Guideline for managing dairy material or product potentially exposed to chemical residues - Part A: Raw milk and raw material

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Version 01

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1 Introduction

It is important that milk and milk products offered for sale do not contain residues at levels that exceed allowable maximum residue limits (MRL). Accordingly NZFSA specifications require that risk management programmes (RMP's) must ensure that intervention occurs when they become aware of residues above the maximum residue limit (MRL), or suspect that the dairy material may contain residues above the MRL.

However in some circumstances the milk or dairy material has been consolidated prior to the processor becoming aware, and the affected milk meets the MRL requirements. In these circumstances it is not necessarily appropriate to dispose of the dairy material if it can be shown to be safe and conforming to trade requirements. This guideline provides guidance on which situations may be considered acceptable and which do not. Where a dairy processor is uncertain of the requirements that are applicable to their situation they are advised to consult their Recognised Agency.

2 Purpose of this Guideline

The purpose of this guideline is to assist RMP operators to determine the steps to be taken at various points when they become aware that raw milk or dairy material is, or is suspected to be, non-conforming. This guideline will also assist the Recognised Agency to determine when an event results in non-conforming product and is required to be managed in accordance with section 5 of the Animal Products (Dairy Processing Specifications) Notice 2006.

3 Application of Raw Milk Acceptance Requirements

The principle applied within this guideline is that, in accordance with Animal Products (Dairy) Approved Criteria for Farm Dairies (DPC2), RMP operators must intervene when raw milk or dairy material is either deemed suspect or shown to exceed accepted limits. Failure to intervene when there is a clear opportunity to do so results in the raw milk and any resultant dairy material or product being classed as non-conforming, and the requirements of the Animal Products (Dairy Processing Specifications) Notice 2006 section 5 apply.

Where non-conforming milk or material is used, regardless of the quantity, the resulting product is also deemed to be non-conforming.

Dilution cannot be used as a means of rectifying non-conforming milk, however it may be used to demonstrate compliance in situations where contamination was not reasonably expected and intervention was not possible prior to consolidation or processing, for example in cases of routine milk testing or late notification.

4 Limitations of this Guideline

This guideline has been prepared to assist RMP operators to comply with regulatory requirement. As such it will be subject to amendment based upon comment from affected parties, including RMP operators, NZFSA Compliance and Investigation Group (GIG), recognized agencies, and laboratories.

There is a second guideline titled Guideline for managing dairy material and product potentially exposed to chemical residues - Part B: Dairy material and product, which has been prepared to assist NZFSA and RA's in making decisions on disposal options for non-conforming dairy material or product.

4.1 Dilution

The dilution calculation provided in this guide is used to determine the effect of consolidation prior to a processor becoming aware that there is, or may be, a residue problem with the dairy material. The calculation as provided makes no allowance for residues that may also be in the base milk. For some residues this may not be appropriate at certain times of the year, even though the base milk contribution is typically not likely to exceed the test limits of detection.

Where any doubt exists the calculation used should assume that the base milk contains the same residue at a level half that of the laboratories limit of detection.

In addition, when applying dilution or consolidation calculations consideration must be given to the possibility that multiple consignments were detected with residues. In such cases the cumulative effect must be taken into account.

4.2 Non-beta Lactam Inhibitory Substances

Consideration needs to be given to the sensitivity of the Inhibitory Substances test to anti-microbial residues, where detection below 4 ug/kg penicillin equivalent may represent a non-compliance for some compounds (typically not beta-lactams). Because such circumstances are relatively uncommon, it is recommended that further information be obtained from the testing laboratory in situations where:

- the residue is not confirmed as being a beta-lactam (penicillin group); and
- the detection was made by the Inhibitory Substances test; and
- the result was 0.003iu/ml to 0.006 iu/ml (2-4 ug/kg) penicillin equivalent.

