



# Green Cleaning

new sustainable systems for cleaning milking machines

## **Regulatory Issues for Trial Work on Commercial Dairy Farms in Victoria**

*27<sup>th</sup> August 2010*



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*in association with*

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## Disclaimer

This report is for the use of the Green Cleaning project's Industry Partners and stakeholders and for no other purpose. No responsibility is accepted in relation to any third party who may use or rely on the whole or any part of this report.

This report aims to provide some guidance in approach to comply with complex State and Territory legislation as it relates to participation in the Green Cleaning project, specifically the trailing of dairy cleansers and sanitisers in CIP re-use systems for farm milking machines in the State of Victoria.

The information contained within this report should not be relied upon to cover every situation which may be encountered on every farm. Individual companies are encouraged to seek their own legal advice or contact the relevant regulatory Authority directly before commencing trial work. Additional non-statutory controls (particularly those implemented through commercial supply contracts) may also place additional restrictions on the ability of individual farms to participate and should be investigated.

The National Registration Scheme as it applies to dairy cleansers and sanitisers is currently being reviewed and changes to the current controls are likely. Whilst this report is current as of 27<sup>th</sup> of August 2010, it is the responsibility of individual companies to seek and apply the appropriate controls whilst undertaking their trial work.

The material presented in this report is based on sources that are believed to be reliable. Whilst every care has been taken in the preparation of the report, AgVet Projects Pty Ltd gives no warranty that the said sources are correct and accepts no responsibility for any resultant errors contained herein or any damages or loss, whatsoever caused or suffered by any individual or corporation.

## Introduction

The Green Cleaning project was initiated by industry in 2008 to research, develop and then commercialise new clean in place (CIP) systems for dairy milking equipment. 'Green Cleaning' systems use low temperature, re-use and energy efficiency principles to save energy, water and chemicals. After initial trial work was successfully completed by AgVet Projects, commercial dairy equipment and chemical companies are aiming to set up their own trial sites on a number of commercial dairy farms in Victoria.

For the commercial companies, the purpose of this new trial work is to:

- further develop and refine the designs of their equipment;
- test and refine their chemical formulations;
- test and define the operating and maintenance parameters for the cleaning system; and
- collect data to support an application for the registration of the chemicals by the APVMA.

For the farmers, milk factories and dairy food safety regulators, the purpose of the new trial work is to:

- collect data to validate the results obtained by the initial trial work;
- identify any inherent risks and determine if any special risk management procedures are required before the new systems are adopted more widely;
- Ensure the operation of the systems is consistent with regulatory requirements.

The purpose of this document is to provide a common understanding of the 'chemical' and 'food safety' regulatory requirements associated with conducting 'Green Cleaning' trial work on Victorian dairy farms. The focus is on ensuring that the risks to food safety are effectively managed whilst the commercial companies and the industry learns more about these new cleaning systems.

The document is divided into two parts. The first part is primarily for the commercial companies ('Industry Partners') who are seeking to set up a trial on a commercial farm. The second is for farmers, milk factory staff and regulators who may be involved with trial work on specific farm sites. Information, instructions, example application forms and permits are appendicised.

## Part 1. For Industry Partners

### Chemical supply and use issues

Industry Partners must obtain a 'Minor Use' Permit from the APVMA to legally supply and/or use unregistered dairy chemicals in Victoria. A Minor Use Permit may also be required to use registered dairy chemicals off-label in Victoria under certain circumstances (esp. if used at a dose rate higher than that stated on the label).

The Green Cleaning project has negotiated a 'template' Minor Use – Research Permit to be issued to companies wishing to undertake further Green Cleaning trial work on commercial dairy farms. Each company will need to individually apply to the APVMA for this permit, using the partially completed application form (see Appendix 1).

The scope and conduct of the trial work undertaken by the Industry Partner must fall within certain constraints to be eligible for the 'template' permit. These are clearly outlined in the 'template' permit (see Appendix 2) and include:

- limiting the location of the trials to dairy farms within Victoria;
- limiting the types of chemicals to be trialled (to those containing well recognised, low risk ingredients); and
- conducting the trials after the farmers has obtained approval from Dairy Food Safety Victoria (DFSV) the dairy company supplied by the farm.

Limiting the scope of the trials has allowed the APVMA (and the dairy industry) to pre-assess the risks from trial work and so ensure these risks are adequately managed through the template Permit's conditions. The timeframes and costs of obtaining a Minor Use Permit from the APVMA will be significantly reduced by limiting the scope of trial work to that covered under a 'template' permit.

Companies that have chemicals or farm circumstances that do not meet the 'template' permit requirements will need to apply for a Category 23 Minor Use Permit. This will be assessed by the APVMA through their normal processes.

