sorptive qualities of the fumigated product (e.g. hay versus steel machinery).

In some cases, this active aeration is done without recapture, in order to reduce aeration time. This compares to the current practice of four to 12 hours of passive aeration, *via* opening the container doors, plus some further aeration during transport. Often this passive aeration occurs overnight, when there are no workers present and does not require any set up or

worker-operation (cf. such as with recapture units). Aeration time and timing has important ramifications for sending out a required number of containers within a 24–48 hour period.

Note that for some export containers, there may be minimal aeration before loading onto the ship, with gas breakdown and passive leaking/aeration occurring during the long sea voyage. In such situations, recapture is an extra task, not a replacement for passive ventilation and so would be an extra cost.

One concern raised related to potential damage to treated produce. Some produce may be harmed by the repeated recycling process of (gradually decreasing) methyl bromide, during recapture. In such cases, fumigator experience was that there should be reduced recapture (e.g. the quickly recaptured first 80%), with swift aeration of the produce to follow or no recapture at all.

Note that degassing of residual methyl bromide (e.g. 50 ppm down to 5 ppm) can take as little as 1 hour, so this is a very different situation. It is also more likely to be done at the container destination rather than at the depot for export and import container-distribution.

4.3.3 Specific costs of recapture

The APVMA noted a number of points with respect to cost. As at September 2006, each recapture unit is leased out at $1,500 per month, so this can become a sizeable cost, depending on the minimum number of units required for efficient throughput. That is separate from replacement of re-usable carbon filters, which are $2,000 each. Some fumigators calculated that the lease and filter costs for them, plus extra work hours to mount, monitor and operate recapture systems, could be in the order of $500,000 pa to $750,000 pa. Note that this costing estimate is based on the current low level of uptake, with only a few units manufactured at a time. This cost could be reduced markedly, with a higher uptake rate and mass production of units.

Even so, fumigators considered the cost to be significant and there was a very real concern that increased costs of fumigation (with recapture) could drive fumigation offshore to cheaper countries (with concomitant concerns then of validating effectiveness of the fumigations). **Note that the Montreal Protocol does not expect adoption of technologies for methyl bromide reduction, if there are no available options or the cost of options is not economical.** This is the philosophy underpinning provision of CUEs.

In short, bearing in mind the other points made regarding mechanics of recapture and issues surrounding Australian implementation, there are serious issues to be solved, before recapture could be considered for mandatory implementation.

Nordiko considered that for fumigation under sheets, and container/container-sized-tents, there is sufficient expertise for these logistics (etc.) to be clarified and made workable, within 12 months of the meeting (i.e. 9/2007). However the fumigators considered that two years would be required. The fumigators plan to form an association of methyl bromide fumigators and have stated that they are willing to work with Nordiko to progress the accumulation of the necessary experience (etc.) on the mainland.

Similarly the bulk grain handlers indicated a willingness to work with Nordiko to commence investigations into recapture of methyl bromide from grain silos and ship's holds. Note that methyl bromide fumigation of Australian silos has been largely replaced by phosphine

treatment and insecticide treatment of structures (e.g. with fenitrothion). However, some overseas governments and grain buyers insist on methyl bromide fumigation.

4.3.4 Conclusions of the recapture meeting

- For under-sheet, container and container-sized tent fumigation, recapture technology is not yet sufficiently developed for mainland Australia fumigation, with respect:
  - cost effectiveness of the recapture units
  - throughput of containers per day per depot
  - throughput time-constraints at depots
  - distance between fumigation depots.

Hence, it was recommended that it not be considered for mandatory implementation until September 2008 at the very earliest: this would give industry two years to develop an operational model.

- For silos and ships' holds, no definitive work on methyl bromide recapture has commenced, and so it is considered that three years (at a minimum) would be needed before a workable operational model might be available.

4.3.5 Developments since the September 2006 meeting

- Belgium is moving to mandatory recapture of 80% of the available gas, from 1 July 2007. The Dutch port of Rotterdam has followed suit [note the TLV equivalent in Holland is 0.25 ppm, as against Europe's 0.5 ppm]. Note that these two European fumigation situations are very concentrated and central, compared to Australia's more widely dispersed and distributed fumigation situations
- Nordiko R & D in Belgium has generated lower cost options e.g. $750 per unit per month, where five units share one 200 kg carbon filter (cf. $1,500 per unit per month, where each unit has a filter).
  - As well, disposable 200 kg filters are now available for $400, but the user assumes the cost and responsibility of the filter's treatment (thiosulphate washing) or disposal (burning or burial) [cf. $2,000 for re-useable filters, where Nordiko assumes the treatment/disposal responsibility]).
- Nordiko R & D in Australia has successfully recaptured available gas from a large-volume tent fumigation of 500 m^3, with plans to successfully recapture gas from a fumigation volume of 700 m^3 (in comparison, a 40-foot shipping container has a volume of 76 m^3).
- As mentioned already, should low dose flexible CT products be approved, this would reduce the quantity of methyl bromide to be recaptured immediately after fumigation. The result would be a lower recapture time and a reduction in the number of carbon filters required.

