Procedure for Approval or Recognition of Dairy Maintenance Compounds

Purpose

The purpose of this document is to describe the MPI process for approving and/or recognising Dairy Maintenance Compounds (DMC). The register of approved and recognised DMCs is maintained by MPI and accessible on the MPI food safety website.

Status Categories

MPI maintains two categories of maintenance compounds to provide for intended uses of the product:

- "Approved" status is for DMCs which MPI has approved for use in farm dairy milking.
- "Recognised" status is for DMCs which are recognised for use in or near dairy processing operations; except where approval is required.

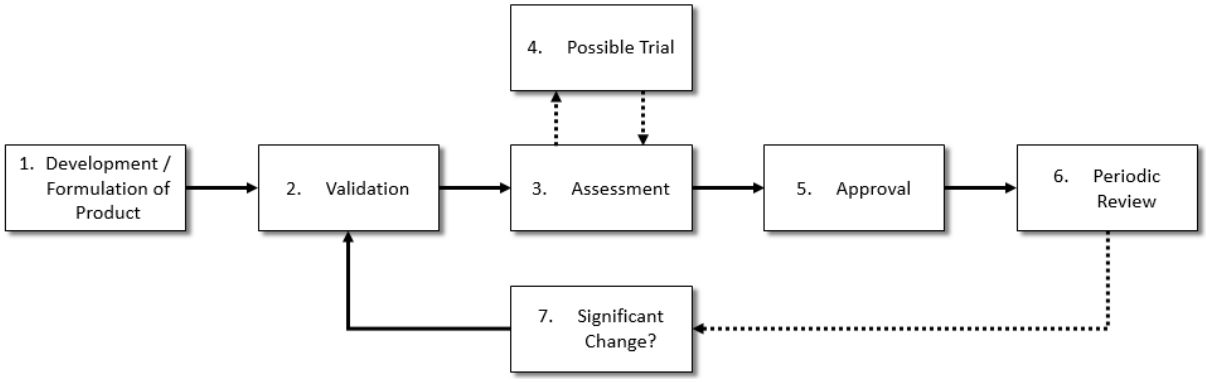
DMCs used in farm dairies must be approved by MPI as per Regulation 24(1)(d) of the Animal Products (Dairy) Regulations 2005. The primary purpose of this is to ensure as much as practicable that the product does not contribute to unfavourable materials in the raw milk.

The difference between the two categories is that while it is mandatory to use approved DMCs at the farm dairy, it is not mandatory to use recognised DMCs in dairy processing operations.

However, compounds used in dairy processing areas must be suitable for the intended purpose. MPI offers the recognised category under Regulation 30 of the Animal Products (Dairy) Regulations 2005 to assess and confirm the suitability of these DMCs using the same principle as those for approval, so that RMP Operators do not have to complete this independently. The alternative category allows for product uses other than direct contact with milking equipment.

A product can be either approved, recognised or both and MPI can attach conditions to the approval associated with any of these categories.

Process



1. Development / formulation of product:

The manufacturer develops/formulates the product and identifies the intended use(s), taking into account both domestic and export market requirements. Consideration must be given to any limitations that may apply, including those related to the characteristics of any water used or the cleaning system.

Chemical Restrictions

The chemicals used in maintenance compounds must not contaminate milk or dairy products. DMC must not contain any compounds on the List of Restricted Chemicals for use in Dairy Maintenance Compounds (currently being drafted).

2. Validation

DMCs must be fit for purpose and perform as designed under all intended uses. The applicant is responsible for gathering all relevant information and objective evidence to demonstrate this, including proposed label instructions which clarify the intended uses of the DMC.

3. Assessment

Applicants must obtain an assessment report on the product from an organisation accepted by MPI as competent to assess the suitability of the product for its proposed use(s) following MPI agreed criteria.

The assessment organisation will provide a report containing a recommendation based on the assessment. This will include, but not be limited to: information on the product; its formulation; proposed use of the compound; product label; supporting validation data.

