New Zealand Food Safety
Haumaru Kai Aotearoa

The DPC's have been withdrawn. For more information on these changes:

Approved criteria, codes of practice, and guidance for dairy

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# DPC 1: Animal Products (Dairy): Approved Criteria for General Dairy Processing

Pursuant to clause 9 of the Animal Products (Dairy Processing Specifications) Notice 2006, I, Carol Barnao, Deputy Director General (Standards) issue the "DPC 1: Animal Products (Dairy): Approved Criteria for General Dairy Processing" for the purpose[s] of-

(1) Setting out additional criteria for the general dairy processing of dairy material or dairy products that are valid and appropriate requirements against which to assess such operations.

(2) The criteria in this document are to be used by recognised agencies and persons when evaluating or verifying a risk management programme covering dairy processing activities unless alternative criteria have been recognised as valid and appropriate, and approved.

Signed at Wellington this 05 / 05 / 2011

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[Signed]

Carol Barnao

Deputy Director General (Standards)

Ministry of Agriculture and Forestry

(Acting under delegated authority)

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## Notice

### 1 Scope and Application

(1) This document sets out additional criteria for the general dairy processing of dairy material or dairy products that, in the view of the Director-General, are valid and appropriate requirements against which to assess such operations.

(2) These criteria are applicable to—
(a) Dairy processors
(b) Dairy risk management programme Operators (RMP Operators).

These criteria are to be read in conjunction with all other requirements and criteria applicable under the Animal Products Act 1999. Other related criteria can be found on the MAF Food Safety website at http://www.foodsafety.govt.nz.

(3) This approved criteria applies from 9 May 2011.

## 2 Outcome

(1) This document sets out the approved criteria for the general dairy processing of dairy material and dairy products against which a risk management programme, risk management programme operator or dairy processor will be assessed and judged to meet the requirements of the Animal Products Act 1999 applicable to dairy processors.

(2) The criteria in this document are to be used by recognised agencies and persons when evaluating or verifying a risk management programme covering dairy processing activities unless alternative criteria have been recognised as valid and appropriate, and approved as set out under section 3.

## 3 Approval of Alternative Criteria

Alternatives to the approved criteria in this document may be recognised as valid and appropriate by the Director-General and approved in writing. Any approved alternative must be kept with the programme and made available during evaluation or verification of the programme.

## 4 Interpretations

Unless the context otherwise requires, the interpretations used by this document are detailed in the MAF document “Glossary of Terms for Dairy” provided on the MAF Food Safety website at http://www.foodsafety.govt.nz.

## 5 Export Requirements and Official Assurances

(1) Processors, RMP operators and exporters of dairy material and dairy product intended for export must identify and ensure compliance with all relevant export requirements in accordance with Part 5 of the Animal Products Act 1999. The relevant export requirements can be obtained from the MAF Food Safety website at http://www.foodsafety.govt.nz.

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## 6 Verification

(1) Verification of the approved criteria contained in this and related criteria, including MAF approved alternative criteria, must be performed by recognised agencies and persons when evaluating and verifying dairy risk management programmes.

(2) If all relevant specifications and approved criteria are complied with then the recognised agency or person provides a recommendation to MAF Approvals for risk management programme registration.

(3) If all approved criteria are not complied with by a dairy risk management programme operator then no recommendation should be provided.

(4) MAF Compliance and Enforcement Group will also assess compliance with approved criteria outlined in this document as part of any allocated systems audits which are part of scheduled activities.

(5) If a critical non-compliance is identified by a recognised agency or person or as part of an MAF Compliance and Enforcement Group audit then registration of a dairy risk management programme may be reviewed by MAF Approvals.

## 7 Reporting Requirements

***Responsibilities***

(1) The risk management programme operator is to report to the recognised agency.

(2) The risk management programme operator or their delegate will sign all reports.

(3) The risk management programme operator and the recognised agency will agree on the method of reporting and the format and content of the report.