5 REVIEW FINDINGS

5.1 Review Findings

5.1.1 Products

Of the 16[20] registered methyl bromide products:

- one product is used for general fumigation only (a 1,000 g/kg product)
- nine are used for both general fumigation and in-field plant-bed/turf soil fumigation and stored soil/compost/hay fumigation (all ~ 1,000 g/kg products)
- one is used for in-field plant-bed/turf soil fumigation and stored soil/compost/hay fumigation only (a 700 g/kg product formulated with 300 g/kg chloropicrin)
- five are used for in-field horticultural-crop soil fumigation only [e.g. for strawberry production]; these contain 300 g/kg, 500 g/kg or 700 g/kg of methyl bromide: the rest of the formulation is chloropicrin.

As briefly noted above, soil fumigation uses can be in-field for horticultural-crops (e.g. beds for strawberry runner production) or for plant-beds/turf (e.g. flower production under cover). It also refers to fumigation of stock-piled soil, compost or straw/hay (e.g. in a nursery). These uses are now permitted under CUEs only, or for QPS situations (e.g. import of soil or export of hay).

General fumigation uses can be both QPS uses (e.g. fumigation of imported wood and of exported grain) and non-QPS uses. Examples of non-QPS uses are fumigation of domestic buildings for rodents and post-harvest fumigation of rice (note that the latter use is covered by a CUE in Australia).

5.1.2 Montreal Protocol

Under the terms of the Montreal Protocol, QPS uses are currently exempt from phase-out. DEW has indicated, and the APVMA accepts, that methyl bromide may continue to be used for QPS uses because:

- there is a significantly lower consumption of methyl bromide for QPS uses compared to non-QPS uses
- in 1991, it was estimated that 71,000 t of methyl bromide were used world wide (developed and developing countries combined, with approximately 22% (15,600 t) used for QPS
- in 2003, it is estimated that global tonnage for methyl bromide usage was approximately 51,000 t with QPS uses estimated at approximately 11,245 t

[20] As mentioned above, there were 16 registered methyl bromide products at the commencement of the review. However, two of these products were voluntarily cancelled when the Final Review Report was released in 2007.

- international treaties mandate methyl bromide treatment of trade products, for phyto-sanitary reasons
- the environmental risk of exotic pests, weeds, diseases etc. from not using methyl bromide in QPS situations is considered to be greater than the environmental risk (ozone-depletion) from QPS uses of methyl bromide.

The APVMA has had regard to the preamble of the Montreal Protocol and contemporary scientific knowledge about the effects methyl bromide.

The review proposes to find that the APVMA is not satisfied that continued use or the product in accordance with existing label instructions would not be likely to have unintended effect that is harmful to the environment, specifically damage to the ozone layer.

5.1.3 Label amendments

The APVMA is, however, satisfied that that the labels of all products can be varied in such a way that continued use of the products, in accordance with the varied labels, would not be likely to have an unintended effect that is harmful to the environment.

The labels can be varied to restrict all uses to only QPS uses and approved CUE situations, providing the user also has a CUE allowing that use in the year of fumigation. DEW has advised that the QPS and CUE related label instructions are acceptable to them.

5.1.4 Public consultation: major recommendations and discussion

The reconsideration (review) provisions within the Agvet Codes require the APVMA to assess current registration and approval conditions.

Continued registration of products that are for soil fumigation only

The APVMA has accepted the point that if products with horticultural-crop[21] soil-fumigation on their labels were cancelled, as proposed in the PRF, this would cause significant disruption.

Such products would then be unregistered, causing difficulty in supply to valid CUE users and necessitating APVMA permits for their supply and use.

The APVMA has assessed this proposal, and agreed that continued registration (albeit very restricted), together with controls imposed by the Montreal Protocol and DEW, poses no greater risk than APVMA permits, and is more practical.

Hence this has been included as a recommendation to the Board: viz. registration of these products be continued and their labels amended to allow use for CUE- approved horticultural

[21] These products are a mixture with chloropicrin (for better fungal control) and contain 300, 500 or 700 g/kg of methyl bromide only, the rest of product is chloropicrin. Currently the only CUE to use these products is strawberry runner production. These products are distinctly different to methyl bromide products used for other soil-related fumigation (e.g. turf, stored soil/compost/hay), which contain 980–1000 g/kg methyl bromide. The other two current Australian CUEs (flower production under cover and rice disinfestation) use the latter products. The two product types are not necessarily interchangeable.

soil fumigation only, tightly linked to DEW legislation and their public list of users who have a relevant CUE [see Attachment 10].

This would leave the products registered, and could obviate the need for any APVMA permits.

Flexible dosage x time (Flexible CT product)

There were valuable suggestions from AQIS, CSIRO Entomology and GrainCorp Operations Limited, to amend the labels to allow flexible dosage/time x temperature, for different insects (including lower doses and reduced times, as well as potentially higher does for a lesser time).

This review examines environmental risk from methyl bromide and whether our approved uses on labels are consistent with the Montreal Protocol. The APVMA has concluded that the environmental risk from methyl bromide is acceptable with current label rates, if use is restricted to QPS and approved-CUE uses only. Further, that this is congruent with the Montreal Protocol. In this sense, flexible CT product is beyond the scope of the review. As well, it would significantly delay the review's conclusion (namely, necessary label amendments).

