This scope document for the review of arsenic is published by the Australian Pesticides and Veterinary Medicines Authority. For further information about this review, contact:

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FOREWORD

The APVMA is the National Registration Authority for Agricultural and Veterinary Chemicals. When reading this document, "APVMA" means "NRA". For information regarding this name change, please visit www.apvma.gov.au.

SUMMARY

The APVMA has initiated reconsideration of the registration and associated label approval(s) of products containing arsenic, specifically those that contain:

- CCA - a combination of copper (copper II sulfate, copper sulfate pentoxide, copper I oxide or cupric oxide), chromium (sodium dichromate or chromium trioxide) and arsenic (arsenic acid, arsenic pentoxide or orthoarsenic acid); or
- arsenic trioxide.

This scope document defines the matters of concern to the APVMA and outlines the information the APVMA requires so that it can conduct a comprehensive scientific assessment of timber treatment products containing arsenic.

The basis of the reconsideration of registrations of products containing CCA or arsenic trioxide is whether or not the APVMA can be satisfied that their continued use:

- would not be an undue hazard to the safety of people exposed to them during their handling or people using anything containing their residues;
- would not be likely to have an effect that is harmful to human beings; and
- would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment.

All associated label approvals are being reconsidered because of concerns that existing label instructions may be inadequate.

The reconsiderations will be made after the APVMA has assessed all the data and other information provided to it for this purpose – the assessment process is hereafter referred to as ‘review’.

It is anticipated that a draft report of the APVMA’s review of arsenic will be available for public comment in mid 2004.

The APVMA’s review will examine the following matters:

- the potential for adverse health effects associated with products containing or treated with arsenic (CCA or arsenic trioxide);
- the environmental effects from the use and disposal of CCA or arsenic trioxide products; and
- the adequacy of instructions and warnings on product labels.
1. INTRODUCTION

Section 31 of the Agvet Codes, authorises the APVMA to reconsider:
(a) the approval of an active constituent for a proposed or existing chemical product;
(b) the registration of a chemical product; and
(c) the approval of a label for containers for a chemical product.

The APVMA has decided to reconsider the registrations of certain products containing arsenic (CCA and arsenic trioxide) on the basis of concerns over toxicological and environmental effects associated with these products. The APVMA will also reconsider the approvals of associated labels to examine the adequacy of label instructions and warnings.

2. NOMINATION OF THE CHEMICAL

In 2002 the APVMA noted action taken by the US EPA to move away from timber treatments containing arsenic by December 2003. This action comes ahead of the completion of the formal assessment of CCA by the US EPA. Since this announcement, various actions have been taken in Europe, Canada and New Zealand, based on claims of potential human health risks associated with CCA. Some of these countries have put in place mitigation measures to minimise exposure until the concerns are investigated.

At this time a number of US studies relating to the potential for human exposure to CCA were also made available. These questioned the safety of CCA when used as a timber preservative on the basis of potential risks to human health, particularly to children.

On the basis of available information, the APVMA has decided to commence a review into the human health and environmental issues associated with products containing CCA and those products containing arsenic trioxide (termite treatments).

Specific details of the concerns that have been raised can be found in Sections 5 and 6 of this document.

3. SCOPE OF THE REVIEW

Having regard to the reasons for nomination of arsenic timber treatments for review, the information already available on this chemical and the way in which it is used in Australia, the scope of the review has been defined.

Given the potential human health concerns which have been raised (Section 5) and environmental concerns (Section 6), together with the concerns raised internationally (Section 7), there are indications that APVMA may not be able to maintain its satisfaction that continued registration of products containing arsenic:
- would not be an undue hazard to the safety of people exposed to them during their handling or people using anything containing their residues;
- would not be likely to have an effect that is harmful to human beings; and
- would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment.
Because of these concerns, it is appropriate that registrations and approvals associated with arsenic be subject to reconsideration under Part 2, Division 4, of the Agvet Codes.

The APVMA’s review will examine the following matters relevant to product registrations and label approvals for arsenic (as appropriate):

- the potential for adverse health effects associated with products containing or treated with arsenic (CCA or arsenic trioxide);
- the environmental effects from the use and disposal of CCA or arsenic trioxide products; and
- the appropriateness or adequacy of label information.

Registrants will be required to undertake certain actions aimed at securing relevant data that might address these matters. However, the public is invited to make submissions to the review regarding any of the matters raised in this scope document (see Section 8).

4. REGULATORY STATUS AND USE PATTERNS IN AUSTRALIA

4.1 Products

As at February 2003 there were nine (9) registered timber preservative products containing CCA and three (3) termite treatment products containing arsenic trioxide. Termite treatment products are formulated as dusts, with timber preservatives available as aqueous concentrates, blending concentrates, liquids, liquid concentrates and pastes.