(4) The recognised agency undertakes its responsibilities in accordance with Animal Products (Dairy): Approved Criteria for Recognition of Agencies and Persons.

### *Exception Reporting*

(5) Any of the following exceptions are to be reported to the recognised agency as soon as practicable, but no later than 24 hours, after the occurrence of the exception or the result is known by the testing laboratory.

(6) Initial notification in writing (eg e-mail, fax) to the recognised agency of an exception is to be followed by a telephone conversation with a person (not an answering service) to confirm receipt. Initial verbal reporting is acceptable, but is to be confirmed in writing within 72 hours.

(7) The following exceptions are to be reported:
- (a) identification of non-conforming dairy material or dairy product, and
- (b) occurrence of a critical non-compliance.

*Commentary*

*Information may come from a variety of sources indicating that dairy material or product is non-conforming, or is reasonably likely to be non-conforming, or that a critical non-compliance has occurred. Information sources include verification audits, operator monitoring and customer/importing country monitoring and/or findings. Where the non-conformance is covered by an exporter non-conformance notification under section 51 of the APA, that notification is deemed to satisfy the exception reporting requirements under this sub clause.*

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(8) Exception reports will include the following:
- (a) a detailed description of the exception;
- (b) the extent of any contamination or potential contamination, e.g. date since last acceptable result, the product lines affected etc;
- (c) description, quantity and location of all non-conforming dairy material or dairy product and whether it is isolated. Where dairy material or dairy product is not isolated, the methods being used to secure it against use;
- (d) the name, title, and contact details of the person responsible for managing the exception;
- (e) the date the traceback will be completed; and
- (f) the corrective actions that are planned, in progress or completed and the schedule for commencement and completion.

(9) As much of the following information as is available at the time is provided to the recognised agency as part of the exception report, with the balance and any updates provided in follow-up reports within 15 working days of the exception report:
- (a) an account of all the actions taken;
- (b) the outcome of the traceback;
- (c) the cause(s) of the exception;
- (d) the evidence that all suspect dairy material or dairy product is identified and isolated;
- (e) the corrective actions that have been completed and those still to be completed, with the date for completion;
- (f) the evidence that the exception has been resolved;
- (g) the identity of safe and truthfully labelled dairy material or dairy product held in isolation;
- (h) the identity of the dairy material or dairy product that is not safe and/or not truthfully labelled;
- (i) a detailed written proposal, from the owner of the dairy material or dairy product, for the disposal of the dairy material or dairy product that is not safe and/or not truthfully labelled.

(10) If the information reported to the recognised agency is inadequate or incomplete, MAF/the recognised agency takes the necessary action to obtain information to verify that risks to dairy material or dairy product safety are adequately managed.

***Farm Daries Regular Reports***

(11) The following information is to be provided to the recognised agency in a manner and frequency agreed with the agency: -

(a) The unique farm dairy identifier for each farm dairy operator given notice to rectify:
  (i) elevated aerobic plate counts; or
  (ii) elevated somatic cell counts.

(b) The unique farm dairy identifier for each farm dairy supply failing to meet any acceptable limits for:
  (i) Chemical residues or contaminants
  (ii) Geometric aerobic plate count average; or
  (iii) Geometric somatic cell count average.

(c) The unique farm dairy identifier for any farm dairy supply suspended or discontinued due to unresolved milk quality failures

(d) The number of farm assessments completed in the last period, the number of non-compliances identified and the number remaining unresolved

(e) Summarised performance trends over time for the milk supply, including:
  (i) raw milk quality conformance and non-conformance:
  (ii) somatic cell count averages;
  (iii) foreign matter incidents;
  (iv) residues, including inhibitory substances
  (v) other information that may be specified by MAF.