Note that for flexible CT product protocols to be useable in Australia, they must also be accepted by the overseas clients who buy Australian exports. These clients often refer to AQIS standards when they mandate methyl bromide treatment of Australian exports in Australia. Hence flexible CT product needs to be accepted by AQIS and the AQIS fumigation standards amended to reflect them.

Consequently a joint APVMA, AQIS and CSIRO-Entomology project is required for flexible CT to be successful, as well as a methyl bromide registrant who is willing to lodge a submission for approval onto their label. This project has been commenced.

At this stage, only lower dose flexible CT could be considered, as until the Montreal Protocol accounting is emissions based (rather than consumption based), then higher doses contravene the Montreal Protocol.

As mentioned above, DEW have advised that current label instructions with respect to QPS uses are adequate and meet the Montreal Protocol requirements.

Recapture of Methyl Bromide

Recapture was recommended by some respondents and a few suggested it be made mandatory. However, it was clear from the stakeholder meeting in September 2006 (see above), that there are significant economic and logistical issues to resolve before this could be considered.

Furthermore, with respect to the Montreal Protocol, recaptured and destroyed methyl bromide is not taken into account in the calculation of methyl bromide use. The formula is simply 'quantities manufactured or imported, less those quantities exported in a given year'.

However, recognised recapture technology is increasingly being adopted (and is mandatory in Tasmania for quarantine use). As mentioned above, Belgium will be making 80% recapture of

available gas mandatory from 1 July 2007 (verified by pre- and post-recapture measurement). The Dutch port of Rotterdam has followed suit.

Note that these European fumigation situations are a very concentrated and central, compared to Australia's more widely dispersed and distributed fumigation situations. Hence the fumigation logistics and cost structure of Australian situation is different, and this needs to be carefully investigated before it could be considered for mandatory implementation.

Therefore the review proposes to recommend that labels only include a reference to recapture technology, whilst the APVMA keeps a watching brief on recapture technology developments and their implications for Australian adoption.

6 REVIEW OUTCOMES AND REGULATORY DECISIONS

On the basis of the evaluation of the submitted data and information, the following regulatory action is made with regard to the continued registrations and approvals of methyl bromide use in Australia.

6.1 Affirm Product Registrations

The APVMA is SATISFIED that the labels of products listed in Table 1 (below) have been varied and that the products meet the prescribed requirements for continued registration.

On this basis the APVMA is SATISFIED that continued registration of the products in accordance with their instructions for use:

- would not be likely to have an effect that is harmful to human beings
- would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment.

Therefore, the APVMA has AFFIRMED the product registrations.

Table 1: Methyl Bromide product labels that have been varied and methyl bromide product registrations that are affirmed.

Product number	Product name	Registrant	Label approval numbers that have been varied	Approval numbers of varied labels
32106	Agrigas M Methyl Bromide Fumigant	BOC Ltd	32106/01	32106/12-100Kg/0607
34060	Agrigas MC Methyl Bromide Fumigant	BOC Ltd	Ψ	34060/12-100Kg/0607
34066	Nufarm Methyl Bromide 980 Fumigant	Nufarm Australia Limited	34066/0604	34066/35-100kg/0607
34067	Nufarm Methyl Bromide 1000 Fumigant	Nufarm Australia Limited	34067/0604	34067/35-100kg/0607
41303	SA Rural Methyl Bromide 980 Fumigant	S.A. Rural Agencies Pty Ltd	41303/0802	41303/100kg/0607
41390	Dibbs Brom-O-Gas 1000 Fumigant	RA Dibbs & Sons Pty Ltd	41390/0303	41390/50-100kg/0607
41394	Dibbs Brom-O-Gas 980 Fumigant	RA Dibbs & Sons Pty Ltd	41394/0203	41394/50-100kg/0607
51126	Nufarm Vertafume	Nufarm Australia	51126/0204	51126/100kg/0607

Product number	Product name	Registrant	Label approval numbers that have been varied	Approval numbers of varied labels
	Soil Fumigant	Limited		
51208	Rural Soil Fumigant 500-500	S.A. Rural Agencies Pty Ltd	51208/1202	51208/100kg/0607
52781	Southern Cross Methyl Bromide 1000 Fumigant	Commercial Fumigation Services Pty Ltd	52781/0503	52781/100kg/0607
53267	Rural Methyl Bromide 1000 Fumigant	S.A. Rural Agencies Pty Ltd	53267/1202	53267/100kg/0607
58001	Southern Cross Methyl Bromide 980 Fumigant	Commercial Fumigation Services Pty Ltd	58001/1103	58001/100kg/0607
59240	Southern Cross Soil Fumigant 500-500	Commercial Fumigation Services Pty Ltd	59240/1104	59240/100kg/0607
59241	Southern Cross Soil Fumigant 700-300	Commercial Fumigation Services Pty Ltd	59241/1104	59241/100kg/0607

Ψ Label approved prior to the commencement of the Agvet Codes

6.2 Cancellation of all but the most recently approved label

The APVMA is NOT SATISFIED that old previously-approved product labels for currently registered products listed in Table 2 (below) contain adequate instructions in relation to the criteria set out in s.14(3)(g) of the Agvet Codes and contain uses patterns recommended to be deleted.