4.2 Current use patterns

Arsenic is registered for use in the control and prevention of damage to timber and timber structures by insects (termites, borers, beetles), wood rot, wood fungus and general timber decay.

Timber is treated with CCA chemicals in specially designed treatment plants using vacuum pressure impregnation processes to protect sapwood from insect and fungal decay. In CCA formulations, copper acts as a fungicide, arsenic acts against insects and chromium fixes the chemicals in the timber to resist leaching. The strength of CCA treating solution can be varied depending on the conditions under which the timber will be used (Norton 1998).

As termite treatments, arsenic dusts are applied to timber both inside and outside the home as well as to living trees where necessary. Within buildings small amounts of product (1-2 g) are dusted into the termite workings with a hand blower. Once applied the treated areas are sealed (with tape) and left undisturbed for 10-20 days. For termite control outside buildings and in tress, only small amounts of the powder are applied, via drilled holes. Application is by hand blower.

5. TOXICOLOGICAL ISSUES

Recently available information relating to the release of arsenic from the surface of treated timber appears to question previous knowledge that CCA was not released from treated wood.
If this is the case, there might be greater potential for human exposure to arsenic while handing and using items constructed from treated timber than was previously thought.

Potential human exposure to arsenic from CCA is thought to arise from treated timber in playground equipment and other timber structures, possibly through transfer of timber surface residues to the hands.

Recent research conducted by the United States Consumer Product Safety Commission (CPSC) has suggested that arsenic might be more carcinogenic than previously recognised, that arsenic is present at significant concentrations on CCA-treated timber and in underlying soil, that the health risks posed by this timber are greater than previously recognised and that past risk assessments in the US were incomplete (CPSC 2003).

New test results from a home sampling program conducted in the US suggest that the levels of arsenic in tested timber may remain high for 20 years (EWG 2002).

There is some evidence to suggest that there may be some degree of exposure during handling or when using items treated with CCA. There are little data on the availability of arsenic from the surfaces of treated timber and this appears to be the main focus of international concerns. However the recent information from the US will assist assessment of the concerns raised in this scope document.

There are suggestions that the burning of CCA-treated timber in homes or in open grounds may result in air emissions of arsenic that may give rise to increased risks of lung cancer. There is also evidence in the literature suggesting acute health effects in families burning such wood in their home (CSTEE 1998). The reconsideration will examine this source of exposure and its impacts on human health.

The use of arsenic-based termite treatment products both inside and outside the home may also have implications for human health and the environment.

6. ENVIRONMENTAL ISSUES

Environmental concerns regarding CCA timber treatments mainly relate to the potential contamination of sites where timber has been treated and where treated timber is disposed. CCA has been extensively used in the past as a timber treatment and there may be the potential for some sites to have been contaminated due to the leaks and spills from treatment plants or drips from freshly treated timbers.

Other possible areas of concern are where treated timbers may have slowly degraded and released the treatment chemicals into the ground, with possible subsequent mobility to other areas and effects on non-target organisms.

The burning of arsenic-treated timber is of environmental concern as the smoke and ash contain high levels of copper, chrome and arsenic, all of which can be toxic to the environment.
7. INTERNATIONAL REGULATORY STATUS OF PRODUCTS CONTAINING CCA

There has been a significant level of action taken internationally in relation to the continued availability and use of CCA timber treatment products.

**US Environmental Protection Agency (US EPA)**

On 12 February 2002, US EPA announced a voluntary decision by industry to move away from timber treatments containing arsenic by December 31 2003, in favour of new alternatives. This transition affects virtually all residential uses of wood treated with CCA, including wood used in play-structures, decks, picnic tables, landscaping timbers, residential fencing, patios and walkways/boardwalks. US EPA will not allow CCA products to be used to treat wood intended for any of these residential uses from 1 January 2004.

The US EPA has not concluded that there is unreasonable risk to the public from these products, but is of the view that any reduction in exposure to arsenic is desirable. This action comes ahead of the US EPA completing its regulatory and scientific assessment of CCA.

**United States Consumer Products Safety Commission (CPSC)**

More recently (February 2003) a report by the United States CPSC raised further concerns about the potential health risks associated with CCA-treated timber in playgrounds.

**PMRA Canada**

Canadian regulatory authorities are working in collaboration with the US EPA to effect similar actions in Canada.

**Commission of the European Communities**

A risk assessment conducted by the EC Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) noted that the main risks associated with CCA were those to human health from the disposal of timber treated with CCA and in particular risks to children’s health from the use of CCA–treated timber in playground equipment. The CSTEE raised further concerns regarding the potential for children to be exposed to CCA through ingestion and/or inhalation of sand particles in playground equipment. They concluded that arsenic is both carcinogenic and genotoxic. The CSTEE also identified a risk to the aquatic environment in certain marine waters.