Where the residue is unknown it is acceptable in such circumstances to assume that the true level of the residue is twice that identified by the Inhibitory Substances test. Where the residue is known, or there is good reason to suspect a particular residue, the sensitivity of the Inhibitory Substances test to that particular residue is to be used in determining conformance. A worksheet and working example is provided on the NZFSA website.

5 Dilution Calculation

As already mentioned, a dilution calculation may be appropriate to determine the status of consolidated milk in a silo. To use the dilution calculation three parameters are required;

- level of contamination (measured as iu/ml or ppb penicillin equivalent)
- volume contaminated; and
- diluted volume.

The level of contamination will typically be based upon a laboratory estimate and reported as “penicillin equivalent”. Where the inhibitor is not identified as being a beta-lactam then allowance must be made for the reduced sensitivity of the test to non-beta-lactam residues.

If the compound is known then an appropriate correction factor may be applied based upon the sensitivity of the test for that compound, as advised by the laboratory. The exception is when the detection was compound specific and no correction factor is needed. Where the correction factor will determine material/product conformance or non-conformance this must be put forward as part of the product disposition request.

For routine analysis of raw milk ex-farm or ex-tanker it is acceptable to assume the safe limit to be 4ppb penicillin equivalent for beta-lactams and 2ppb penicillin equivalent for all other inhibitory substances.

5.1 Mixing Efficiency

Without any adjustment for mixing efficiency the calculation would assume that there is complete mixing of the silo contents, which would rarely be the case. As such operators using the dilution calculation should apply an appropriate estimation of the mixing efficiency. By default a factor of 0.5 should be applied.

However, where the silo isn't subject to discrete batch processing such as feed and bleed situations no dilution allowance can typically be applied.

When the silo is batch filled, agitated and is of sufficient volume to reach the agitator blade(s) then higher mixing efficiencies are justified. The operator should provide engineering data, trial data or in process compositional data to support the factor elected.

If the silo is agitated and a mixing factor >0.5 is used then identify the time in the silo, the number of agitator blades, percentage of silo filled (or volume filled and capacity), and the volume or % fill required to reach first agitator blade.

Note: due to the application of factors for mixing efficiency and non-batch processing and simplification of the calculation used, it is possible for the estimated residue level to exceed the actual level determined in the non-conforming source milk. In such cases the level initially determined in the non-conforming source milk will apply.

$$\textbf{Estimated Residue level (iu/ml or ppb)} = \frac{\textbf{Level of contamination}^{1}\ \textbf{(iu/ml or ug/kg)} \times \textbf{Volume contaminated}^{2}}{\textbf{(Silo volume}^{3}\ \textbf{x mixing efficiency factor}^{4)}}$$

A worksheet is provided on the NZFSA website, complete with working examples.

[1]Level of contamination, as determined n the consignment contaminated
[2]Volume contaminated = the contaminated consignment volume
[3]Silo volume = the minimum opportunity for dilution in the silo, allowing for batch or continuous processing
[4]Mixing efficiency factor = by default 0.5 applies. For a typical process complete mixing of half the silo contents is a reasonable assumption. Where multiple silo transfers are involved and/or supporting data can be provided to demonstrate the actual mixing efficiency for the dairy material and silo concerned is greater than 0.5 the details should be submitted in a product disposal request.

6 Farm Level Actions

When advising a recipient that milk delivered exceeded or may have exceeded the acceptable limit the RMP operator must also advise all pervious potentially affected consignments giving

- Date of delivery
- Time
- Volume
- Tanker delivery ID information

The recipient should then determine if the levels in the receiving silo exceed the limit based on the compound concentration of the known (current) incident.

7 Export Requirements

In some cases the importing country and/or the official assurance provided to the importing country may not allow for any exposure of a particular residue or contaminant. In such cases the dairy product is non-conforming, the Recognised Agency must be notified and an official disposition request must be submitted for the Director-Generals consideration.