On this basis, these previously-approved labels (Table 2, below) are cancelled.

Table 2: The following label approvals are deemed not to contain adequate instructions and have been cancelled.

NCRIS No	Product Name	Registrant	Label Approval Numbers
32106	Agrigas M Methyl Bromide Fumigant	BOC Limited	Ψ
34066	Nufarm Methyl Bromide 980 Fumigant	Nufarm Australia Limited	34066/0204 34066/0298 Ψ
34067	Nufarm Methyl Bromide 1000 Fumigant	Nufarm Australia Limited	34067/0204 34067/0298 Ψ
41303	SA Rural Methyl Bromide 980 Fumigant	S.A. Rural Agencies Pty Ltd	Ψ
41390	Dibbs Brom-O-Gas 1000 Fumigant	RA Dibbs & Sons Pty Ltd	41390/1002 Ψ
41394	Dibbs Brom-O-Gas 980 Fumigant	RA Dibbs & Sons Pty Ltd	41394/1002 Ψ
51126	Nufarm Vertafume Soil Fumigant	Nufarm Australia Limited	51126/0998
51208	Rural Soil Fumigant 500-500	S.A. Rural Agencies Pty Ltd	51208/1198
52781	Southern Cross Methyl Bromide 1000 Fumigant	Commercial Fumigation Services Pty Ltd	52781/1200 52781/0400
53267	Rural Methyl Bromide 1000 Fumigant	S.A. Rural Agencies Pty Ltd	53267/1000

Ψ Label approved prior to the commencement of the Agvet Codes

Note:

The products:

- Nufarm Bromopic 700:300 Soil Fumigant (product number 41488), and
- Nufarm Fungafume Soil Fumigant (product number 51125)

were voluntarily cancelled before the end of the review, and so are not included in the tables above.

ATTACHMENT 1

Registered products containing methyl bromide (as at 23 April 2007)

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

Ψ Label approved prior to the commencement of the Agvet Codes

α For descriptions of soil uses and general uses, see Directions for Use table at Attachments 3 and 4.

β All products contain 980 g/kg or 1000 g/kg methyl, except: 41488 (700 g/kg), 51255 (300 g/kg), 51226 (500 g/kg), 51208 (500 g/kg), 59240 (500 g/kg) and 59241 (700 g/kg). The remainder of each product is chloropicrin. Note that these latter products are used for soil fumigation only.

NOTE: Two products (41488 and 51125) were voluntarily cancelled when the review findings were released in May 2007, and so do no longer form part of the review.

ATTACHMENT 2

Stopped[α] products containing methyl bromide (as at 23 April 2007)

Product Number	Product Name	Fumigation Uses[β]	Registrant	Label Approval Numbers	Expiry date for supply and use
34059[γ]	A.I.C Bromo-Chlor 700-300 Fumigant	Soil only	S.A Rural Agencies Pty. Ltd.	34059/1202 34059/0999 34059/01 Ψ	30-June-2007
51207	Rural Soil Fumigant 300-700	Soil only	S.A Rural Agencies Pty. Ltd.	51207/1202 51207/1198	30-June-2007

[α] Stopped products can no longer be manufactured, but existing product can be sold at retail outlets. Such purchased product and product already on farms (etc) can be used (as per the label) for a further period as determined by the APVMA. The period in this case ends on 30/6/2007.

Ψ Label approved prior to the commencement of the Agvet Codes

[β] For descriptions of Soil uses, see Directions for Use table at Attachment 3.

[γ] The product 34059 contains 700 g/kg of methyl bromide, whilst 51207 contains 300 g/kg of methyl bromide. The remainder of each product is chloropicrin. Note that both of these products are used for soil fumigation only.

The registrant confirmed in June 2006, that there are no stocks of these two products held by contractors or retail premises.

ATTACHMENT 3

Current methyl bromide label for soil fumigation

Crop/Situation[#]	Pest[$]	Product-Rate*	Minimum exposure time	Aeration** time before planting	Critical Comments
Flowers, bulbs, nursery and horticultural crops	*Fusarium* and *Verticillium* wilts, *Sclerotinia, Pythium, Rhizoctonia,* nematodes, weeds, weed seeds, insects, rodents.	500 kg per ha or 50 g per m^2	24 hours	At least 14 days (Increase time if weather becomes wet or cold)	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 30 cm and at a depth of 15-20 cm. To seal in fumigant, cover immediately behind tynes with plastic sheet and seal edges. (Aeration time before planting is 21-28 days for 59240)
Plant beds, turf and other local areas	Nematodes, insects and weed seeds. For nutgrass control, use double dosage-rates.	50 g per m^2	24 hours	48 hours	If NOT using a sealed, pressure injection unit: the area to be fumigated should be well cultivated and the soil should be moist, but not wet. Make a furrow (150 mm deep) around the plot to be treated and lay polythene or other plastic sheeting over cover supports (e.g. inverted bottles or wire hoops) with its edges in the furrow; Connect plastic hoses to the cylinder; Seal edges of the sheet in furrow by filling with soil and tramp down;
Well-rotted compost, manure and top soil		300 g per m^3	24 hours	72 hours	
Mulching straw or hay	Rodents (34060[#] only)	120 g per 1 bale	48 hours	24 hours	
Plant beds, turf & other local areas	Damping-off fungi such as species of P*ythium*,	100 g per m^2	24 hours	72 hours or longer	