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***Reporting on Demand***

(12) The recognised agency may request, from time to time, additional information or data on dairy material or dairy product handling, composition or properties to:

(a) investigate food safety problems or potential risks;
(b) report to MAF, or
(c) support official assurances

(13) Where a dairy processor refuses to accept and transport milk, refer Animal Products (Dairy Processing Specifications) Notice 2006, the affected risk management programme operators and dairy processors must be notified of the rejection without delay, and details of the refusal must be recorded and made available when requested.

(14) To minimise delays in the certification process, information in support of official assurances is sent to the Manager (Certification) within the MAF Verification Animal and Food Products Group.

*Commentary*

*RMP operators should inform their recognised agency or MAF of any other pertinent information relating to food safety or regulatory.*

## 8 Dairy Product Safety

(1) The following product outcomes apply to all dairy products (for human consumption) and are not to be exceeded at any point during the product's shelf life, when handled and stored in accordance with manufacturer's specifications.

(2) Routine testing of product safety attributes may not be required where a HACCP Plan refer "Dairy HACCP Plans" can demonstrate an equivalent level of confidence in meeting these product safety outcomes.

### *Wholesomeness and Foreign Matter*

(3) All dairy products must be wholesome and must not contain any foreign matter that constitutes a food safety hazard.

(4) The manufacturer's risk management programme must define what constitutes a food safety and non food safety hazard for the products manufactured within the scope of the risk management programme.

### *Pathogenic Micro-organisms*

(5) This section lists microbial Product Safety Limits (PSLs). Key Points are as follows:

(a) The limits described must not be exceeded at any time during the product's shelf life (assuming the product is handled and stored according to the manufacturer's guidelines).

(b) Where a risk management programme documents the requirement for routine pathogen testing, the testing is initiated as soon as possible, and not later than seven days after the completion of product manufacture.

(c) The manufacturer's HACCP Plan, developed in accordance with Dairy HACCP Plans, is used to provide the basis for the sampling and testing plan for the parameters described in Table A1.0.

(d) In the event that pathogenic micro-organisms do exceed the limits in Table A1.0, the product is deemed to be non-conforming.

(e) 'Retesting After Issue of Final Laboratory Result': Use of results from retesting of product previously found to contain pathogens in excess of limits contained in this Standard is not permitted. However additional testing may be carried out on previously untested product to establish limits of non-conformance in a product lot (e.g. where determination of cut-off points is required).

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(f) 'Retesting Prior to Issue of Final Laboratory Result': Where the laboratory has unequivocal evidence that the 'suspect' result arises from a failure of its internal systems (NB this requires clear documentation) then the use of retest results may be permitted. This is regarded as a 'laboratory internal retest' and each instance is reported refer to Animal Products (Dairy) Approved Criteria for Recognition of Agencies and Persons.

(g) All dairy products manufactured in New Zealand, must comply with microbiological limits specified in the Australia New Zealand Food Standards Code (FSC) (refer to http://www.foodstandards.govt.nz for the current food standards).

**Table A1.0 PSLs for Pathogenic Bacteria (Human Consumption)**

| Pathogen | General PSLs (1, 3) | Specific PSLs (2, 3) | Explanatory Notes / Comments |
|---|---|---|---|
| *Salmonella spp.* | ND/25g | ND/250g | ND = not detected in the volume tested<br>Composite of samples collected throughout the production run as defined by the manufacturer's RMP |
| *L. monocytogenes* | ND/25g (4) | ND/25g | ND = not detected in the volume tested<br>Composite of samples collected throughout the production run as defined by the manufacturer's RMP |

| Pathogen | General PSLs (1, 3) | Specific PSLs (2, 3) | Explanatory Notes / Comments |
|---|---|---|---|
| *Coagulase Positive Staphylococci* (*S. aureus*) | 1000/g | 10/g, 100/g | The limit of 10/g applies to powdered infant formula products only.<br>In all cases it is critical that sampling and testing are performed in a way that correctly estimates the maximum number of *S. aureus* reached in a product. This is important because the risk posed by released enterotoxin is 'estimated' by the bacterial load |
| *B. cereus* | 1000/g | 100/g (5) | |
| *E. coli* | 100/g | 10/g | |
| E. sakazakii<br>(Cronobacter spp.) | | ND/300g(6) | Composite of samples collected throughout the production run as defined by the manufacturer's RMP.<br>Acceptable composite procedures would include continuous sampling or 30 x 10 g. In situations where the history of the product is known alternative sampling criteria may be acceptable. |

(1)General PSLs: For product to be consumed by the general population.

