

Operational Guideline: Dairy Risk Management Programme Amendments - Difference between Significant and Minor

31 July 2006

This document provides guidance and examples for each of the clauses in the Animal Products (Dairy Risk Management Programme Specifications) Notice 2005 relevant to significant amendments. The guidance and examples given will not cover every possible scenario and will not necessarily hold true for every situation, so each amendment will need to be considered on a case by case basis. It may be necessary to consult with a recognised agency or the New Zealand Food Safety Authority (NZFSA) if further elaboration is required.

If a change would be a significant amendment under one clause of the Dairy Risk Management Programme (RMP) Specifications 2005 and a minor amendment under another, then it must be considered as a significant amendment.

The operator should document the basis for the decision and make this available to accredited evaluators, recognised agencies or the NZFSA if required. It may be necessary to consult with technical experts and keep their written guidance on file.

Note that there may be situations where a recognised premises evaluator may be involved in signing off a project to expand or modify a premises but this may not result in a significant change to the RMP.

1. Major Alterations to Processing Facilities or Equipment

27. Significant amendments to the risk management programme

(1) The following activities that result in changes to the risk management programme require registration as an amendment in accordance with section 25 of the Act—

(a) Major alterations to the processing facilities which may impact on fitness for the intended purpose of the dairy material or dairy product

Altering the physical boundaries of the RMP

Any amendment where the physical boundary of the RMP is increased is considered a significant amendment. Where the physical boundaries of the RMP are reduced advice should be sought from NZFSA.

Removal of buildings/facilities

Justification should include consideration of:

- What consequential changes are needed as a result of removing the buildings/facilities e.g. if processing activities are moved to a new building, are any alterations needed to ensure its suitability for this type of processing?
- Are any new hazards or other risk factors introduced as a result of altered process flows, new environmental conditions etc?

Examples of Significant Amendments	Examples of Minor Amendments
Removal of facilities/equipment that prevents essential processes from being carried out, e.g. removal of a blast freezer.	Removal of redundant or disused facilities/buildings.

Construction of new buildings and facilities

When deciding whether building construction is a significant or minor amendment the operator should consider:

- Whether the construction results in duplication of existing processes;
- Any impact on the existing buildings or facilities or operations;
- Any change to the physical boundaries.

Examples of Significant Amendments	Examples of Minor Amendments
Construction of a new store, new processing room, new packing room etc where this is not a duplication of an existing operations or facilities.	Construction of a new facility where it can be shown that it will not introduce risks to existing processes and products.
Construction on a new site.	Construction of a new cold store where the RMP includes a process for cold storage.

Building and facility alterations

Justification should consider:

- The extent of alterations needed;
- The impact of the alterations on the process and operations, e.g. changes to process flow, new process steps;
- Whether the alterations will change the use of the existing facilities, room or area;
- Whether the change impacts on the effectiveness of a critical control point (CCP).

Examples of Significant Amendments	Examples of Minor Amendments
Reconfiguration or reconstruction of a processing area where there has been a substantial change to the process or a new hazard or risk is identified.	Reconfiguration or reconstruction of a processing area where it can be shown that the process has not changed and no new hazard or risk has been identified.
An accumulation of minor changes which together would be the equivalent of a significant amendment.	Minor alterations to processing facilities such as: Repairs and maintenance; Changes to equipment layout to improve process flows where this does not introduce new hazards; Introduction of a new production line, which duplicates an existing line within an existing area; Equipment changes to bag sealing; Alterations to stable ingredient (e.g. salt) storage Changes to essential services where this does not introduce new hazards.

Examples of Significant Amendments	Examples of Minor Amendments
Changing the use of a room so that it becomes part of a Critical Hygiene Area, except where the RMP already contains buildings or facilities included in the Critical Hygiene Area.	Construction in non-processing areas such as amenities, support facilities and engineering facilities, but not to change them to a higher standard of use.

New processing equipment

Justification should include consideration of:

- What is involved in its installation, commissioning and/or validation, location, hygiene, maintenance etc;
- What the equipment is used for, e.g. whether it is used for a process step that is essential for food safety;
- How the new equipment might affect the process flow;
- Whether the new equipment duplicates existing equipment.

Examples of Significant Amendments	Examples of Minor Amendments
New processing equipment that is essential for food safety, e.g.: <ul style="list-style-type: none"> • new technology, e.g. filtration as a microbiocidal step; • Adding or reducing plates in a pasteuriser; • Alterations to pasteuriser flow rates. 	New processing equipment that is not essential for food safety e.g.: <ul style="list-style-type: none"> • new conveyor belts; • new mixers, blenders; • new cheese curd cutting equipment.

