Ministry for Primary Industries
Manatū Ahu Matua

Guidance Document

Dairy Maintenance Compounds Procedure for Approval

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Title

Guidance Document: Dairy Maintenance Compounds Procedure for Approval

About this document

This guidance document is issued by the Food Regulation Directorate, New Zealand Food Safety, Ministry for Primary Industries. It describes the process to be followed when seeking approval of a Dairy Maintenance Compound.

Related Requirements

(1) This document should be read in conjunction with the:

a) Animal Products Act 1999;
b) Animal Products Regulations 2021;
c) Raw Milk for Sale to Consumers Regulations 2015;
d) Animal Products Notice: Raw Milk for Sale to Consumers;
e) Animal Products Notice: Production, Supply and Processing;
f) Operational Code: NZCP1: Design and Operation of Farm Dairies

Document history

Version Date	Section Changed	Change(s) Description
13/07/2022	1-5	New document

Contact Details

New Zealand Food Safety
Approvals Operations
PO Box 2526
Wellington 6140

Email: approvals@mpi.govt.nz

Disclaimer

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Contents

Purpose

The purpose of this document is to describe the NZFS process that relates to the assessment and approval of maintenance compounds for use in dairy processing, including farm dairies.

NZFS maintains a register of approved Dairy Maintenance Compounds which includes the conditions that have been applied to each product to ensure appropriate use. The register can be found on the NZFS website at Register of approved maintenance compounds (dairy)

Dairy Maintenance Compounds

This guidance document describes the process for getting a maintenance compound approved by NZFS for use in dairy processing.

Detergents, sanitisers and other maintenance compounds used in and adjacent to farm dairies and by dairy maintenance compounds (refer to Regulation 53 of the Animal Products Regulations 2021). The Animal Products Notice: Production, Supply and Processing, and the Animal Products Notice: Raw Milk for Sale to Consumers set out further requirements.

In addition, if you are operating a risk management programme (RMP), you must ensure that all maintenance compounds used are suitable for their intended use.

Definitions

Dairy Maintenance Compound (DMC) means, in relation to any premises or place where dairy material or dairy product is processed, any substance—

a) used for maintaining, repairing, servicing, cleaning, or sanitising equipment or surfaces or air that may be the source of, or result in, contamination of dairy material, dairy product, or associated things; or
b) used for treating water; or
c) used for pest control.

MPI means the Ministry for Primary Industries

NZFS means New Zealand Food Safety

Regulations means the Animal Products Regulations 2021

RMP means Risk Management Programme

1 Dairy Maintenance Compounds

1.1 Approval requirements

(1) Dairy processors are required to only use dairy maintenance compounds (DMCs) that are suitable for the intended use, that is they;

a) will provide some form of benefit when used as instructed;
b) will not result in acceptable residues in milk and the products made from milk; and
c) will not cause undue corrosion or deterioration of the equipment and materials that they are likely to come into contact with, when used as instructed.

(2) Requirements for farm dairies

a) Maintenance compounds (chemicals) used in and around farm dairies must be approved by NZFS or MPI for use in farm dairies. This includes compounds used to:

i) clean, sanitise or maintain the milking plant (including the bulk milk tank);
ii) clean or maintain other areas in or adjacent to the farm dairy;
iii) compounds used for water treatment and pest control; and
iv) compounds use to clean or condition teats and udders, unless they are ACVM registered veterinary medicines.

(3) Requirements for dairy manufacturers and dairy stores

a) Maintenance compounds used in dairy manufacturing premises and dairy stores don't have to be approved by NZFS or MPI, but they must be suitable for the intended use, and the dairy processor or RMP operator must evidence that the DMCs they use are suitable. There are two ways to do this:

i) Dairy manufacturers and dairy store operators can undertake their own assessment of the DMC and confirm suitability. There are various ways of doing this, including obtaining evidence from the DMC supplier or other sources (such as academic papers), obtaining evidence of approval by a reputable organisation for the same use, or undertaking a trial. The most suitable option will depend on the intended use; or
ii) Dairy manufacturers and dairy store operators can use DMCs that have been approved by NZFS/MPI for the intended use. In this case no additional evidence is required, and no assessment is needed.

b) What each compound is intended to be used for and how it should be used will be clear from the container label or instructions provided by the DMC supplier, though it is recommended that processors check the NZFS/MPI register to see if there are any additional conditions that apply.