### Food safety issues

Victorian dairy farmers can only produce milk for human consumption under licence from Dairy Food Safety Victoria (DFSV). A condition of licence is that the dairy premises must have and implement an approved, documented food safety plan. Farm food safety plans usually follow a

'generic' food safety plan developed by the milk company that the farm supplies. These 'generic' company food safety plans are based on HACCP principles outlined in the Code of Practice for Dairy Food Safety (DFSV 2002).

The food safety plan for every licensed dairy premises operating in Victoria will have already been approved by DFSV. Most farm food safety plans will specify that the detergents and sanitisers used on surfaces that come into contact with milk are registered by the APVMA and are used according to label directions (requirement 3.2.2.1 in DFSV's Code of Practice). Therefore the existing food safety plans on trial farms will need to be modified to allow unregistered and 'off-label' chemical use for trial work on licensed dairy farms in Victoria.

Modifying the farm's food safety plan is a fairly simple matter and needs to be undertaken by the dairy licence holder (farmer) in association with the milk factory they supply. Some draft paragraphs to insert into the farms food safety plan are shown in Appendix 3 but variation between farm plans is to be anticipated.

Once the modifications have taken place to allow the use of trial chemicals, the farm's new food safety plan will need to be submitted to DFSV for approval. The trial work can only proceed once written approval has been received back from DFSV. This procedure is the responsibility of the farmer and is explained in more detail in Part 2.

## Part 2. For Farmers and Milk Company Staff

### Food safety issues

Victorian dairy farmers can only produce milk for human consumption under licence from Dairy Food Safety Victoria (DFSVM). It is a condition of licence is that the dairy premises must have and implement an approved, documented food safety plan.

The farm's food safety plan usually follows a 'generic' food safety/milk quality program developed by the milk company and will have already been approved by DFSVM to allow the farm to supply milk in the current year.

Most farm food safety plans will specify that the detergents and sanitisers used to clean milking machines are:

- registered by the Australian Pesticides and Veterinary Medicines Authority (APVMA); and
- are used according to label directions.

Most of the chemical cleaning regimes being trialled for use in the 'Green Cleaning' systems by our Industry Partners are based on using new formulations of existing products (unregistered chemicals), or existing products in novel ways ('off-label' use). Therefore the existing food safety plans for most trial farms will need to be modified to ensure the conditions of the farm's dairy licence are not breached.

Modifying the farm's food safety plan is a fairly simple matter. The sections regarding the use of agricultural chemicals and dairy cleaning procedures need to be examined in collaboration with your dairy company representative and if required, a variation appended. An example variation for insertion into the farm's food safety plan is given in Appendix 3.

The example variation will allow the use of unregistered chemicals and registered chemicals 'off-label' under approval of the APVMA. The Industry Partners have the responsibility of securing APVMA approval in the form of a Minor Use – Research Permit (see Part 1). The APVMA has set some strict criteria for the Industry Partners before they get issued with this Permit. Some of the Permit conditions relate to how the trial will be undertaken on farm, and so the Permit conditions should be a point of discussion between the farmer, the dairy company's representative and the Industry Partner in charge of running the trial. An example APVMA Minor Use Permit that has been tailored to the 'Green Cleaning' trial work is shown at Appendix 2.

Once the required modifications to the farm's food safety plan have been determined, the farm's new food safety plan will need to be submitted to DFSV for approval. The responsibility for this task rests with the farmer (as the dairy licence holder), although the milk company should be able to support them in this process. An example application letter and food safety plan variation are shown in Appendix 3 and would meet DFSV requirements.

Written approval from DFSV must be received before the trial work can commence. This approval will then form a part of the farm's food safety plan.

Notification to DFSV should also be sent when finishing the trial work.

## Appendices

1. Instructions and application for a Minor Use Research Permit (Category 23) – Green Cleaning project template APVMA application form
2. Model AVPMA Minor Use Research Permit - Permit to allow the supply and use of chemicals in the conduct of trials to evaluate chemical re-use systems for cleaning farm milking equipment
3. Application to DFSV to vary a dairy farm's food safety plan

# Appendix 1

**Instructions and Application for a Minor  
Use Research Permit (Category 23)**

# Instructions from the APVMA for Industry Partners

## Requirements for Industry Partners in lodging research permit applications with APVMA

Suppliers of unregistered products for the conduct of trials to evaluate chemical re-use systems for cleaning farm milking equipment will need to individually apply to the APVMA for research permits.

The APVMA is open to consideration of applications that allow for some flexibility in the products (active ingredients and formulations) to be used. As a guide these should be within the scope of those details and requirements contained in the attached document (draft permit template).