Crop/Situation[#]	Pest[$]	Product-Rate*	Minimum exposure time	Aeration** time before planting	Critical Comments
Decomposed compost and manure	R*hizoctonia* and F*usarium*, soil-borne fungi such as S*clerotinia* and V*erticillium*	600 g per m^3	24 hours	72 hours or longer	Connect applicator and turn on the valve of the cylinder; Refer to General Instructions for more detailed instructions. If using a sealed, pressure injection unit: Thoroughly cultivate the soil and ensure it is kept in moist conditions for 5 to 7 days prior to treatment; Methyl bromide is applied to the soil by means of a sealed pressure injection unit, with tyne spacing of 30 cm and at a depth of 15 - 20 cm; To seal in fumigant, cover immediately behind tynes with plastic sheet and seal edges.

Note: 1-bale is approximately 20 –30 kg

\# this is a combination of all soil-related uses, across all methyl bromide products. Each situation only applies to those products which already have that particular use pattern. It is not intended to convey that all methyl bromide products can be used for all the uses above.

$ some products have only a few of the pests listed in each Crop/Situation.

** one product (41488[#]) states 14 days aeration before planting, for all six soil-fumigation uses above.

* the same product rates are used for products containing 700 g/kg, 980 g/kg or 1000 g/kg of methyl bromide, for all six uses above.

There are three products with 500 g/kg methyl bromide and two with 300 g/kg methyl bromide. They use the same product rates as above, but these five products are registered only for the first use listed in the table (above), and only for control of *Fusarium/Verticillium* wilts, *Rhizoctonia*, *Pythium* and nematode control.

Other instructions appearing on labels that relate to soil fumigation, include:

- **DO NOT** use when soil temperature at 10–15 cm depth is less than 10 ^{o}C
- If soil temperature is between 10–15 ^{o}C, double the aeration and exposure times listed (in the Directions for Use table)

- **DO NOT** fumigate when very cold, very wet or very dry
- **DO NOT** fumigate within 50 cm of roots of desirable vegetation
- **DO NOT** plant or sow for at least 14 days after removal of plastic.

ATTACHMENT 4

Current methyl bromide label for general fumigation

Situation#	Pests controlled	Product-Dosage* g/m^3	Temperature (^{o}C)	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
		40-48	10-15	3 hours	(10 - 16.7 kPa absolute pressure)
Buildings and similar structures	Rodents	4	> 4	5 hours	

this is a combination of all general fumigation uses, across all methyl bromide products. Each situation only applies to those products which already have that particular use pattern. It is not intended to convey that all methyl bromide products can be used for all the uses above.

* product dosage rates are based on products containing 1000 g/kg or 980 g/kg methyl bromide.

All the above uses can be QPS related or non-QPS. Some non-QPS uses are now CUEs (if granted): e.g. post-harvest fumigation of rice. Other instructions that appear on labels and relate to general fumigation, include:

- **DO NOT** fumigate more than once as commodity is likely to become unfit for use
- **DO NOT** treat seeds intended for planting or sowing.

Prevent leakage of fumigant, ensure all windows, doors and other openings are sealed and the area is sign-posted. When fumigating buildings, grain trucks and ship's holds, apply the fumigant from outside the structure. After fumigation, aerate the structure well and keep animals, children and unauthorised persons away from the treatment area until free from methyl bromide, as indicated by an appropriate measuring device. Refer to General Instructions for more detailed instructions.

ATTACHMENT 5

Proposed label: methyl bromide for general QPS@ and current approved CUE** fumigation

Situation#	Pests# controlled	Dosage* g/m^3	Temperature (°C)	Exposure time	Critical Comments
Quarantine and Pre-Shipment (QPS) or current Approved Critical Use Exemption (CUE) fumigation of: General grains, 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. It is recommended that recapture technology to recapture methyl bromide at the end of the treatment be used where appropriate. Note that recapture of methyl bromide at the end of the treatment, for re-use or destruction, may be a legal requirement in some states. Mandatory recordkeeping## and reporting++ requirements apply.
		32-40	10-15	24 hours	
		32-40	> 15	3 hours	Under sustained vacuum (10 - 16.7kPa absolute pressure). It is recommended that recapture technology to recapture methyl bromide at the end of the treatment be used where appropriate. Note that recapture of methyl bromide at the end of the treatment, for re-use or destruction, may be a legal requirement in some states. Mandatory recordkeeping## and reporting++ requirements apply.
		40-48	10-15	3 hours	
Quarantine and Pre-Shipment (QPS) or current Approved Critical Use Exemption (CUE) fumigation of	Rodents	4	> 4	5 hours	It is recommended that recapture technology to recapture methyl bromide at the end of the treatment be used where appropriate. Note that recapture of methyl bromide at the end of the treatment, for re-use or destruction, may be a legal

buildings & similar structures	requirement in some states. Mandatory recordkeeping## and reporting++ requirements apply.