The assessment report will identify whether the product has been confirmed as suitable for the proposed purpose when used in accordance with label instructions, or whether the product has been assessed as sufficiently suitable to allow further work to be undertaken within production environments in order to complete the validation requirements (i.e. suitable for provisional approval or recognition).

For further information on the assessment of DMCs, including detergents and sanitisers used to maintain the milking plant in farm dairies, contact:

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4. Field Trials

Field trials may be required to demonstrate efficacy of the DMC for the intended use as presented on the label and to assess residue carryover when used per label. See **Appendix 1 Field Trial Requirements**.

5. Approval

The applicant completes the *DPF 15: Application for Dairy Maintenance Compound Recognition* form and submits this to MPI along with the full assessment report, product label, any relevant supporting information – such as trial data and/or trial reports - and the prescribed fee. For formulated products MPI may require some of the information to be submitted in electronic form.

Approval or recognition:

MPI will process the application, taking into consideration the assessment report, and either:

i. Decline the application, or;

ii. Provide provisional approval or recognition for a particular reason, or;

iii. Approve as a dairy maintenance compound for use in farm dairy milking plant (with or without conditions), and/or;

iv. Recognise as a dairy maintenance compound for use in other dairy processing operations (with or without conditions).

Applicants must adhere to the scope of the approval/recognition and any conditions imposed.

Provisional statuses may be granted in situations where there is a lack of sufficient information to support full approval, but there is adequate information to allow use of the compound in a restricted or controlled basis. The primary use of this approval is for products intended to have direct contact with milking equipment surfaces and allows the applicant to obtain more data and/or fulfil all product use validation requirements, such as through on-farm trials.

MPI does not share confidential information, such as formulation details, with external parties without the consent of the applicant. As part of the approval process MPI may need to consult an expert panel or reference group to confirm the product suitability, particularly when international trade needs to be considered. On such occasions the applicants consent will be sought before any confidential details are shared.

6. Review

All approval or recognition statuses will be subject to periodic review. The review date will be determined by a number of factors and is at the discretion of the Director-General. A review may be under taken earlier if, in the opinion of the Director-General, the review is warranted for the particular approval or recognition concerned. As part of any review MPI may require further information from the original applicant.

A DMC that appears on the MPI register as being past the review date continues to carry the statuses identified.

7. Significant change to DMCs

The approval or recognition for a DMC applies to the information as submitted to MPI. Minor changes as defined in **Appendix 1: Field Trial Requirements** must be recorded but do not need MPI approval. More significant changes will require separate approval of the change by MPI. Likewise significant changes to the label, intended use and any name change will also require re-approval.

Withdrawal of approval or recognition

Approval or recognition may be withdrawn at any time should the Director-General believe that there is no longer sufficient evidence to support the compounds suitability for use. Such a determination would follow a review of the approval/recognition and any subsequent information gained, for example from residue monitoring, plant hygiene assessments, audits of dairy processing operations or modified label statements. Where possible, applicants would be advised in advance and have the opportunity to provide additional information. When withdrawing an approval or recognition the Director General of MPI may specify phase out periods to allow the product to continue to be used, but not sold.

Appendix 1: Field Trial Requirements

Field trials may be required to demonstrate efficacy of the DMC for the intended use as presented on the label and to assess rinsability and residue carryover when used per the label. MPI determines whether field trials are required, by granting a provisional status. The specific requirements of the field trial can be organised into two categories, with MPI determining which category applies. In some circumstances only a rinsability assessment, residue carryover test or an efficacy trial will be required. However for most new products all three of these trial components will be required. Full trial requirements may be waived for products that are already approved or recognised for use in a similar application, though rinsability assessments and residue carryover tests (point f and g below) are likely to be required unless suitable data has been collected.

Definitions

Minor change (no field trials required) is defined as:

- no more than two existing components affected (excluding water);
- neither compound changed by >10%;
- no new components added to formulation.