(4) Requirements for other dairy processing activities operations

a) Maintenance compounds used for in other dairy processing activities, such as cleaning, sanitising, or maintaining tankers, transport containers (tanks) and transport units, must be approved by NZFS or MPI. As with farm dairies, this includes compounds used for treating the water used for cleaning or rinsing and compounds used for pest control. This requirement also applies to the compounds used on the outside of equipment or nearby if there is any possibility of contaminating milk or food contact surfaces.

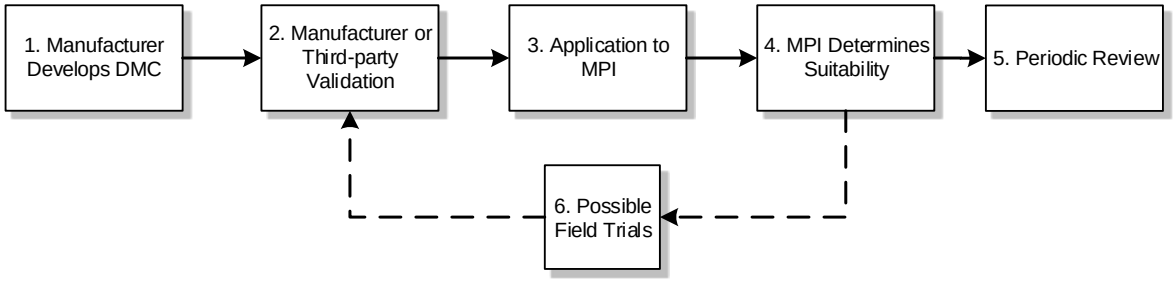
(5) NZFS maintains two types of approvals for DMCs. These are:

a) Approved for use in farm dairies; and
b) Approved for use in dairy processing (formerly this was referred to as “recognised”).

(6) In both cases the label will clarify the nature of the intended use.

(7) NZFS can attach conditions to when approving a DMC, and so it's worthwhile checking to see what conditions have been applied to the DMCs you are or intend using. The register of NZFS approved maintenance compounds is available here.

1.2 Process



1.3 Development / formulation of product

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

(2) **Chemical considerations and restrictions**
Dairy maintenance compounds:

a) must not contaminate milk or dairy products when used as directed;
b) must not result in undue corrosion or deterioration of equipment, facilities or consumables;
c) must provide a demonstrable benefit;
d) should not contain any compounds on the DMC List of Restricted Chemicals. Applications for DMC approval must identify any restricted chemicals in the formulation, and must provide justification for their use.

(3) The chemical manufacturer, DMC applicant, or both are responsible for determining suitability prior to validation.

1.4 Validation

(1) 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.

(2) The nature of product validation will differ according to the risk profile of the product, and the potential for contamination of milk or food or adverse effect on equipment, consumables and facilities. Likewise, the extent of validation information required with an application will depend on the type of product and its use, and its general risk profile. In general, validation will involve obtaining objective evidence that the DMC is suitable for its intended use. This information will usually come from trials, or relevant experiments along with research and information from other sources. Considerations will include consideration of adverse effects as well as proving a positive benefit. In some cases, information may have been already assessed and found to be suitable by a reputable organisation for the same use, in which case this may well be sufficient evidence of the DMCs validity.

(3) When confirming that a DMC will not result in residues in milk or food when used as intended, NZFS guidance on estimated residue carryover can be used in place of, or to support, trial data. The guidance will not address all situations, in which case trials may be required or relevant information sourced from elsewhere.

(4) Refer to section 4 for more detailed requirements related to DMC validation.

1.5 Application for Approval

(1) The applicant completes the DPF15 Dairy maintenance compound approval application form**Error! Hyperlink reference not valid.** and submits this to NZFS Approvals along with the validation report or summary (if required for the type of product), the product label, any relevant supporting information – such as trial data and/or trial reports - and the prescribed fee. NZFS may request that formulation information is also submitted in electronic form.

1.5.1 Approval types

(1) NZFS will process the application, taking into consideration the assessment report, and either:

a) approve (with or without conditions);
b) provide provisional approval, generally to allow for trials;
c) request further information due to a lack in confidence that the DMC is suitable for the intended use based on the label instructions and information provided. This may be clarification on the intended use(s) or further information to confirm suitability such as the full validation report, further independent assessment, or further trials. This is more likely with novel compounds; or
d) decline the application.

(2) DMCs may be approved for:

a) use in farm dairies;
b) use in dairy processing; or
c) both of the above.