2. Changes to Key People

27. Significant amendments to the risk management programme

(1)(b) major changes to key people involved in the operation of the risk management programme, including employees, contractors or agents, which might impact on fitness for the intended purpose of the dairy material or dairy product:

Justification should consider and include:

- Does the person have a key responsibility described in the RMP?
- Does the person agency have a key role in RMP verification activity?

Examples of Significant Amendments	Examples of Minor Amendments
	<ul style="list-style-type: none"> • Change of responsible person named in the RMP NOTE This change will need to be notified to NZFSA. • Change in plant operator. • Change in maintenance contractor.
	<ul style="list-style-type: none"> • Change in RMP verification recognised agency. NOTE This change will need to be notified to NZFSA.

3. Alterations to the Processing Environment

27. Significant amendments to the risk management programme
(1)(c) major alterations to the processing environment which might impact on fitness of purpose

Justification should consider and include:

- What is the potential for the change to adversely affect the fitness for purpose of the product?
 Consider nature of the processing (e.g. enclosed vs. exposed product)?

Examples of Significant Amendments	Examples of Minor Amendments
<ul style="list-style-type: none"> Changes that can alter the processing environment temp and humidity 	<ul style="list-style-type: none"> Altering floor layouts in Standard Hygiene areas

4. Relocating Processing Operations

27. Significant amendments to the risk management programme
(1)(d) relocating processing operations to a new physical address (except where this is already permitted under the risk management programme)

This is always a significant amendment.

5. New Dairy Material or Dairy Product

27. Significant amendments to the risk management programme
(1)(e) processing dairy material or dairy product that is not covered by the risk management programme,

Primary processing of a new dairy material

Primary processing of a new dairy material not currently covered by the RMP should always be considered a significant amendment except as agreed by the NZFSA. Such agreement may nevertheless require the operator to notify the NZFSA of changes so that it can maintain an accurate registration database and for other administrative reasons.

Processing of a new dairy product

Processing of a new dairy product (refer to product categories) not currently covered by the RMP should always be considered a significant amendment except as agreed by the NZFSA.

Processing of dairy material or dairy product for a different end consumer

For example:

- changing from human to animal consumption or vice versa;
- changing from general consumers to specific at risk groups where the RMP does not ensure that product is fit for this new intended purpose , e.g. babies, immuno-compromised people.

Justification should include consideration of the consumers the RMP currently covers

Examples of Significant Amendments	Examples of Minor Amendments
Where the RMP only covers processing for general consumption and the operator wants to start processing for susceptible population consumption.	If all product is produced to human consumption standards according to the RMP, but the operator now wants to produce animal feeds for the domestic market. Note that risks involved in production of animal feed will need to be managed in the RMP. Management of loss stream product needs to be considered as a product output.

6. Ceasing Production

27. Significant amendments to the risk management programme
1(f) permanently ceasing to process a particular type of dairy material or dairy product.

7. New Process or Process Modifications

27. Significant amendments to the risk management programme
(1)(g) process modifications that impact on the outcomes for dairy material or dairy product

Where an existing process flow does not adequately describe the new/amended process

Justification should include consideration of:

- What is changing with the new process – are the steps that are essential for food safety being altered?

- Does the process align with an industry Code of Practice, e.g. do critical product parameters align with those specified in an approved Code?

Examples of Significant Amendments	Examples of Minor Amendments
Amendment to process flow eg additional filters fitted that affect flow rates to heat treatment equipment.	Removal of an external storage silo.

Where the categories of processing that are included in the registration details change

Adding new categories of processing not currently covered by the RMP should always be considered a significant amendment. This applies whether the product is intended for human or non human consumption.

Refer to the NZFSA process categories table:

Adding a new process category is always a significant amendment.

Examples of Significant Amendments	Examples of Minor Amendments
Where a new dairy material or product is being added to an RMP that is not approved for the class of the dairy product or material.	Where a new dairy material or product is being added to an RMP that is approved for the class of the dairy product or material.

8. Changes in dairy material or product outcomes

27. Significant amendments to the risk management programme
1(h) changes to outcomes or introduction of new outcomes for dairy materials or dairy products

Justification should include consideration of:

- Are the outcomes related to fitness for purpose
- Are the outcome parameters new?
- Are the outcomes a more or less stringent outcome for an existing parameter?

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Examples of Significant Amendments	Examples of Minor Amendments
New product outcome – food safety microbial parameter.	New product outcome – colour grading of product.