Situations where the product concentration is modified but the ingredients and their relative ratios are not changed and the working concentration does not change by more than 10% are also deemed to be minor changes.

Moderate change defined as:

- no more than two existing components affected (excluding water);
- component(s) changed by >10%;
- no new components added to formulation.

Major change defined as: addition of new components to formulation or changes to more than two of the existing components.

Trial requirements

1. Requirements for Moderate Formulation Change:
    a. Minimum 4 farm dairies, with at least 2 x Rotary and 2 x Herringbone
    b. Minimum trial period 8 weeks, consisting of:
        i. 1 week to establish the baseline levels prior to use of the trial compound;

ii. 6 weeks trialling the new product; and

iii. 1 week on return to an approved product.

c. Cleaning regime must be established prior to commencement and provided to the organisation undertaking the trial.

d. Each Farm Dairy Operator to confirm no deviation from the cleaning regime occurred throughout the trial (unless the trial is abandoned)

e. The applicant or their associates must not compromise the integrity of the trial at any time (no interventions or involvement permitted by applicant for last 4 weeks of the trial)

f. A rinsability (residue carryover) assessment is required to be undertaken once per farm dairy, and may be at any time prior to, during or after completing the efficacy trial (further details are set out below).

g. In addition, residue testing of the milk is required to be undertaken at least twice during the trial, with one sample taken during the first half of the trial and one taken in the second half of the trial. Samples are to be taken from the bulk milk tank (BMT) after the first row has been milked.

Note: The applicant is responsible for determining the most appropriate compounds to measure based on the formulation, the risk profile of the constituents, and the availability of accredited test methods.

h. Hygiene assessments of the milking plant are to be undertaken by a suitably qualified farm dairy assessor (unless MPI agree to an alternative person) immediately prior to commencement of the trial, 3 weeks into the trial, and at the completion of the trial. The hygiene assessment must consider any effect on rubber and silicone components.

i. APC/Bactoscan, Total Coliforms and thermodurics are to be tested at a frequency of 3 per 10 day period throughout the trial.

j. Trials run over the period May 1 to August 31 must be extended by 1 week for each week within this period, up to a maximum of 4 weeks.

2. Requirements for new DMC or major change:

a. Minimum 6 farm dairies, with at least 3 x Rotary and 3 x Herringbone.

b. Minimum trial period 11 weeks, consisting of:

i. 1 week to establish the baseline levels prior to use of the trial compound;

ii. 9 weeks trialling the new product; and

iii. 1 week on return to an approved product.

c. Cleaning regime must be established prior to commencement and provided to the organisation undertaking the trial.

d. Farm Dairy Operator to confirm no deviation from the cleaning regime throughout the trial (unless the trial is abandoned or reset).

e. The applicant or their associates must not compromise the integrity of the trial at any time (no interventions or involvement permitted by applicant for last 4 weeks of the trial).

f. A rinsability (residue carryover) assessment is required to be undertaken once per farm dairy, and may be at any time prior to, during or after completing the efficacy trial. Further details are set out below.

g. Residue testing of the milk is required to be undertaken at least twice during the trial, with one sample taken during the first half of the trial and one taken in the second half of the trial. Samples are to be taken from the BMT after the first row has been milked.

   Note: The applicant is responsible for determining the most appropriate compounds to measure based on the formulation, the risk profile of the constituents, and the availability of accredited test methods.

h. Hygiene assessments of the milking plant are to be undertaken by a suitably qualified farm dairy assessor immediately prior to commencement of the trial, 4 - 5 weeks into the trial, and at the completion of the trial. The hygiene assessment musty consider any effect on rubber and silicone components and sensory observations.

i. APC/Bactoscan, Total Coliforms and thermodurics are to be tested at a frequency of 3 per 10 day period throughout the trial.

j. Trials run over the period May 1 to August 31 must be extended by 1 week for each week within this period, up to a maximum of 4 weeks.