(3) Applicants are responsible for adhering to the scope of the approval and any conditions imposed.

(4) Provisional approval may be given in situations where there is insufficient information available to support full approval, but there is adequate information to allow for monitored use of the compound. The primary purpose of this approval is for products intended to have direct contact with equipment surfaces and allows the applicant to obtain validation or functional data, such as through trials on equipment that is in a production setting.

(5) NZFS does not share confidential information, such as formulation details, with external parties without the consent of the applicant. In rare situations NZFS may request permission from the applicant to consult with a panel of experts. This is only requested when it is necessary to consult more widely to ensure assessments are comprehensive, relevant to current industry requirements and will not impede the trade in dairy products.

1.6 Periodic review

(1) All approvals will be subject to periodic review. The review date will be determined by a number of factors and is at the discretion of NZFS. A review may be undertaken earlier if, in the opinion of the Director-General, the review is warranted for the approval concerned. As part of any review NZFS may require further information from the original applicant.

(2) A DMC that appears on the NZFS register as being past the review date continues to carry the statuses identified.

(3) **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 will be advised in advance and have an opportunity to provide additional information. When withdrawing an approval NZFS may specify phase out periods to allow the product to continue to be used, but not sold.

1.7 Field trials

(1) In some situations, it may be necessary to undertake field trails in order to confirm suitability and/or assess residue carryover. If the trials are to be carried out in facilities that are in production (e.g. farm dairies during the milking season) then approval from NZFS will be required before the trials commence. To support trials NZFS will typically provide an approval with additional conditions and a reduced period until review.

(2) Trials will only be approved when:
a) there is information to support the trial;
b) there will be sufficient oversight to ensure that non-conforming dairy material or product will be identified and managed;
c) the trial terminated early if necessary; and
d) agreement will be sought from the risk management programme operator responsible for activities at the farm dairy.

1.8 Periodic review

(1) At the time of each approval NZFS will set a review date. Applications for approval renewal should be submitted to NZFS at least one month prior to the review date. When reviewing applications for renewal NZFS may seek further information.

(2) Failure to apply for renewal will result in a DMC approval being withdrawn on the assumption that the product is no longer intended to be commercially available.

2 Changes to Approved DMC

(1) From time-to-time manufacturers may consider making changes to approved DMCs. For instance:
a) Product name changes;
b) Minor changes to formulation; or
c) Changes to a label or instructions for use.

(2) Product name changes should:
a) use the DPF15 application form;
b) identify the new product name and old product that is to be replace;
c) identify when the new product will replace the old product (NZFS will withdraw approval from this date, but will allow use by dairy processors for a run-out period; and
d) identify an appropriate “run-out” period for the old product (default 6 months).

(3) Minor changes to formulation may have a significant effect on the functionals performance of a DMC. As such minor changes will need to be assessed and validated to confirm suitability.

(4) For changes to labels or instructions, the application will need to clarify the date at which instructions change. A change to working compound strength will typically require validation information to support the change.

(5) If a change is being made to use instructions and a minor change to formulation at the same time, the applicant will also need to outline how the roll-out will manage two forms of the same product in use at the same time to ensure each product is used correctly.

3 DMC Categories

Table 1: Compounds not requiring validation

Ref	Compound	Intended Use
DA1	Ethanol 70% to 95%	spot sanitising of equipment, including food contact surfaces, provided product is allowed to fully evaporate prior to production recommences.
DA2	Compounds not intended for use in, or immediately adjacent to, processing areas or processing area entry	laundry products; amenity cleaners, sanitises, shower gel and shampoo/conditioner; de-odorisers and air-fresheners; oven cleaners; dishware cleaners.

Table 2: Validation required - details not required by NZFS

Ref	Intended Use	Comment
DB1	Wipes, single use towels/towelette	Not for use on food contact surfaces. Not for milking animal teats unless ACVM approved for this use.
DB2	Hand soaps, hand sanitisers, barrier creams and hand wipes	Not for use on food contact surfaces.
DB3	Floor cleaners	
DB4	Drain unblockers, Moss/mould/lichen removers	Not for use in processing areas.
DB5	vehicle external cleaner	Not for use on food contact surfaces.
DB6	Grease and lubricants	Not used in processing areas.
DB7	Contact with teats and udders	compounds with ACVM registration for the use .