++ QPS = Quarantine and Pre-shipment. The Ozone Protection and Synthetic Greenhouse Gas Management Regulations 1995 set out what are QPS uses.
Quarantine relates to fumigations performed by, or with the authorisation of, a Commonwealth, State or Territory authority to prevent the introduction, establishment or spread of a pest or disease in Australia, a State or a Territory.
Pre-shipment relates to fumigations carried out on a commodity, before it is exported, to meet the requirements of the importing country or a law of the Commonwealth.

@ CUE: Critical Use Exemption. This is an approved non-QPS++ use of methyl bromide, granted by the Parties to the Montreal Protocol.
Exempt persons are listed on the Non-QPS Exemption List, posted on the Department of the Environment and Water Resources [DEW] website (www.environment.gov.au/atmosphere/ozone/publications/exemption-list.html). Exempt persons must not use quantities of methyl bromide in excess of their allocated amount, specified on the Non-QPS Exemption List, and are only permitted to use methyl bromide for the purpose for which the exemption was granted. Approved CUEs must be current in the year of methyl bromide use.

$$ Methyl bromide is used for a Non-QPS application if it is used for an application that is not a QPS++ application and other than as a feedstock.

+ Exemption holders are required to report all use under their exemption, within 14 days of the end of each 6 month period staring January and July, to Department of the Environment and Water Resources [DEW], in an approved form.

Anyone who uses methyl bromide must keep a record of the details of every fumigation performed, for a period of five years, in an approved form. Inspectors appointed under the Ozone Protection and Synthetic Greenhouse Gas Management Act 1989 may audit these records at any time.

Other instructions that appear on labels that relate to general fumigation, include:

- **DO NOT** fumigate more than once as commodity is likely to become unfit for use
- **DO NOT** treat seeds intended for planting or sowing.

Prevent leakage of fumigant, by sealing all windows, doors and other openings and ensure that the area is sign-posted. When fumigating buildings, grain trucks and ship's holds, apply the fumigant from outside the structure. After fumigation, aerate the structure well and keep animals, children and unauthorised persons away from the treatment area until free from methyl bromide, as indicated by an appropriate measuring device. Refer to General Instructions for more detailed instructions.

ATTACHMENT 6

Proposed label: methyl bromide for plant bed/turf soil-related QPS[@] and current approved CUE[+] fumigation

Crop/Situation#	Pest[$]	Product-Rate*	Minimum exposure time	Aeration** time before planting	Critical Comments
Plant beds, turf & other local areas: QPS and current Approved CUE treatments **ONLY**.	Nematodes, insects and weed seeds.	50 g per m^2	24 hours	48 hours	Where possible, treat inside a fumigation chamber. If not using a sealed pressure injection unit:
Well-rotted compost, manure and top soil: QPS and current Approved CUE treatments **ONLY**.	For nut grass control in QPS situations, use double dosage rate.	300 g per m^3	24 hours	72 hours	The area to be fumigated should be well cultivated and the soil/compost should be moist but not wet. Make a furrow (150 mm deep) around the plot to be treated and lay tarpaulin, polythene or other plastic sheeting over cover supports (e.g. inverted bottles or wire hoops), to enclose the material to be fumigated. Ensure the sheeting edges are in the furrow.
Mulching straw or hay: QPS and current Approved CUE treatments **ONLY**.		120 g per 1 bale	48 hours	24 hours	
Plant beds and other local areas: QPS and current Approved CUE treatments **ONLY**.	Damping-off fungi such as species of P*ythium*, R*hizoctonia* and F*usarium*, soil-borne fungi such as S*clerotinia* and V*erticillium* causing plant disease	100 g per m^2	24 hours	72 hours or longer	Connect plastic hoses to cylinder. Thoroughly seal edges of sheet in the furrow, by filling with soil and tramping down. Connect applicator and turn on valve on the cylinder. Refer to General Instructions section for more detailed instructions.

Crop/Situation#	Pest[$]	Product-Rate*	Minimum exposure time	Aeration** time before planting	Critical Comments
Decomposed compost and manure: QPS and current Approved CUE treatments ONLY.		600 g per m^3	24 hours	72 hours or longer	If using a sealed, pressure injection unit: Thoroughly cultivate the soil and ensure it is kept in moist conditions for 5 to 7 days prior to treatment; Methyl bromide is applied to the soil by means of a sealed pressure injection unit, with tyne spacing of 30 cm and at a depth of 15 - 20 cm; To seal in fumigant, cover immediately behind tynes with plastic sheet and seal edges. It is recommended that recapture technology to recapture methyl bromide at the end of the treatment, be used where appropriate. Note that recapture of methyl bromide at the end of the treatment, for re-use or destruction, may be a legal requirement in some states. Mandatory recordkeeping[##] and reporting[++] requirements apply.