Applicants must obtain provisional approval from MPI and both Farm Dairy Operator and RMP Operator must agree to trial proceeding for all field trials.

Farm Dairy Selection:

All applicants undertaking farm trials should endeavour to select milking plants of a type that falls within the scope of intended use per the label, and will include:

1. the most difficult to clean and/or sanitise;
2. the most difficult to rinse free of chemical residues
3. a cross section of water quality

Applicants can request an exemption to field trial requirements which will be assessed on a case by case basis. Additionally MPI may require applicants to undertake more extensive field trials, including for minor changes.

Rinsability Assessment

The purpose of the rinsability assessment is to confirm that label rinsing instructions are adequate to protect milk from residues and that the performance of other maintenance compounds used will not be adversely affected.

The rinsability assessment is undertaken after use of the product as detailed on the label and in the trial cleaning regime (excluding the water rinse). The milking plant and BMT must then be rinsed with water in accordance with the label instructions, with the rinse water collected and a representative sample taken and labelled for analysis. The estimated volume of rinse water is also to be recorded.

The milking plant and BMT are then rinsed two further times using the minimum volume of water needed to contact all treated surfaces. Again a representative sample is to be taken and labelled after each rinse, and the volume of rinse water collected is to be recorded.

The three samples and the source water used for rinsing are to be tested for pH and conductivity. The results are to be recorded in the rinsability assessment along with the identity of the lab or person undertaking the analysis and their relevant qualifications. Testing does not require an accredited laboratory but the calibration details of equipment used for testing are to be recorded.

Information and data requirements:

Trial design

1. The trial design must be documented prior to the trial commencing and include:
    a. The purpose of the trial;
    b. The scope of the trial, e.g. sanitising milking equipment and BMT;

c. A description of each farm involved in the trial, for example:

   i. dairy type such as rotary or herringbone

   ii. dairy size;

   iii. BMT size; and

   iv. dairy company supplied;

d. Key personnel/organisations involved in the trial, including the RMP Operator(s) who have given their consent for the trial to proceed;

e. The time period that the trial is intended to run over;

f. A description of the DMC including the intended use conditions and any restrictions on use;

g. The proposed cleaning regime to be used during the trial including:

   i. any specific deviations from label instructions for individual farms such as manual cleaning; and

   ii. the full cleaning regime to be followed and, for each farm, the working solution strengths, volumes and temperatures;

h. An assessment of risks associated with use of the product during the trial, identifying:

   i. Any measures to be taken to ensure the integrity of the trial will not be compromised;

   ii. Measures to be taken to ensure the integrity of raw milk will not be compromised; and

   iii. The people to be alerted should any adverse events occur that results in the raw milk being adversely affected;

i. Reference to the MPI provisional approval to proceed to trial.

Trial report

2. A trial report is to be provided to MPI at the conclusion of the trial that includes:

   a. An executive summary (optional);

   b. A description of the trial, highlighting deviations from the trial design;

c. A summary of the analytical test results, an analysis of the findings, and any observed deviations from the baseline data. The full set of raw results should be appended to the report;

d. The rinsability assessment results and the residue results;

e. The findings from hygiene assessments, with all assessment reports appended;

f. A statement from the farm dairy assessor or farm dairy assessment organisation summarising their observations, noting whether the product as used appeared to be suitable, marginal or unsuitable;

g. The results of any additional microbiological or chemical testing undertaken over the duration of the trial;

h. Confirmation from the Farm Dairy Operator that no adjustments were made to the cleaning regime and no unplanned cleaning occurred;

i. Overall trial outcome;

j. Any other relevant observations noted during the trial such as deficiencies, modified use instructions or further work needed.

In situations where an approved DMC is found to no longer be suitable for the intended use the MPI approval will be withdrawn and the original trial information reviewed. If the accuracy/integrity of the trial design and trial information is questionable, MPI may require more intense field trial criteria to be applied by the applicant in the future.

Contact for enquiries

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