Table 3: Validation required – validation summary to be provided with new applications

Ref	Intended Use	Comment
DC1	Detergents, sanitisers, surfactants and other cleaners	
DC2	Membrane cleaners	

DC3	Wipes, single use towels/towelette	Use on food contact surfaces or milking animal teats.
DC4	Boiler chemicals (no possible product contact) Coolant/heat exchange solutions (no possible product contact)	2 plate/membrane separation and pressure differential to ensure contamination cannot occur.
DC5	Corrosion inhibitors	not for product/product surface contact.
DC6	De-scalers Solvents Surface Coatings	non-food contact surfaces.
DC7	Grease and lubricants	used in processing areas.
DC8	Enzymes	deactivated after use.
DC9	Water treatment products	
DC10	Pesticides	Processing area out of action during use and cleaned after use.
DC11	Transport unit external cleaner	
DC12	ACVM registered compound	Approved for the same use.

Table 4: Validation required – full validation report to be provided with new applications

Ref	Intended Use	Comment
DD1	Boiler Chemicals with food contact or addition to food (includes Culinary steam)	
DD2	Food Contact Surface Coatings	Food contact surfaces.
DD3	Fogging compounds	
DD4	Pesticides (excluding rodenticides)	Used in processing areas.
DD5	Rodenticides	
DD6	Compounds not covered elsewhere	

4 Validation

An applicant seeking to gain approval for a DMC is responsible for ensuring that the DMC is suitable for its intended use and won't result in unacceptable residues in dairy material or dairy products when used as instructed.

For the compounds listed in Table 1: *Compounds not requiring validation*, no validation is required when the product is for the intended use indicated.

4.1 Validation of a DMC

A DMC must be validated for each intended use, for example a sanitiser intended to be used to sanitise food contact surfaces and as a water treatment must be validated for each purpose.

If validation will require field trials to confirm aspects of suitability or residues carryover, then the DMC application will need to make it clear that the purpose is to undertake field trials and provide sufficient justification that the trials will not result in dairy material or product contamination (including trial design – see section 5. Field trials).

Validation may be conducted overseas provided the applicant has access to the validation purpose and report.

4.2 Internationally Recognised Approval as an alternative to validation

For a DMC that falls under Table 2 or Table 3, NZFS may accept an approval that has been completed by an overseas competent authority or internationally recognised organisation as an alternative to completing a validation or providing a validation summary. In such cases the approval certificate, report or website reference provided must clearly identify the intended use and any applicable conditions. Examples of acceptable organisations are:

U.S. National Sanitation Foundation (NSF)

Australian Department of Agriculture, Fisheries and Forestry (DAFF)

Australian Pesticides and Veterinary Medicines Authority (APVMA)

Association of Official Analytical Chemists (AOAC)

European Commission

Global Proficiency Limited (prior to 1 July 2022)

In exceptional circumstances NZFS may accept an alternative to validation and approval by an internationally recognised organization. In such cases there will need to be sufficient evidence to confirm suitability.

4.3 Validation report

A validation report is expected to be prepared by a suitably qualified and skilled person upon completion of the validation. The validation report should cover the following:

- Name of product
- Organisation that performed the validation
- Ingredients
- Intended Use
- Validation design:
  - Scope and purpose of the validation
  - Criteria against which effectiveness will be determined
  - Facilities/equipment (eg farm dairy type; milking machine manufacturer; CIP/non-CIP

  - Trial design (trial protocol)
  - Time of year validation undertaken
  - Geographical location (eg country/region where validation was done)

- Results and analysis
- Unexpected Findings (if any)
- Summary of other tests done as needed e.g. corrosion test, foaming test, taint test
- Changes proposed based on analysis (if any)
- Conclusion, including a summary of:

  - Efficacy (does the DMC provides the intended beneficial effect)
  - Chemical residue, odour and taint carryover to milk/food
  - Adverse effects on contact materials e.g. corrosion or accelerated rubberware deterioration

4.4 Validation required to be completed, but details not required by NZFS

For each DMC covered by Table 2, each intended use needs to be validated. However, NZFS doesn't require the validation report or a validation summary. In some situations NZFS may request further information, which might include validation information, especially in the case of novel or innovative products.

4.5 Validation required to be completed – Summary or alternative approval to be provided

For each DMC covered by Table 3, each intended use is to be validated to confirm suitability. However, for new applications the applicant only needs to supply NZFS with either:

a) a summary of the validation for each intended use; or
b) an approval that has been completed by an overseas competent authority or internationally recognised organization as set out in cluse 4(2).