++	QPS = Quarantine and Pre-shipment. The Ozone Protection and Synthetic Greenhouse Gas Management Regulations 1995 set out what are QPS uses. Quarantine relates to fumigations performed by, or with the authorisation of, a Commonwealth, State or Territory authority to prevent the introduction, establishment or spread of a pest or disease in Australia, a State or a Territory. Pre-shipment relates to fumigations carried out on a commodity, before it is exported, to meet the requirements of the importing country or a law of the Commonwealth.
@	CUE: Critical Use Exemption. This is an approved non-QPS++ use of methyl bromide, granted by the Parties to the Montreal Protocol. Exempt persons are listed on the Non-QPS Exemption List, posted on the Department of the Environment and Water Resources [DEW] website (www.environment.gov.au/atmosphere/ozone/publications/exemption-list.html). Exempt persons must not use quantities of methyl bromide in excess of their allocated amount, specified on the Non-QPS Exemption List, and are only permitted to use methyl bromide for the purpose for which the exemption was granted. Approved CUEs must be current in the year of methyl bromide use.
$$	Methyl bromide is used for a Non-QPS application if it is used for an application that is not a QPS++ application and other than as a feedstock.
+	Exemption holders are required to report all use under their exemption, within 14 days of the end of each 6 month period staring January and July, to Department of the Environment and Water Resources [DEW], in an approved form.
##	Anyone who uses methyl bromide must keep a record of the details of every fumigation performed, for a period of five years, in an approved form. Inspectors appointed under the Ozone Protection and Synthetic Greenhouse Gas Management Act 1989 may audit these records at any time.
#	This is a combination of all soil-related uses, across all methyl bromide products. Each situation only applies to those products which already have that particular use pattern. It is not intended to convey that all methyl bromide products can be used for all the use above.
$	Some products have only a few of the pests listed in each Crop/Situation. Product number 59241 claims control of weeds and weed seeds.
**	product number 59240 states an aeration time before planting of 21-28 days.
*	The same product rates are used for products containing 700 g/kg, 980 g/kg or 1000 g/kg of methyl bromide, for the use above.

There are three products with 500 g/kg methyl bromide and two with 300 g/kg methyl bromide. They use the same product rates as above, but these five products are registered only for the first use listed in the table (above), and only for control of *Fusarium/Verticillium* wilts, *Rhizoctonia*, *Pythium* and nematode control.

Other instructions appearing on labels that relate to soil fumigation, include:

- **DO NOT** use when soil temperature at 10–15 cm depth is less than 10 ^{o}C
- **DO NOT** fumigate within 50 cm of roots of desirable vegetation
- If soil temperature is between 10–15 ^{o}C, double the aeration and exposure times listed (in the Directions for Use table)
- **DO NOT** fumigate when very cold, very wet or very dry
- **DO NOT** plant or sow for at least 14 days after removal of plastic.

ATTACHMENT 7

Proposed label: methyl bromide for horticultural soil fumigation for QPS++ or current approved CUE@ fumigation

Crop/Situation#	Pest$	Product-Rate*	Minimum exposure time	Aeration** time before planting	Critical Comments
Flowers, bulbs, nursery and horticultural crops: QPS and current Approved CUE treatments ONLY.	*Fusarium* and *Verticillium* wilts, *Pythium, Rhizoctonia,* nematodes,	500 kg/ha or 50 g per m^2	24 hours	At least 14 days (increase time if weather becomes cold)	ONLY use a sealed, pressure injection unit: Thoroughly cultivate the soil and ensure it is kept in moist conditions for 5 to 7 days prior to treatment; Methyl bromide is applied to the soil by means of a sealed pressure injection unit, with tyne spacing of 30 cm and at a depth of 15 - 20 cm; To seal in fumigant, cover immediately behind tynes with plastic sheet and seal edges. Mandatory recordkeeping## and reporting+ requirements apply.

++ QPS = Quarantine and Pre-shipment. The Ozone Protection and Synthetic Greenhouse Gas Management Regulations 1995 set out what are QPS uses.
Quarantine relates to fumigations performed by, or with the authorisation of, a Commonwealth, State or Territory authority to prevent the introduction, establishment or spread of a pest or disease in Australia, a State or a Territory.
Pre-shipment relates to fumigations carried out on a commodity, before it is exported, to meet the requirements of the importing country or a law of the Commonwealth.

@ CUE: Critical Use Exemption. This is an approved non-QPS++ use of methyl bromide, granted by the Parties to the Montreal Protocol.
Exempt persons are listed on the Non-QPS Exemption List, posted on the Department of the Environment and Water Resources [DEW] website (www.environment.gov.au/atmosphere/ozone/publications/exemption-list.html). Exempt persons must not use quantities of methyl bromide in excess of their allocated amount, specified on the Non-QPS Exemption List, and are only permitted to use methyl bromide for the purpose for which the exemption was granted. Approved CUEs must be current in the year of methyl bromide use.

$$ Methyl bromide is used for a Non-QPS application if it is used for an application that is not a QPS++ application and other than as a feedstock.

\+ Exemption holders are required to report all use under their exemption, within 14 days of the end of each 6 month period staring January and July, to Department of the Environment and Water Resources [DEW], in an approved form.

Anyone who uses methyl bromide must keep a record of the details of every fumigation performed, for a period of five years, in an approved form. Inspectors appointed under the Ozone Protection and Synthetic Greenhouse Gas Management Act 1989 may audit these records at any time.

\# This is a combination of all soil-related uses, across all methyl bromide products. Each situation only applies to those products which already have that particular use pattern. It is not intended to convey that all methyl bromide products can be used for all the use above.

$ Some products have only a few of the pests listed in each Crop/Situation. Product number 59241 claims control of weeds and weed seeds.