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(2)Specific PSLs: For products that are specifically designated for, and are likely to form, a substantial part of the dietary intake of more susceptible members of the population (i.e. infants and young children, the old, pregnant and immuno-compromised).

(3)Sampling Rates: If testing is required, the rate of sampling for each organism/product combination should be decided as part of a HACCP analysis performed on the manufacturing process.

(4) Listeria monocytogenes: Limits of ND/25g and 100/g have now been adopted by the Joint FAO/WHO Food Standards Programme, Codex Committee on Food Hygiene in the "Draft Guidelines for the Control of Listeria monocytogenes in Foods". In the future, it may be appropriate to adopt a PSL of 100/g in circumstances where it can be shown that growth is extremely unlikely to occur during the life of the product. MAF through its Listeria Strategy will be developing policy on how the limit of 100/g may be applied to foods and to revise the criteria within the FSC.

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(5)*Bacillus cereus*: This limit only applies to product designated as infant formula.

(6) Enterobacter sakazakii (Cronobacter spp.): This limit only applies to product designated as infant formula, human milk fortifiers or formula for special medical purposes intended for infants when intended as the sole source of nutrition.

## 9 Chemical Contaminants and Residues of Agricultural Compounds and Veterinary Medicines

(1) Dairy material and dairy products must not contain:

(a) residues exceeding the limits specified in the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2011 or subsequent amendments; or

(b) chemical contaminants exceeding the limits specified in this Approved Criteria under section 10 Specified Contaminants; or

(c) Standard 1.4.1 of the Food Standards Code (Contaminants and Natural Toxicants, refer to http://www.foodstandards.gov.au/foodstandards/).

(2) In addition to subclause (1), dairy material and dairy product intended for export must not contain levels of chemical contaminants or residues that exceed limits specified by:

(a) Codex; or

(b) the intended importing country.

(3) Risk management programmes must contain a suitable sampling and testing plan for chemical contaminants and residues identified through HACCP Identification and Analysis as presenting a risk. In doing so the RMP operator should refer to the MAF National Chemical Contaminants Programme and may defer to the monitoring conducted under that programme for compounds shown to be managed effectively.

(4) In the event that a chemical contaminant or residue is present in dairy material or dairy product at a level that exceeds an applicable limit as specified in (1) and (2) of this section, the dairy material and/or dairy product is deemed to be non-conforming.

## 10 Specified Contaminants

Table A2.0 Regulatory limits for specified contaminants

| | Nitrate (mg/kg) | Nitrite(mg/kg) |
|---|---|---|
| Specified population (excluding ingredients1) | 50 | 5 |
| General population (and ingredients 1 ) – Milk Powders | 150 | 5 |
| General population (and ingredients 1 ) – Protein Products | 150 | 15 |

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(1) Product in breech of the regulatory requirements is non-conforming and is required to follow the normal exception and product disposal process.

(2) In addition, each manufacturer is required to set, and adhere to, process hygiene limits appropriate to their operations and product in order to satisfy Regulation 8(1) of the Animal Products (Dairy) Regulations 2005 Processing in a manner that minimises contamination and the ALARA (as low as reasonably achievable) principle applied under the Food Standards Code standard 1.4.1: Contaminants and Natural Toxicants.