Applicants (suppliers) should submit:

1. A completed APVMA permit application form (Category 23 Research Permit Application) and submit the necessary permit fee of \$665;
2. Copies of draft labels for the corresponding product labels containing the relevant instructions for use and handling the product to be supplied to trial collaborators;
3. Details on the quantity of product to be used, numbers of locations/properties involved (if known) and details of trial collaborators should be contained within the application form;
4. A modified version of the draft permit, including nominations for the active constituents proposed and their maximum level;
5. The application form should nominate/list the range of non-active ingredients to be used in formulated products including their maximum level, and
6. A discussion of any additional measures to be implemented to ensure that no unacceptable residues occur in milk.

Completed application forms and accompanying supporting information as outlined above should be submitted to:

The Screening Officer  
Australian Pesticides & Veterinary Medicines Authority  
PO Box 6182  
Kingston ACT 2604

For additional enquiries relating to permit applications please contact:

Alan Norden  
Manager, Minor Use  
APVMA  
Ph: 02 6210 4769  
[alan.norden@apvma.gov.au](mailto:alan.norden@apvma.gov.au)

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**Australian Government**  
**Australian Pesticides and  
Veterinary Medicines Authority**

**Category 23**

## Application for a Research Permit

| 1. FEE & CATEGORY DETAILS (MUST BE COMPLETED)  |            |                         |  |
|--|------------|-------------------------|--|
| Proposed category number: <b>23</b>  |            | Fee enclosed: \$ 665.00 |  |
| <i>Refer to Ag MORAG or Vet MORAG on the APVMA website for a description of Category 23 requirements</i>   |            |                         |  |
| This research permit application is for trial use of agricultural or veterinary chemical products in a (check one box only):                           |            |                         |  |
| <input checked="" type="checkbox"/> field trial (includes trials involving growers / farmers under minimal supervision)                                |            |                         |  |
| <input type="checkbox"/> product evaluation trial  |            |                         |  |
| <input type="checkbox"/> research facility (includes small scale trials that are not covered by small scale trial permit PER7250)                      |            |                         |  |
| The proposed research involves (check one box only):   |            |                         |  |
| <input type="checkbox"/> unapproved / 'off'-label' use of a registered agricultural or veterinary chemical product                                     |            |                         |  |
| <input type="checkbox"/> use of an unregistered agricultural or veterinary chemical product  |            |                         |  |
| 2. APPLICANT/REGISTRANT CONTACT DETAILS (MUST BE COMPLETED)  |            |                         |  |
| Full name of applicant/registant (can be a company):   |            |                         |  |
| Name of contact person:  |            |                         |  |
| Position/title:  |            |                         |  |
| ACN / Overseas equivalent number:  |            |                         |  |
| Street address:  |            |                         |  |
| Postal address:  |            |                         |  |
| Email:   | Telephone: | Facsimile:              |  |
| 3. APPROVED PERSON DECLARATION (MUST BE COMPLETED)   |            |                         |  |
| <i>I hereby declare that the information provided with this application is complete and correct.</i>   |            |                         |  |
| Full name of approved person (can be a company):   |            |                         |  |
| Position/title:  |            |                         |  |
| Postal address:  |            |                         |  |
| Name of contact person in the company:   |            |                         |  |
| Email:   | Telephone: | Facsimile:              |  |
| Correspondence about this application should be addressed to: <input type="checkbox"/> Applicant/registant or <input type="checkbox"/> Approved person |            |                         |  |
| Signature (MUST be in ink): _____ Date: _____  |            |                         |  |
| <i>False declaration may lead to prosecution under the Agricultural and Veterinary Chemicals Code Act 1994.</i>  |            |                         |  |

NOTE: When an applicant elects to appoint a different approved person, a letter of authority is required. Refer to MORAG Volume 1 'Procedures for making an application' for additional information on approved persons.

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| <b>4. REGISTERED PRODUCT DETAILS (IF APPLICABLE)</b>                         |
|--|
| If the product to be used is registered in Australia complete the following: |
| <b>Product name:</b>   |
| <b>APVMA product number:</b>   |

| <b>5. UNREGISTERED PRODUCT DETAILS (IF APPLICABLE)</b>  |
|---|
| <b>Product name:</b>  |
| <b>Product name:</b>  |
| <i>(If more than one product, provide product names and formulation details as an attachment to this application)</i> |

| <b>UNREGISTERED PRODUCT FORMULATION DETAILS</b>  |
|--|
| <b>Column One:</b> For every constituent, provide the following information:-  |
| <ul style="list-style-type: none"> <li>Common chemical name of the constituent, including purity if applicable (eg 93% purity, sufficient to give 100 g/L) (Australian approved names to be used where they exist, trademarked names not to be used on their own)</li> </ul>   |
| <b>Column Two:</b> For each constituent, provide the Chemical Abstract Service Registry Number (CAS Number) where available  |
| <b>Column Three:-</b>  |
| <ul style="list-style-type: none"> <li>If a constituent is manufactured to an APVMA active constituent Standard, quote the relevant active constituent approval number (eg. 50001); OR</li> <li>If a constituent is manufactured to an acceptable compendial Standard, quote the standard and the year (eg BP2004); OR</li> <li>If a constituent is manufactured to a manufacturer's specification, mark 'MS' and ensure that a copy of the specification issued by the manufacturer is included with Chemistry &amp; Manufacture data.</li> </ul> |
| <b>Column Four:</b> Nominal concentration of the constituent, including overages & allowing for purity (eg. g/kg, g/L, mg/tablet).   |
| <b>Column Five:</b> The purpose or purposes of the constituent (eg. active, binder, solvent, preservative).  |

