Procedure for Approval of Novel Technologies, Alternative Premises and Equipment Designs

Purpose

The purpose of this document is to describe the MPI process for approving novel technologies including alternative premises and equipment designs for use on, in or at farm dairies. The register of Alternative Premises and Equipment Designs for Farm Dairies is maintained by MPI and accessible on the MPI food safety website.

Premises (including animal housing), facilities, equipment and essential services are required to meet the requirements set out in *Operational Code: NZCP1*: *Design and Operation of Farm Dairies*. However, there is provision within NZCP1 (clause 3.10 Alternative Premises and Equipment Designs) that enables new technologies and novel designs to be assessed on the basis that these are often complete systems and may not have been contemplated when NZCP1 was drafted.

What are Novel Technologies?

The term novel technologies including alternative premises and equipment designs refers to designs that do not meet the requirements set out in MPI Notices or the *Operational Code: NZCP1*: *Design and Operation of Farm Dairies*.

This may be because NZCP1 had not anticipated the design/application, or new control and/or mitigation measures that have been introduced as an integrated system which ensures that milk will be protected. This can be the case for automation and designs adapted for minor species.

Acceptance Criteria

Novel technologies, alternative premises and equipment designs that do not meet the requirements of NZCP1 are deemed to be suitable if they have been assessed and confirmed as acceptable through this procedure, and they have been listed as approved on the MPI Register of Alternative Premises and Equipment Designs for Farm Dairies. The register will hold the following information:

1. The manufacturer/supplier of the equipment.
2. The trade name of the equipment item or design.
3. The outcome of the MPI assessment:
    a. Approved (accepted as a suitable alternative);
    b. Not Approved (insufficient evidence to confirm suitability);

c. Provisional (accepted for the purpose of facilitating on-farm trials); or

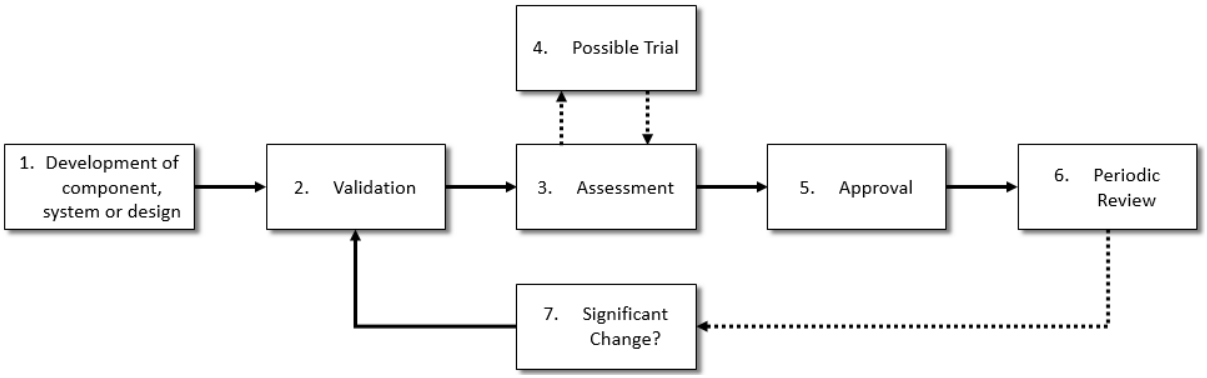
d. On-hold (Awaiting further data before a determination can be made).

4. Any restrictions (e.g. on location, construction, installation or use).

5. Date of determination

6. Date of review.

Process



1. Development / formulation of component, system or design:

The manufacturer develops/formulates the product or design 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 maintenance, cleaning and inspection.

2. Validation

All technologies / designs must be fit for purpose and perform as intended under all situations likely to be encountered when used per instructions. The applicant is responsible for gathering all relevant information and objective evidence to demonstrate this and submit a validation report to support their application.

3. Assessment

The applicant completes the *Application for Novel technologies or Alternative Premise and Equipment Design* form and submits this to MPI for assessment along with the validation report. The assessment will consider whether the technology/design has been confirmed as suitable (i.e. validated) for the proposed purpose when used in accordance with label instructions. If the technology/design cannot be fully validated until it is in routine use, but is assessed as sufficiently suitable to allow further trial work to be undertaken within a production environment, then a provisional approval may be granted.

New technologies/designs that have not been fully validated will only be considered for provisional approval when MPI is confident that sufficient control measures and safeguards will be applied during the period of provisional approval.

4. Field Trials

Field trials may be required to demonstrate feasibility of the technology/design for the intended use as presented in the application, and to assess the ongoing suitability in a production environment. See **Appendix 1 Field Trial Requirements**

5. Approval

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

i. Approve for use in the farm dairy (with or without conditions);

ii. Provide provisional approval to conduct field trials;

iii. Request additional information (placing the application on hold); or

iv. Decline the application.