[1] As defined in the Clarification for Ingredient Exports October 2008 publication http://www.foodsafety.govt.nz/elibrary/industry/fsc-clarification-for-ingredients.htm

## 11 Composition and Nutrient Fortification

(1) All dairy products manufactured in New Zealand, must comply with composition and nutrient fortification limits specified in the Australia New Zealand Food Standards Code (FSC) unless there is a valid exemption in place (refer to http://www.foodstandards.govt.nz for the current food standards). Refer to the MAF Food Safety website http://www.foodsafety.govt.nz for a list of current exemptions. Exporters may request exemptions where the formulation is only manufactured for export and they can demonstrate that the formulation:

(i) Complies with the importing country composition and nutrient fortification requirements, or

(ii) Is approved or allowed for sale or importation by the competent authority in the importing country.

## 12 Radionuclides

(1) Radionuclide levels in dairy product are monitored under a regulated control scheme which establishes the national status of radionuclides. Where individual product levels are needed, for assurances relating to certification, separate testing will be required.

## 13 Dairy HACCP Plans

(1) All Hazard Identification and Analyses or HACCP Plans are to be developed in accordance with the Codex document entitled, "Hazard Analysis and Critical Control Point (HACCP) system and guidelines for its application". Excerpts from this document are included in this document as bold italics.

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Recommended International Code of Practice, General Principles of Food Hygiene, http://www.codexalimentarius.net (Reference CAC/RCP1 – 1969/Rev. 4 2003).

(2) Additionally, a useful guideline to the application of HACCP can be obtained from the following:

(a) MAF Food: Dairy operational guideline, "Dairy HACCP Plan Guideline" provides information to assist in meeting the outcomes required by this Standard. A copy of this guideline can be obtained from the MAF Food Safety website http://www.foodsafety.govt.nz

(b) "Food Quality and Safety System – A Training Manual on Food Hygiene and the Hazard Analysis and Critical Control Point (HACCP) System (see Food and Agriculture Organisation of the United Nations,: http://www.fao.org/docrep/W8088E/w8088e00.htm )

***Requirements Prior to HACCP***

(3) HACCP is not a stand-alone programme but is part of a larger control system which builds on a series of prerequisite programmes. Prerequisite programmes are documented systems covering GMP-based food hygiene activities that have the potential to influence the hygiene status of the product and/or control hazards. Therefore, prior to implementation of a HACCP Plan, there is a requirement for the organisation to develop and implement applicable prerequisite programmes.

(4) In addition to the HACCP Plan requirements, supporting systems should be developed when necessary to complement the HACCP Plan. These are simply tools that form part of the overall HACCP Plan but do not directly influence the hygiene status of the product and/or control hazards. This includes, for example, but is not limited to:

(a) labelling (refer to Animal Products (Export Requirements – Dairy Products Notice 2005); and

(b) reporting (refer to Reporting Requirements)

### *HACCP Team*

(5) The food operation should assure that the appropriate product specific knowledge and expertise is available for the development of an effective HACCP Plan. Optimally, this may be accomplished by assembling a multidisciplinary team. Where such expertise is not available on site, expert advice should be obtained from other sources.

### *Scope of HACCP Plan*

(6) The scope of the HACCP Plan should be identified. The scope should describe which segment of the food chain is involved and the general classes of hazards to be addressed (e.g. does it cover all classes of hazards or only selected classes?).

### *Describe Product*

(7) A full description of the product should be drawn up, including relevant safety information such as: composition, physical/chemical structure (including Aw, pH, etc.), microcidal/static treatments (heat-treatment, freezing, brining, smoking, etc.), packaging, durability and storage conditions and method of distribution.

### *Identify Intended Use/Intended Consumer*

(8) The intended use should be based on the expected uses of the product by the end user or consumer. In specific cases, vulnerable groups of the population, e.g. institutional feeding, may have to be considered.

(9) The description of the intended use should identify, where appropriate:
- (a) normal usage conditions, e.g. appropriate storage temperatures, and how it is likely to be eaten;
- (b) potential for abuse of the product, e.g. the likelihood on incorrect storage or handling of the product, resulting in unacceptable growth of microorganisms.