| Column One               | Column Two | Column Three         | Column Four   | Column Five            |
|--------------------------|------------|----------------------|---------------|------------------------|
| Constituent name         | CAS number | Constituent standard | Concentration | Purpose in formulation |
| (a) Active constituent/s |            |                      |               |                        |
|                          |            |                      |               |                        |
| (b) Other constituent/s  |            |                      |               |                        |
|                          |            |                      |               |                        |

|  |  |  |
|--|--|--|
| Total weight/weight (solids, semi-solids) or weight/volume (liquids)   |  |  |
| Specific gravity (SG) (liquids only)   |  |  |
| Formulation type: (eg. pour-on, tablet, powder, paste, aerosol, wettable powder, emulsifiable concentrate etc.)  |  |  |
| Does the product contain any ingredients with a risk of transmitting agents of animal spongiform encephalopathies?    No   | Does the product contain genetically-modified organisms or products?    No |  |
| For imported ingredients of biological origin, copies of relevant AQIS Permits to Import Quarantine Material or a copy of the completed application form must be attached <span style="float: right;">Attached <input type="checkbox"/></span> |  |  |

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## 6. IMPORTATION DETAILS FOR UNREGISTERED PRODUCT

**Check one box only:**

- Unregistered product is not imported into Australia.
- for unregistered veterinary products manufactured in Australia, provide the formulator's MLS licence No:
- Unregistered product is imported into Australia.
- application should be made for a Consent to Import for unregistered products that require importation – see <http://www.apvma.gov.au/qa/consent.shtml>
- Quantity imported/to be imported:  
Port or location entering  
Australia:  
Estimated date of arrival:  
Importing agent/s:  
Name of formulator of product:  
Street address of formulator:

For veterinary products provide evidence of the overseas formulator's GMP compliance as an attachment to this application.

## 7. SUPPLIER OF UNREGISTERED PRODUCT

Name of supplier:

Address of  
supplier:

## 8. PROPOSED USE OF PRODUCT UNDER PERMIT

|  |   |
|--|---|
| Target crop, or situation, or animal   | Dairy farm milking machines   |
| Disease or pest or purpose   | Cleaning and sanitising milking machines  |
| Application rate or dose rate  | Alkaline detergent: Name & conc.<br>Acid detergent/sanitiser: Name & conc.<br>Other (specify): Name & conc. |
| Timing and frequency of applications or doses  | After each milking  |
| Method of application or route of administration   | Mechanically dosed CIP re-use system  |
| If relevant, period between last application or last dose, and harvest or grazing or slaughter or milking (withholding period) | N/A   |
| Any special precautions  | As per draft permit conditions  |
| Extent of proposed use (eg area or quantity of crop to be treated, or number of animals, number of farms)                      | [Insert number of farms (max 25)]   |
| Date and duration of the trial   | Until 31 <sup>st</sup> December 2012  |
| Location of proposed trial   | VICTORIA only<br><br>Specific locations (if applicable):<br>Full list retained by applicant                 |

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Persons to be covered by the permit:  
(*check the most relevant*)

- All persons undertaking the trial are direct employees of the applicant.
- One or more nominated individuals (trial collaborators). *Provide details below.*
- Trial collaborators have not yet been finalised. *Provide reason below.*

Details of persons involved in the research trial (*if applicable*):

[insert your company] will be responsible for the trial at each farm site and the collation of data. The farm manager and staff will be helping on a day to day basis. The milk company that collects milk from the farm will be advised of activities and will be actively monitoring and reporting on the quality and safety of the milk, in association with Dairy Food Safety Victoria.

Details of persons who hold an animal research licence (*veterinary chemicals only*):

N/A

**Veterinary chemicals only:** This section is not applicable

## 9. FOOD RESIDUES AND FATE OF PRODUCE (MUST BE COMPLETED)

Indicate as appropriate:

- proposed research use is **NOT FOOD-PRODUCING**.
- proposed research use **IS FOOD-PRODUCING**. Produce from the trial will be disposed of in a manner that will not result in consumption by humans or animals.