** product number 59240 states an aeration time before planting of 21-28 days.

* The same product rates are used for products containing 700 g/kg, 980 g/kg or 1000 g/kg of methyl bromide, for the use above.

There are three products with 500 g/kg methyl bromide and two with 300 g/kg methyl bromide. They use the same product rates as above.

Other instructions appearing on labels that relate to soil fumigation, include:

- **DO NOT** use when soil temperature at 10–15 cm depth is less than 10 ^{o}C
- If soil temperature is between 10–15 ^{o}C, double the aeration and exposure times listed (in the Directions for Use table)
- **DO NOT** fumigate when very cold, very wet or very dry
- **DO NOT** fumigate within 50 cm of roots of desirable vegetation
- **DO NOT** plant or sow for at least 14 days after removal of plastic.

ATTACHMENT 8

Invittee list for recapture meeting in Melbourne, 6 September 2006

Matthew Head	GrainCorp, Melbourne
Alan Jones	GrainCorp, Melbourne
Jeanette Marszal	ABB, Adelaide
Stephen Buick	ABB, Adelaide
Ern Kostas	CBH, Perth
Wayne Studdert	ISS Fumigation, Sydney
Bruce Matar	Commercial Fumigation Services, Adelaide
Shawn Miley	Kilquick Pest Control Pty Ltd, Brisbane
Greg Ross	Container Fumigations, Melbourne
John Richards	Capital Quarantine and Capital Cold Storage, Hobart
Geoff Needham	P & O, Sydney
Ken Brash	Nordiko, Sydney
Wil Grullemans	Nordiko, Sydney
Ken Fitzpatrick	Nordiko, Sydney
Ross Rickard	AQIS, Canberra
David Cox	AQIS, Canberra
Colin Waterford	CSIRO, Canberra
Jan Van Someren Graver	CSIRO consultant, Canberra
Annie Gabriel	Dept Environment & Heritage (DEH*), Canberra
George Dowing	DPI Victoria (Chemical Standards), Melbourne
Karyn DiFlorio	DPI Victoria (Plant Standards), Melbourne
Alex Simovski	Workcover Victoria, Melbourne
Damon Jones	EPA Victoria , Melbourne
Chris Trogh	Mebrom[#] Thailand (Ayoma Co. Ltd.), Bangkok
Jennifer Zheng	Mebrom[#] Thailand (Ayoma Co. Ltd.), Bangkok
Ron Marks	APVMA, Canberra

*: Montreal Protocol section. DEH is now called the Department of Environment and Water Resources [DEW]
[#]: Mebrom is a Belgium company that supplies methyl bromide and other fumigant gases.
(we believe that Belgium will move to compulsory recapture on 1/1/2007)

ATTACHMENT 9

Methyl bromide labels proposed for cancellation (as at 23 April 2007)

NCRIS No.	Product Name	Fumigation Uses*	Registrant	Label Approval Numbers
32106	Agrigas M Methyl Bromide Fumigant	General only	BOC Limited	Ψ
34066	Nufarm Methyl Bromide 980 Fumigant	Soil & General	Nufarm Australia Limited	34066/0204 34066/0298 Ψ
34067	Nufarm Methyl Bromide 1000 Fumigant	Soil & General	Nufarm Australia Limited	34067/0204 34067/0298 Ψ
41303	SA Rural Methyl Bromide 980 Fumigant	Soil & General	S.A. Rural Agencies Pty Ltd	Ψ
41390	Dibbs Brom-O-Gas 1000 Fumigant	Soil & General	RA Dibbs & Sons Pty Ltd	41390/1002 Ψ
41394	Dibbs Brom-O-Gas 980 Fumigant	Soil & General	RA Dibbs & Sons Pty Ltd	41394/1002 Ψ
41488#	Nufarm Bromopic 700:300 Soil Fumigant	Soil only	Nufarm Australia Limited	41488/0200 Ψ
51125#	Nufarm Fungafume Soil Fumigant	Soil only	Nufarm Australia Limited	51125/0998
51126#	Nufarm Vertafume Soil Fumigant	Soil only	Nufarm Australia Limited	51126/0998
51208#	Rural Soil Fumigant 500-500	Soil only	S.A. Rural Agencies Pty Ltd	51208/1198
52781	Southern Cross Methyl Bromide 1000 Fumigant	Soil & General	Commercial Fumigation Services Pty Ltd	52781/1200 52781/0400
53267	Rural Methyl Bromide 1000 Fumigant	Soil & General	S.A. Rural Agencies Pty Ltd	53267/1000

Ψ Label approved prior to the commencement of the Agvet Codes

* For descriptions of soil uses and general uses, see Directions for Use table at Attachments 3 and 4.

All products contain 980 g/kg or 1000 g/kg methyl, except: 41488 (700 g/kg), 51255 (300 g/kg), 51226 (500 g/kg), 51208 (500 g/kg), 59240 (500 g/kg) and 59241 (700 g/kg). The remainder of each product is chloropicrin. Note these latter products are used for soil fumigation only.

NOTE: Two products (41488 and 51125) were voluntarily cancelled when the review findings were released in May 2007, and so do no longer form part of the review.