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### *Product Safety Outcomes*

(10) The HACCP team must determine what the organisation intends to achieve in terms of product safety outcomes for each product.

### *Construct Flow Diagram*

(11) The flow diagram should be constructed by the HACCP team. The flow diagram should cover all steps in the operation. When applying HACCP to a given operation, consideration should be given to steps preceding and following the specified operation.

(12) The inputs must be described. These include raw materials, ingredients, food additives, and wrapping and packaging materials or containers that come into direct contact with or form part of the product, e.g. plastic bag liners etc.

(13) Edible outputs should also be shown. Each of these may initiate a separate process flow diagram of its own and form part of another HACCP Plan with a different end product.

(14) The flow diagram should include all activities which impact on the process which has been scoped e.g. reworking etc. Where trials have the potential to impact on mainstream processes, the impact should also be subject to a hazard analysis.

### *On-site Confirmation of Flow Diagram*

(15) The HACCP team should confirm the processing operation against the flow diagram during all stages and hours of operation and amend the flow diagram where appropriate.

(16) It is important that the process flow diagram reflects what is actually happening with the process. On completion, the process flow diagram should be confirmed.

### *Hazard Identification, Hazard Analysis and Control Measures*

(17) List all potential hazards associated with each step, conduct a hazard analysis, and consider any measures to control identified hazards (SEE PRINCIPLE 1).

***List All Potential Hazards***

(18) The HACCP team should list all of the hazards that may be reasonably expected to occur at each step from primary production, processing, manufacture, and distribution until the point of consumption.

(19) All biological, chemical and physical hazards should be considered.

(20) Identify the hazard source and be specific in terms of the actual hazard. The level of specificity is determined by the extent of hazard identification required to ensure effective hazard control. (e.g. for raw milk instead of writing “biological hazard” be more specific and write “pathogenic bacteria, such as *E. coli*, Listeria spp, Salmonella spp, *Staphylococcus aureus*”). This will ensure that the control measures are relevant and effective in controlling the specific hazard(s) identified.

***Conduct a Hazard Analysis***

(21) The HACCP team should next conduct a hazard analysis to identify for the HACCP Plan, which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to the production of a safe food. In conducting the hazard analysis, wherever possible the following should be included:

(a) the likely occurrence of hazards and severity of their adverse health effects; (see footnote) { The likely occurrence of hazards and severity of their adverse health effects gives the probability of occurrence and severity of illness};
(b) the qualitative and/or quantitative evaluation of the presence of hazards;
(c) survival or multiplication of microorganisms of concern;
(d) production or persistence in foods of toxins, chemicals or physical agents; and
(e) conditions leading to the above.

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(22) Once all potential hazards that are reasonably likely to occur have been identified, analyse each hazard and decide which are significant in relation to the designated product outcome. A significant hazard is one that is likely to occur at unacceptable levels.

***Control Measures***

(23) The HACCP team must then consider what control measures, if any, exist which can be applied for each hazard. More than one control measure may be required to control a specific hazard(s) and more than one hazard may be controlled by a specified control measure.

(24) For each hazard identified as reasonably likely to occur, list the control measures or prerequisite programmes that are in place. Control measures are specific to the process step where the hazard has been identified whereas prerequisite programmes control hazards that could come into contact with product and are more generic in nature.

(25) A control measure/prerequisite programme must be effective in controlling the specific hazard(s) identified, implemented and working on a consistent basis. Where control is not effective the HACCP team should determine the gaps and implement controls as necessary.

***Determine Critical Control Points (SEE PRINCIPLE 2)***

(26) There may be more than one CCP at which control is applied to address the same hazard. The determination of a CCP in the HACCP system can be facilitated by the application of a decision tree [e.g. Figure A1.1], which indicates a logic reasoning approach. Application of a decision tree should be flexible, given whether the operation is for production, slaughter, processing, storage, distribution or other. It should be used for guidance when determining CCPs. This example of a decision

tree may not be applicable to all situations. Other approaches may be used. Training in the application of the decision tree is recommended.