**Specify method of disposal of produce in residues section (subpart 1.5) of the Application Overview.**

- proposed research use **IS FOOD-PRODUCING**. Produce from the trial will be supplied or otherwise made available for consumption by humans or animals. **Scientific argument must be provided in residues section (sub-part 1.5) of the Application Overview, and complete one of the following:**
  - The current MRL will not be exceeded when the product is used as proposed.
  - A temporary MRL is proposed for the commodities involved. Residue data to support the establishment of the temporary MRL have been provided with this application.
  - The proposed research use will not result in any detectable or quantifiable residues.

## 10. EXPORT OF PRODUCE FROM TRIAL

Check one box only:

- produce from the trial will not be exported.
- produce from the trial will be exported. **Provide details of destination countries and relevant overseas residue/tolerance limits in residues and trade section (sub-part 1.5) of the Application Overview.**

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## APPLICATION OVERVIEW

Refer to MORAG Volume 3, Part 1 explanatory notes when completing this section.

The application overview sub-parts 1.1 — 1.10 should not exceed 20 pages.

### 1.1 Introductory Information

#### (a) Completed application form

*[The completed application form is all that is required for section 1.1 (a)]*

#### (b) Executive summary

*[Describe the purpose of the application and your reasons for submitting the application. Provide justification for the application]*

*[Briefly summarise the issues associated with the application]*

To conduct trials to refine the final chemistry and test the efficacy of chemical solutions to clean milking machines using a Clean-In-Place (CIP) chemical re-use system as a part of the Green Cleaning project.

#### (c) Quantity likely to be used for the duration of the permit

*[Estimate the quantity of product likely to be used for the duration of the permit.]*

**[Estimate total quantity of each concentrate to be used in trial (all farms)]**

#### (d) Registration status overseas for this and related formulations

*[Provide details of any known current or previous applications or approvals in other countries for products containing the same active constituent]*

**[Insert]**

#### (e) Related submissions before the APVMA

*[Give the status of any previous or current applications that you have made to the APVMA for any other product containing this active constituent]*

**[Insert if any]**

#### (f) Indicate whether the data presented with this application contradicts or changes the conclusions made from data provided previously

Not applicable

### 1.2 Chemistry and Manufacture

*[Declare whether a separate chemistry (Part 2) dossier/s has been provided. If a separate Part 2 has not been provided, justify why it should not be required]*

*[Briefly (in one paragraph) summarise any stability studies that have been submitted in Part 2]*

*[For unregistered products insert the product's batch release and expiry specifications here]*

Ingredients limited to those of known chemistry as listed on Schedule A of draft permit.

|          |                             |                   |               |
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## 1.3 Toxicology

*[Declare whether a separate toxicology (Part 3) dossier/s has been provided. If a separate Part 3 has not been provided, justify why it should not be required]*

*[Briefly summarise any toxicology studies that have been submitted in Part 3]*

Ingredients limited to those of known toxicity as listed on Schedule A of draft permit.

## 1.4 Metabolism & Kinetics

*[Declare whether a separate metabolism & kinetics (Part 4) dossier/s has been provided.*

*If a separate Part 4 has not been provided, justify why it should not be required]*

*[Briefly summarise any metabolism & kinetics data that have been submitted in Part 4]*

Not applicable

## 1.5 Residues and trade considerations (food crops/animals only)

*[Declare whether a separate residues & trade (Part 5) dossier/s has been provided.*

*If a separate Part 5 has not been provided, justify why it should not be required]*

*[If a Part 5 dossier has been provided, insert below the summary section of the residues studies (Part 5A) and any trade data (Part 5B)]*

Milk companies will be managing the risks to domestic and international markets.

Food safety risks are managed by the farm's food safety plan which is approved by Dairy Food Safety Victoria.

## 1.6 Occupational Health and Safety

*[Declare whether a separate OH&S (Part 6) dossier/s has been provided.*

*If a separate Part 6 has not been provided, justify why it should not be required]*

*[Briefly summarise any OH&S data that have been submitted in Part 6]*

Chemicals will be mechanically dosed from their containers, eliminating exposure of farm workers to the concentrate.

Waste / uncaptured chemical wash solutions are discharged into the dairy's effluent system.

## 1.7 Environmental Safety

*[Declare whether a separate environment (Part 7) dossier/s has been provided.*

*If a separate Part 7 has not been provided, justify why it should not be required (for non-biological veterinary products applicants must address VICH Phase I criteria)]*

*[Briefly summarise any environmental data that have been submitted in Part 7]*

Chemical solutions will be discharged into the farm's effluent system before being diluted and distributed onto the farm. Effluent will not leave the farm.

## 1.8 Target Species Efficacy and Safety

*[Declare whether a separate efficacy & safety (Part 8) dossier/s has been provided.*

*If a separate Part 8 has not been provided, justify why it should not be required]*

*[If a Part 8 dossier has been provided, insert below the summary section of the efficacy and safety studies]*

N/A

|          |                             |                   |               |
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## 1.9 Other Trade Aspects

*[Declare whether a separate non-food trade (Part 9) dossier/s has been provided.*

*If a separate Part 9 has not been provided, justify why it should not be required]*

*[Briefly summarise any non-food trade data/argument that have been submitted in Part 9]*

These risks are managed by the milk company.