The CSTEE considered that there are serious knowledge gaps in relation to arsenic-treated timber in landfills. It concluded that it would be advisable to exercise caution by limiting the use of arsenic-based timber treatment to those situations where it is "absolutely necessary" (such as railway sleepers, electric power transmission and telecommunication poles and in cooling towers). Member states are to adopt and publish the provisions necessary to comply with the EC directive (2003/02/EC) by 30 June 2003 and apply the provisions by 30 June 2004.

The EC will review timber treatment products. Full dossiers for evaluation must be presented by 28 March 2004.
ERMA New Zealand

ERMA are investigating the claims of a report by a US scientist, Dr Richard Maas, entitled “Release of total chromium, chromium VI and total arsenic from new and aged pressure treated lumber”. It has commissioned a study on CCA, which will consider the Maas report and other available information about the public health risks related to the use of CCA treated timber particularly around homes and in children’s playgrounds. The resulting report, expected to be available by the end of February 2003, will provide advice as to whether the levels of public and occupational health risk may justify further regulatory action.

7. NEXT STAGES IN THE REVIEW

The formal review will now commence and will deal with the aspects outlined in this scope document.

Interested parties are requested to provide data addressing the issue raised in this scope document. These must reach the APVMA by no later than 31 May 2003. Submissions can be sent either by email to chemrev@apvma.gov.au or by mail to:

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7.1 Announcement of the review

The availability of the review scope document coincides with the APVMA’s formal announcement of the review. Registrants are separately notified of their responsibilities as part of this review.

7.2 Data assessment

The Therapeutic Goods Administration (TGA) and Environment Australia (EA) will conduct the technical assessment of data submitted for the review of arsenic. These agencies will advise the APVMA about the concerns identified in sections 5 and 6.

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

1. The APVMA is satisfied that products containing arsenic (and/or their labels) continue to meet the conditions to which registration or approval are currently subject and affirms the registration and/or approvals; or
2. The APVMA is satisfied that the conditions to which the registration and/or approval is currently subject can be varied in such a way that the requirements for continued registration or approval will be complied with, and varies the conditions of approval or registration; or
3. The APVMA is not satisfied that the conditions continue to be met and suspends or cancels the registration or approvals.
7.3 Consultation throughout review process

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

The draft of the review report summary along with proposed recommendations will be made available for comment to stakeholders and the public via the APVMA website or direct communication.

The availability of both draft and final reports will be announced publicly. Major stakeholders will be approached directly and all reports will be made available on the APVMA website.
Appendix 1: References


Appendix 2: Registered products containing arsenic

<table>
<thead>
<tr>
<th>Product No</th>
<th>Product Name</th>
<th>Registrant</th>
<th>Label Number(s)</th>
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<tbody>
<tr>
<td>30691</td>
<td>Tanalith CP Wood Preservative Paste</td>
<td>Koppers Arch Wood Protection (Aust) Pty Limited</td>
<td>Ψ</td>
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<tr>
<td>39884</td>
<td>Tanalith O Type C Oxide Wood Preservative</td>
<td>Koppers Arch Wood Protection (Aust) Pty Limited</td>
<td>Ψ</td>
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<td>40092</td>
<td>Impretect CS</td>
<td>Osmose Australia Pty Limited</td>
<td>40092/0698</td>
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<tr>
<td>41482</td>
<td>Impretect CO</td>
<td>Osmose Australia Pty Limited</td>
<td>41482/0698</td>
</tr>
<tr>
<td>41680</td>
<td>Sarmix 3 CCA Salts</td>
<td>Osmose Australia Pty Limited</td>
<td>Ψ</td>
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<tr>
<td>41681</td>
<td>Sarmix Oxcell C-680 For Timber Treatment</td>
<td>Osmose Australia Pty Limited</td>
<td>41681/0698</td>
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<td>51821</td>
<td>A&amp;C CCA Salt Wood Preservative</td>
<td>A&amp;C Chemicals Pty Ltd</td>
<td>51821/0799</td>
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<td>51822</td>
<td>A&amp;C CCA Oxide Wood Preservative</td>
<td>A&amp;C Chemicals Pty Ltd</td>
<td>51822/0899</td>
</tr>
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<td>55939</td>
<td>Timtech C Oxide Wood Preservative</td>
<td>Timtech Chemicals Pty Limited</td>
<td>55939/1002</td>
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<td>48410</td>
<td>Aldi Arsenic Trioxide Termite Dust</td>
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<td>48909</td>
<td>Garrard’s Termite Powder Insecticide</td>
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<td>48909/01</td>
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<td>51234</td>
<td>One Bite Arsenic Trioxide Termite Treatment</td>
<td>Young’s Enterprises Pty Ltd</td>
<td>51234/1098</td>
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</table>

Ψ Label deemed approved at the commencement of the Agvet Codes and so not having an approval number.