(27) If a hazard has been identified at a step where control is necessary for safety, and no control measure exists at that step, or any other, then the product or process should be modified at that step, or at any earlier or later stage, to include a control measure.

(28) CCPs can be identified by means other than the Codex Decision Tree, as long as meaningful analysis of each identified significant hazard is undertaken in relation to expected product outcomes for the product.

(29) The existence or non-existence of a CCP should never be assumed without working through some systematic decision making process.

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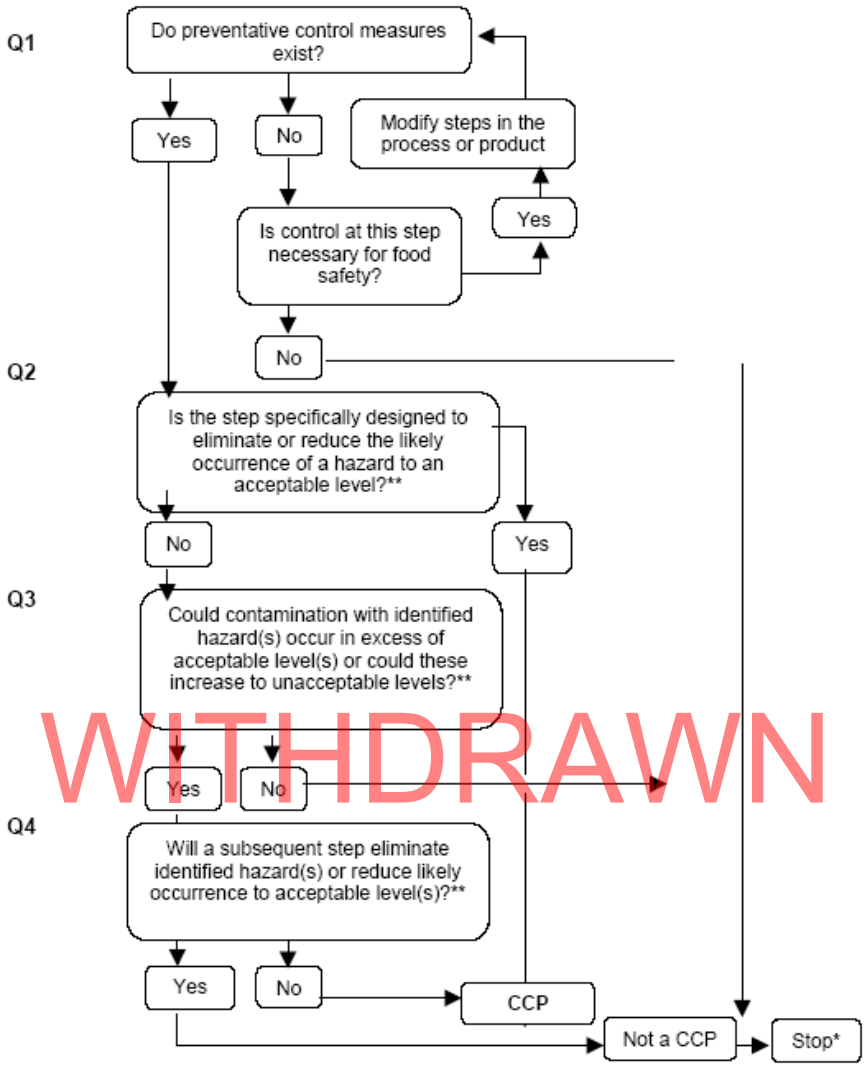
**Figure A1.1: Codex Alimentarius Decision Tree to Identify CCPs**

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* Proceed to the next identified hazard in the described process.