## 1.10 Special Data

*[Declare whether a separate special data dossier/s (Part 10), relating to antibiotic resistance or genetically-modified organisms, has been provided.*

*If a separate Part 10 has not been provided, justify why it should not be required]*

*[Briefly summarise any data on antibiotic resistance or GMOs that have been submitted in Part 10]*

[Insert if any]

## Attachments

Attachments (where applicable) should be indicated in the table of attachments and attached to this Application Form and Overview.

### Table of attachments

| Attachment   | Attached? |
|--|-----------|
| Two copies of the product label (if product is unregistered) |           |
| GMP certificates/documentation                               |           |
| AQIS import permit (if relevant)                             |           |
| Letter of Authority for Approved Person                      |           |
| Animal Ethics Committee approval                             | N/A       |
| Other (specify)  |           |

### Please return the fully completed application to:

Attn. Mr. Alan Norden  
The Screening Officer  
Australian Pesticides & Veterinary Medicines Authority  
PO Box 6182  
Kingston ACT 2604

|          |                             |                   |               |
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# Appendix 2

**Model AVPMA Minor Use Research Permit -  
Permit to allow the supply and use of  
chemicals in the conduct of trials to  
evaluate chemical re-use systems for  
cleaning farm milking equipment**

# DRAFT PERMIT FOR CONSIDERATION

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## PERMIT TO ALLOW THE SUPPLY AND USE OF CHEMICALS IN THE CONDUCT OF TRIALS TO EVALUATE CHEMICAL RE-USE SYSTEMS FOR CLEANING FARM MILKING EQUIPMENT

Permit Number – PER [APVMA to complete]

This permit, is issued under section 114 of the Agvet Codes, to allow those persons stipulated below to conduct trials in Victoria, as defined in the conditions of use, with agricultural chemical active constituents or products, whether such active constituents or products are approved or registered or not.

The permit also allows those persons stipulated below to possess any active constituent or chemical product described below for the purposes described under this permit.

### Permit Holder:

XXXX

Address

Town, State

### CONDITIONS OF USE

#### 1. *Persons who can conduct trials under this permit:*

All persons who are trained or experienced in the handling and use of dairy cleansers and dairy sanitisers as part of their normal duties;

#### 2. *Jurisdictions in which this permit applies*

Victoria only

#### 3. *Products/Actives that can be used under this permit*

Chemicals and chemical constituents (actives and/or excipients) which are currently in products legally used to clean and/or sanitise food surfaces in Australia (see Schedule A).

The chemical products cannot include:

- new or novel active ingredients;
- any chemical constituent or chemical product where that active constituent or chemical product is prescribed by legislation in Victoria; or
- any active constituent or chemical product whose use has been prohibited under the Agricultural and Veterinary Chemicals (Administration) Regulations 2004.

Details of the chemical products to be used under this permit are given at Schedule C:

#### 4. *Purpose/Situation*

For the conduct of trials on licensed dairy farms to gather data about the efficacy, food safety and milk quality performance of chemical re-use systems for cleaning farm milking machines.

# DRAFT PERMIT FOR CONSIDERATION

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## **ADDITIONAL CONDITIONS**

5. The trial chemicals must be clearly labelled in accordance with the standard requirements of the Ag Labelling Code as shown in Schedule D. The label must clearly state that the chemical product is for research purposes only.
6. The chemical supplier must provide the farm manager with a copy of this permit and the relevant MSDS for the chemicals being evaluated.

### **OH&S risk management**

7. The undiluted chemicals must be dosed into the tanks directly from their containers, without being handled by the operator.

### **Food Safety risk management**

8. The farm owner and farm manager must have the written consent of the milk factory they supply to participate in the trial.
9. The permit holder must notify the milk quality manager of the milk factory supplied by the trial farm of the ingredients of any chemical formulation that is not routinely rinsed from the pipe work prior to the next milking, unless that chemical product has already been registered by the APVMA for this use.
10. Farms undertaking the trial must meet the requirements of their Dairy Licence.
11. A food safety program approved by Dairy Food Safety Victoria (DFSV) must be implemented to ensure appropriate systems are in place to isolate and withhold milk that is suspected of being unsuitable for sale. In these circumstances the farmer must contact their milk company representative and have the milk tested for its suitability for human consumption prior to release. DFSV must be notified if there is a potential risk to food safety.
12. Farms must have the written approval of Dairy Food Safety Victoria to vary their food safety plan in order to participate in the trial.

### **Environmental risk management**

13. Surplus (undiluted) chemical must be returned to the chemical supplier for disposal. Diluted chemical solutions discharged from the re-use system must be contained on the farm.
14. Chemical containers must be disposed of according to label directions.