8 Action Limits and Applicable MRLs

The dairy National Chemical Contaminants Programme (NCCP) monitors compliance to an extensive list of compounds and the most relevant New Zealand, Codex and international maximum residue and contaminant limit associated to these compounds. These action limits are available on the NZFSA website for RMP operators.

Any particular compound action limit nominated in the list may not apply for the intended market for the dairy material and product affected, but they do serve to prompt an “action” that will include, as a minimum, confirmation of the applicable MRLs for that market (ie for exported products, Codex and the importing country) and to determine product conformance status. Milk in the farm bulk milk tank that is intended to be eligible for all markets is expected to meet all Action Limits.

The following sets out the specific regulatory requirements with respect to residues or contaminants in dairy material including raw milk and dairy products.

8.1 New Zealand and Australia Only

Dairy material and product processed with the intention of sale in New Zealand and Australia only must comply with:

- New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2005; and
- For incidental constituents/contaminants (other than residues of agricultural compounds and veterinary medicines), the New Zealand (Australia New Zealand Food Standards Code) Food Standards 2002.

8.2 Export

In accordance with NZFSA DPC1: Animal Products (Dairy) Approved Criteria for General Dairy Processing and DPC2: Animal Products (Dairy) Approved Criteria for Farm Dairies, dairy material and product processed with the intention of export other than to Australia must comply with:

- Codex Alimentarius (2005) List of Codex Maximum Residue Limits for Veterinary Drug Residues in Food
- Codex Alimentarius (2006) List of Codex Pesticide Residues in Food: Extraneous Maximum Residue Limits
- Export requirements issued under Part 5 of the Animal Products Act 1999
- Country specific requirements.

9 Possible Scenarios

The following scenarios give guidance for the steps expected to be taken when raw milk or dairy material does, or is suspected to, contain non-conforming levels of chemical residues.

9.1 Milk On-Farm

Milk Suspect[5]	**Milk > MRL**[6]	**Milk <= MRL**
↓	↓	↓
Reject **unless** able to demonstrate acceptable[7]	Reject	Accept[8,9]
↓	↓	↓
Document as withheld on-farm and report[9]	Document as withheld on-farm and report[9]	If milk 2ppb or above farm level action is required[10]
↓	↓	
Farm Level Action Required[10]	Farm Level Action Required[10]	

[5]Suspect includes (but is not limited to) notification of possible contamination, all consignments supplied following a detection above applicable limits through to, but not including, a consignment confirmed as compliant.
[6]For inhibitory substances tests (eg Delvo) the MRL is deemed to be equivalent to 2ppb benzyl penicillin equivalent unless beta-lactam only, in which case the MRL is deemed to be 4ppb. (4 ppb = 4 ug/kg = 0.006 iu/ml penicillin equivalent).
[7]By subjecting to a test capable of detecting the compound(s) of concern at an appropriate level of sensitivity, or a suitably qualified person determining through accepted means that milk is not suspect as per the RMP. If the use of any compound is not permitted for milking animals or use of the compound on milking animals is prohibited by the intended market, then all resultant dairy product is automatically deemed to be non-conforming.
[8]Acceptance assumes further consolidation will occur and as such provides no direct guarantee that product will meet all MRL's.
[9]Document event, reasoning and fate of milk. Report to the Recognised Agency as part of routine monthly reporting, unless shown not to exceed the MRL prior to collection.
[10]If milk was offered for supply then action as specified in a registered RMP as per DPC2. Typically this involves traceback and farmer education, and if >MRL then some form of sanction. The traceback may uncover further (historic) consignments that are deemed suspect and require follow up action with processor(s). Where the alert was farmer generated then appropriate action would be to review on-farm procedures.

9.2 Milk In Tanker

1. Was there a reasonable opportunity to intervene prior to collection?

2. Was the milk ex farm bulk milk tank shown to be below the MRL for the compound(s) of concern when using an appropriate test with sufficient sensitivity prior to collection?

If the answer to Q1 is yes and the answer to Q2 is no then the milk is not suitable for human consumption. The fate/disposal of the milk must be recorded.