Typically, no validation information is required for a renewal, but NZFS may request this information or may request revalidation if circumstances or applicable standards may have changed.

In the case of a summary of the validation, the summary is to include:

- Name of product
- Ingredients
- Intended Use
- Outline of validation design
- Unexpected Findings (if any)
- Summary of other tests done as needed e.g. corrosion test, foaming test, taint test
- Conclusion, including summaries of:

  - Efficacy (does the DMC provide the intended beneficial effect)
  - Chemical residue, odour and taint carryover to milk/food
  - Adverse effects on contact materials e.g. corrosion or accelerated rubberware deterioration

4.6 Validation required – full validation report to be provided

For each DMC covered by Table 4, each intended use covered by Table 4 will need to be validated to confirm suitability, and for new applications the full validation report (as set out in subclause (3)) is to be provided to NZFS for each use covered by Table 4.

Typically, no validation information is required for a renewal, but NZFS may request this information or may request revalidation if circumstances or applicable standards may have changed.

If your validation report does not include all the relevant content identified in subclause (3), either include the missing information as an attachment to the validation report or provide justification for not including the information.

5 Field Trials

(1) 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. As outlined in clause 1.7, NZFS will determine whether field trials are required and appropriate. The specific requirements of the field trial can be organised into two categories, with NZFS determining which category applies. Details on field trial design will be outlined separately.

(2) In some circumstances only a residue carryover trial or an efficacy trial will be required. Residue trials will typically require the product to be used for at least five days and as such the trial would be completed within a seven day period. Full trial requirements may be waived for products that are approved for use in a similar application, though rinsability and carryover assessments (point g.) are likely to be required unless suitable data has been collected.

(3) All definitions below are to be used as a guide of intent only, as with justification equivalence to the factors in each category can be granted:

a) **Minor changes** that do not require field trials are 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.
b) **Moderate change** defined as: no more than two existing components affected (excluding water); component/s changed by >10%; no new components added to formulation.
c) **Major change** defined as: addition of new components to formulation or changes to more than two of the existing components.

(4) Subclause (5) sets out the standard trial design for a moderate formulation change and subclause (6) sets out the standard trial design for a new formulation or where a significant change has been made to the formulation. NZFS will consider alternative trials designs.

(5) **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 7 weeks trialling the new product and 1 week on return to an approved product. The baseline level is to be established prior to commencement (1 week).
c) Cleaning regime must be established prior to commencement and provided to the Trial Body
d) Farm Dairy Operator to confirm no deviation from the cleaning regime 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. NZFS will provide the

design outline for rinsability assessments and will confirm the analyte or analytes to be monitored. In addition, residue testing of milk is required to be undertaken at least twice during the trial, once during the first three weeks and once during the last three weeks, with samples taken from the bulk milk tank after the first row has been milked.

g) Hygiene assessments of the milking plant are to be undertaken by a competent farm dairy assessor (unless NZFS agree to an alternative) immediately prior to commencement of the trial, 3 weeks into the trial, and at the completion of the trial.
h) APC/Bactoscan, Total Coliforms and thermodurics are to be tested at a frequency of 3 per week throughout the trial.
i) 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.

(6) **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 10 weeks, consisting of 9 weeks trialling the new product and 1 week on return to an approved product. The baseline level is to be established prior to commencement (1 week).
c) Cleaning regime must be established prior to commencement and provided to the Trial Body.
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 trial. NZFS will provide the design outline for rinsability assessments and will confirm the analyte or analytes to be monitored. In addition, residue testing of milk is required to be undertaken at least twice during the trial, once during the first three weeks and once during the last three weeks, with samples taken from the bulk milk tank after the first row has been milked.
g) Hygiene assessments of the milking plant are to be undertaken immediately prior to commencement of the trial, 4 - 5 weeks into the trial, and at the completion of the trial.
h) APC/Bactoscan, Total Coliforms and thermodurics are to be tested at a frequency of 3 per week throughout the trial.
i) 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.

(7) Applicants must obtain provisional approval / recognition from NZFS and both Farm Dairy Operator and RMP Operator must agree to trial proceeding for all field trials.

(8) **Farm Dairy Selection:** all applicants undertaking farm trials should endeavour to select milking plants of a type that, within scope of intended use per the label, are:

a) the most difficult to clean and/or sanitise;
b) the most difficult to rinse free of chemical residues; and
c) have a cross section of water quality.

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

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