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

Provisional status 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 technology/design on a restricted or controlled basis as described at step 3. This 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 design details, with external parties without the consent of the applicant. In some situations a panel of experts may need to review the information provided to ensure the assessment is fair, comprehensive, relevant to current industry requirements, and will not impede the trade in dairy products. If this is the case MPI will seek approval from the applicant to share the application information and associated test reports with the expert panel.

6. Review

Approvals may be subject to periodic review. The review date will be determined by a number of factors and is set by MPI. A review may be under taken earlier if MPI determines that a review is warranted for the particular approval concerned. As part of any review MPI may require further information from the original applicant.

Any technology / design that appears on the MPI register as being past the review date continues to carry the status identified.

7. Significant change to novel technology designs

The approval for a novel technology applies to the design as submitted to MPI. Minor changes that have no material impact on operational performance, functionality or maintenance of the novel technology must be recorded but do not need MPI approval. More significant changes will require separate approval of the change by MPI.

Withdrawal of approval

Approval may be withdrawn at any time should MPI consider that there is no longer sufficient evidence to support suitability for use. Such a determination would follow a review of the approval and any subsequent information gained, for example from farm dairy assessments, audits of dairy processing operations or modified instructions for use. Where possible, applicants will be advised in advance and have the opportunity to provide additional information. When withdrawing an approval, MPI may specify phase out periods to allow current installations with the technology/design to continue to operate (with or without special conditions applied).

Appendix 1: Field Trial Requirements

Field trials may be required to demonstrate feasibility of the technology/design for the intended use as presented in the application, and to assess the ongoing suitability in a production environment. MPI determines whether field trials are justified and necessary, and if so will grant a provisional status.

Applicants must obtain provisional approval from MPI, and both the Farm Dairy Operator and the RMP Operator (dairy company) must agree to the trial before proceeding. Field trial must be conducted in association with a farm dairy assessment organisation acceptable to MPI (currently QCONZ and AsureQuality), with a farm dairy assessor monitoring the activity throughout the trial. At the conclusion of the trial a report is to be prepared and submitted to MPI by the applicant, with the farm dairy assessors report attached.

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, or may require trials when changes are made to the design or use. If the accuracy or integrity of a trial, trial design or trial report is questionable, MPI may require further trials or additional trial criteria to be applied.

Trial requirements

1. Requirements for trial design:
    a. Minimum 6 farm dairies.
    b. Minimum trial period 11 weeks, consisting of:
        i. 1 week to establish the baseline levels prior to the trial properly commencing;
        ii. 9 weeks trialling the new product; and
        iii. 1 week on return to an approved product.
    c. Cleaning regime must be documented prior to commencement and provided to the farm dairy assessment organisation.
    d. Farm Dairy Operator to confirm no deviation from the cleaning regime throughout the trial (unless the trial is abandoned or reset).
    e. The integrity of the trial must not be compromised (no interventions or adjustments made during the trial).

f. Hygiene assessments are to be undertaken immediately prior to commencement of the trial, 4 - 5 weeks into the trial, and at the completion of the trial.

g. APC/Bactoscan, Total Coliforms and thermodurics are to be tested at a frequency of 3 per week throughout the trial.

h. A rinsability assessment and/or residue testing may be required depending upon the nature of the component, system or design. Refer to Procedure for Approval or Recognition of Dairy Maintenance Compounds, Appendix 1: Field Trial Requirements for more details.

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.

Farm Dairy Selection:

The nature of the farms to be selected for trials will depend on the nature of the design or component to be trialled. Consideration should be given to the inclusion of a range of farm dairy types, with a bias toward those that are likely to prove more challenging.

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 identifying the activities and equipment/facilities involved;

    c. Key personnel/organisations involved in the trial, including the RMP operator(s) (dairy companies) who have given their consent for the trial to proceed

    d. The number of farms included in the trial, a relevant description of each farm trial, and the dairy company supplied;

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

    f. A description of the component, system or design to be trialled including any parameters critical to the process as well as the intended use conditions and any restrictions on use;

    g. The proposed cleaning regime to be used during the trial if this is relevant;

    h. An assessment of risks associated with use of the component, system or design 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. How success will be measured

j. Reference to the MPI 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 any deviations from the trial design;

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

d. The results of any additional testing undertaken over the duration of the trial;

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 component, system or design as used appeared to be suitable, marginal or unsuitable;

g. Confirmation from the farm dairy operator that no adjustments were made during the course of the trial;

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

i. Overall trial outcome;

3. Additional information to be provided with an application includes:

a. Confirmation that all materials of construction meet NZCP1 or if not, the justification for its use; and

b. A summary of the known or suspected deviations from NZCP1 along with the supporting rationale/evidence that an equivalent outcome will be achieved.

The trial design and trial report are to be provided to MPI at the conclusion of the trial.

In situations where an approved component, system or design 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 future.

Contact for enquiries

MPI Approvals
PO Box 2526
Wellington 6140
approvals@mpi.govt.nz