### **Data Requirements**

15. The permit holder must keep and maintain for 2 years detailed records including:
  - the names of the persons conducting or controlling the trials;
  - the trial farms' contacts and addresses of where the trials are being conducted;
  - details about the trials conducted, including the dates that the trials were conducted, chemical formulations/products used, their rates and frequency of use;
  - the results of tests undertaken on trial farms, as specified in Schedule B; and
  - the method of disposal of the discharged chemical solutions.
16. The following information must be kept on farm and made available to the farm manager, their milk factory representative and/or food safety auditor during the trial period:
  - the name and contact details of the permit holder's representative for the trial;
  - the dates that the trials were conducted;
  - the names of chemicals being used and the main active ingredient(s); and
  - the chemical concentration and the dose rate required to achieve it.
17. The information specified in Condition 15 must be made available to the APVMA upon request.

**This permit remains in force until 31<sup>st</sup> December 2012.**

**DATED:** [APVMA to complete]

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## Schedule A:

### List of chemicals used singularly or in combination covered under this permit:

| Chemical class     | Active  | Description   | Registration status  |
|--------------------|---|---|--|
| Acid               | Sulfuric Acid   | Mineral acid  | In dairy cleansers currently registered by the APVMA. Eg. Klenz All Temp Acid Detergent Sanitiser, Albright Low Foaming Acid   |
|                    | Formic Acid   | Organic Acid  | Formic acid is included in the list of active constituents excluded from the requirements of APVMA approval but is not in any other currently registered dairy cleansers. Used widely as a terminal sanitiser in dairy manufacturing plants and breweries. |
|                    | Phosphoric Acid   | Mineral acid  | In dairy cleansers currently registered by the APVMA. Eg. APVMA Number 55486   |
|                    | Glycolic Acid   | Hydroxyl acid   | In dairy cleansers currently registered by the APVMA. Eg. APVMA Number 55486   |
| Alkali             | Potassium Hydroxide                                       | Inorganic alkaline salt                                       | In dairy cleansers currently registered by the APVMA. E.g. Milestone Dairykleen Alkaline Detergent for Milking Machines and Bulk Tanks, Dairy Power Assist Low Foam Pre-cleaning Additive  |
|                    | Alkaline salts  | Inorganic alkaline salt                                       | In dairy cleansers currently registered by the APVMA. E.g. Milestone Dairy Proof Foaming Sanitizer for Milking Machines  |
|                    | Sodium Hydroxide  | Inorganic alkaline salt                                       | In dairy cleansers currently registered by the APVMA. Eg. APVMA Number 30124   |
| Anionic surfactant | Dodecylbenzene Sulphonic Acid / alkyl aryl sulphonic acid | Wetting agent and antimicrobial agent under acidic conditions | In dairy cleansers currently registered by the APVMA. E.g. Dairy Power Defender Low Foam Acid Sanitiser (where the active is listed under the name alkyl aryl sulphonic acid)  |
| Antimicrobial      | Benzalkonium Chloride                                     | Quaternary ammonium compound                                  | In dairy cleansers currently registered by the APVMA. E.g. Milestone Dairy Proof Foaming Sanitizer for Milking Machines, Dairy Power Hysan Alkaline Dairy Detergent and Sanitiser, APVMA Number 55486  |
| Miscellaneous      | Various actives and excipients                            | These cover a multitude of functions in formulations          | Only chemicals which are:<br>APVMA Excluded AC;<br>Processing aids as per Standard 1.3.3 of the AFSANZ Code;   |

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|  |  |  |  |
|--|--|--|--|
|  |  | including solubilisation, stabilization, hydrotroping, viscosity modification, cloud point modification, wetting, defoaming, emulsifying, crystal modification, anti-lumping, sanitizer augmentation and other functions | AQIS General Acceptance; and/or NZFSA Man 15 Generic (Incidental Food Contact) |
|--|--|--|--|

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## Schedule B: Testing protocol

The following tests must be undertaken on each trial farm.

1. A test of the source water quality to assess its suitability prior to the commencement of the trial. As a minimum an assessment of water hardness, iron content, pH, suspended solids/turbidity and bacterial content is recommended.
2. Testing of the numbers of bacteria present in bulk milk collected for human consumption
  - Method - by a method approved by the milk factory supplied by the farm (usually Total Plate Count or Bactoscan)
  - Frequency – daily until the farmer and milk factory are satisfied that the performance of the re-use cleaning system is adequate, after which the frequency of testing will be determined by the milk factory.
  - Commencement – daily testing should commence a week prior to the new re-use system being put into operation for the first time and following any significant change to the operating parameters of the cleaning regime (for example to the concentration, temperature, time, water source etc).
3. Testing of the bulk milk for inhibitory substances
  - Method - by a method approved by the milk factory supplied by the farm
  - Frequency – as per normal milk factory policy
4. A visual inspection of each trial plant by a technically competent person at least twice during the data collection period, including at the commencement and the end of trialling the new chemical products.
  - Suggested sites for examination- inside of the claw bowl, inside of the milk line and inside of the receiveal can
  - A more thorough examination of the internal surfaces of the milking plant may be required if a build up of fat, protein or other deposits are identified at these sites.
5. Additional testing for chemical residues or other quality parameters if requested by the milk factory supplied by the farm