Tanker Milk Suspect[11]	**Tanker Milk > MRL**[12]	**Tanker Milk<= MRL**
↓	↓	↓
Reject (unless able to demonstrate milk ex-farm is acceptable)[13]	Reject	Accept[14,15]
↓	↓	
Document as withheld and report[15]	Document as withheld and Report[15]	
↓	↓	
Farm level action required[16]	Farm level action required[16]	

[11]Suspect includes (but is not limited to) notification of possible contamination, all consignments supplied following a detection above applicable limits through to, but not including, a consignment confirmed as compliant.
[12]For inhibitory substances tests (eg Delvo) the MRL is deemed to be equivalent to 2ppb benzyl penicillin equivalent unless beta-lactam only, in which case the MRL is deemed to be 4ppb. (4 ppb = 4 ug/kg = 0.006 iu/ml penicillin equivalent).
[13]By subjecting to a test capable of detecing the compound(s) of concern at an appropriate level of sensitivity, or a suitably qualified person determining through accepted means that milk is not suspect as per the RMP. If the use of any compound is not permitted for milking animals or use of the compound on milking animals is prohibited by the intended market, then all resultant dairy product is automatically deemed to be non-conforming.
[14]Acceptance assumes further consideration will occur and as such provides no direct guarantee that product will meet all MRL's.
[15]Document event, reasoning and fate of milk. Report to the Recognised Agency as part of routine monthly reporting. Reporting to the Recognised Agency is not required where tests confirm that the farm supply was compliant.
[16]If milk was offered for supply then action as specified in a registered RMP. Typically this involves traceback and farmer education, and if >MRL then some form of sanction. The traceback may uncover further (historic) consignments that are deemed suspect and require follow up action with processor(s).

9.3 Milk In Silo

If the milk ex farm bulk milk tank was shown to be below the applicable limit for the compound(s) of concern using an appropriate test with sufficient sensitivity prior to collection, or was the milk ex tanker was shown to be below the applicable limit for the compound(s) of concern, using an appropriate test with sufficient sensitivity prior to unloading then,

i. The milk is conforming dairy material

ii. Retain records and no further action required by the recipient.

In all other situations the dairy material in the silo is suspect. The dairy material in the silo can be processed provided the resultant dairy material/product[17]can and will be detained. The fate of the milk and all its components must be recorded and accounted for. Refer to Part B Guideline on disposal decisions for inhibitory substance decisions in dairy material/product for determining the status of the processed material/product.

Note that:

It is recommended that as the material in the silo is processed samples are taken and tested at regular intervals. The results of these samples may assist in confirming that the material is conforming.

Farm level action - if Milk was offered for supply then action as specified in a registered RMP. Typically this involves traceback and framer education, and if >MRL then some form of sanction. The traceback may uncover further (historic) consignments that are deemed to suspect and require follow up action with processor(s).

[17] For inhibitory substances tests (eg Delvo) the MRL is deemed to be equivalent to 2ppb benzyl penicillin equivalent unless beta-lactam only, in which case the MRL is deemed to be 4ppb. (4 ppb = 4 ug/kg = 0.006 iu/ml penicillin equivalent).

9.4 Milk Processed

If the milk ex farm bulk milk tank was shown to be below the applicable limit for the compound(s) of concern using an appropriate test with sufficient sensitivity prior to collection, or was the milk ex tanker was shown to be below the applicable limit for the compound(s) of concern, using an appropriate test with sufficient sensitivity prior to unloading then,

iii. The milk is conforming dairy material

iv. Retain records and no further action required by the recipient.

In all other situations refer to Guideline for managing dairy material and product potentially exposed to chemical residues. Part B: Dairy material and product.

Farm level action - if Milk was offered for supply then action as specified in a registered RMP. Typically this involves traceback and framer education, and if > applicable limit then some form of sanction. The traceback may uncover further (historic) consignments that are deemed to suspect and require follow up action with processor(s).