Note: The tests and data required for compliance with this permit may not be sufficient to support an application for full product registration or an application for a change to an existing chemical product's registration (ie a change to the approved label). Permit holders are advised to seek advice from the APVMA before starting trial work so that any additional data requirements can be accommodated.

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## Schedule C: Details of chemical products being trialled

| Chemical product 1   |
|--|
| <b>Product name:</b><br>(as per label)                                   |
| <b>Purpose of formulation:</b><br>(alkali/acid detergent, sanitiser etc) |
| <b>Product concentration:</b>  |
| <b>Dose rate:</b>  |
| <b>Maximum concentration in solution:</b>                                |
| <b>Active ingredient(s):</b>   |

| Chemical product 2   |
|--|
| <b>Product name:</b><br>(as per label)                                   |
| <b>Purpose of formulation:</b><br>(alkali/acid detergent, sanitiser etc) |
| <b>Product concentration:</b>  |
| <b>Dose rate:</b>  |
| <b>Maximum concentration in solution:</b>                                |
| <b>Active ingredient(s):</b>   |

| Chemical product 3   |
|--|
| <b>Product name:</b><br>(as per label)                                   |
| <b>Purpose of formulation:</b><br>(alkali/acid detergent, sanitiser etc) |
| <b>Product concentration:</b>  |
| <b>Dose rate:</b>  |
| <b>Maximum concentration in solution:</b>                                |
| <b>Active ingredient(s):</b>   |

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## Schedule D: Product labels

[Applicant to attach copies of labels]

# Appendix 3

**Application to DFSV to Vary a Dairy Farm's  
Food Safety Plan**

## **Instructions from DFSV for farmers and factory staff**

### Requirements for farmers in lodging applications to vary a food safety plan

Farmers intending to use unregistered chemicals or registered chemicals 'off-label' to clean their milking plant as a part of the 'Green Cleaning' trial need to first obtain written approval from DFSV to vary their food safety plan.

The application needs to be made by the Dairy Licence holder.

The applicant needs to provide details of the dairy farm premises, the milk company supplied and the chemical company undertaking the trial work. A proforma letter follows and can be used as a template.

The application letter should also include the variation/amendment which will be attached to the farm's food safety plan documentation. An example which is suitable for most food safety plans is provided and can be used as a template.

There is no application fee.

Applications should be sent to:

Attn. Dr Craig Miller  
Manager, Service Integration  
Dairy Food Safety Victoria  
PO Box 840  
Hawthorn, VIC 3122

Applicants cannot start the trial work until they have received written approval from DFSV, usually within 14 days.

For enquiries relating to applications please contact Craig Miller on (03) 9810 5900.

Your Name

Your Address

Re: Variation to Food Safety Plan

Date

Dear Sir,

I seek approval to vary my farm's food safety plan to participate in the 'Green Cleaning' trial work. The variations I seek will be appended to my farm documentation and are detailed overleaf.

Details:

|                      |        |      |
|----------------------|--------|------|
| Dairy License number |        |      |
| Business name        |        |      |
| Farm address         |        |      |
| Postal Address       |        |      |
| Contact name         |        |      |
| Contact details      | Mobile | Home |

|                       |      |       |
|-----------------------|------|-------|
| Milk company supplied |      |       |
| Supplier number       |      |       |
| Milk company contact  | Name | Phone |

|   |      |       |
|---|------|-------|
| Name of company responsible for conducting the 'Green Cleaning' trial work: |      |       |
| Company contact   | Name | Phone |

Please advise me if these changes meet with your approval.

Regards

Your Name

## Appendum to Food Safety Plan of a Dairy Premises

### Status

This variation forms part of the Food Safety Plan for dairy premises licence number .....

Date approved by Dairy Food Safety Victoria .....

### Use of detergent and sanitisers for cleaning milking machines

Dairy chemicals approved for use by the APVMA will be used to clean and sanitise milking machines after each milking. Approval can be in the form of a Minor Use Permit issued by the APVMA.

### Program for cleaning milking machines

Milking machines will be cleaned after each milking in accordance with written protocols under direction of the dairy chemical supplier.

### Record keeping

Additional farm records specified by the APVMA will be kept and made available on request.

### Validation

Dairy hygiene and food safety will be monitored in line with written protocols and dairy company requirements.