** Acceptable levels (and conversly, unacceptable levels) are determined in relation to the product outcome required for a particular hazard.

***Establish Critical Limits for Each CCP (SEE PRINCIPLE 3)***

(30) Critical limits must be specified and validated if possible for each Critical Control Point. In some cases more than one critical limit will be elaborated at a particular step. Criteria often used include measurements of temperature, time, moisture level, pH, Aw, available chlorine, and sensory parameters such as visual appearance and texture.

(31) When the critical limits for a critical control point have been met, the process and/or product is deemed to be safe at that point in the process because the product

outcomes have been met. Consequently, where critical limits are exceeded, then the process or product may be deemed to be unsafe.

(32) The critical limits must be measurable, achievable and appropriate to the CCP and hazard(s) being controlled and wherever possible, there should be a scientific basis for the control process and the limits set for each CCP. This information may be found in scientific publications, challenge studies (these must be properly designed to show the destruction, elimination or control of the hazard concerned) and government regulatory agency standards and guidelines. Validation of critical limits proves product outcomes are achieved.

(33) It is important when setting critical control point limits, the variability of any monitoring equipment or process should be considered. The rationale for selected critical limits should be documented.

(34) Once the critical limits have been determined they should be proven ("validated"). This involves the scientific activity/data that demonstrates that the specific hazard(s) at the CCP is eliminated or reduced to an acceptable level, i.e. compliant with product outcomes.

***Establish a Monitoring System for Each CCP (SEE PRINCIPLE 4)***

(35) Monitoring is the scheduled measurement or observation of a CCP relative to its critical limits. The monitoring procedures must be able to detect loss of control at the CCP. Further, monitoring should ideally provide this information in time to make adjustments to ensure control of the process to prevent violating the critical limits. Where possible, process adjustments should be made when monitoring results indicate a trend towards loss of control at a CCP. The adjustments should be taken before a deviation occurs. Data derived from monitoring must be evaluated by a designated person with knowledge and authority to carry out corrective actions when indicated. If monitoring is not continuous, then the amount or frequency of monitoring must be sufficient to guarantee the CCP is in control. Most monitoring procedures for CCPs will need to be done rapidly because they relate to on-line processes and there will not be time for lengthy analytical testing. Physical and chemical measurements are often preferred to microbiological testing because they may be done rapidly and can often indicate the microbiological control of the product. All records and documents associated with monitoring CCPs must be signed by the person(s) doing the monitoring and by a responsible reviewing official(s) of the company.

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(36) Monitoring procedures should provide information on:

(a) who will undertake the monitoring (this person must be trained and have appropriate responsibility to initiate corrective action, or a computer with appropriate recording and software controls);
(b) frequency of the monitoring including statistically valid sampling regimes;
(c) what will be monitored;
(d) where monitoring will occur; and
(e) how critical limits will be monitored.

***Establish (CPP) Corrective Actions (SEE PRINCIPLE 5)***

(37) Specific corrective actions must be developed for each CCP in the HACCP system in order to deal with deviations when they occur. The actions must ensure that the CCP has been brought under control. Actions taken must also include proper disposition of the affected product. Deviation and product disposition procedures must be documented in the HACCP record keeping.

(38) Where the critical limits for a CCP have been exceeded, the following corrective actions must be taken:

(39) Bring the defective process back under control.

(40) Determine and control any affected product. All product processed back to the point where the CCP was known to be within limits must be considered “affected” and be treated in accordance with “Management of Non-conforming Dairy Material and Dairy Product” and “Reporting Requirements”.

(41) Take action to ensure the non-conformance does not recur. In this regard the investigation should determine the root cause of the problem, take action to prevent recurrence and follow up with monitoring and reassessment to ensure the corrective action is effective. This step may involve reassessment of the control measures and/or modification of the HACCP Plan.

(42) Corrective action responsibilities should be defined in the HACCP Plan, and recorded.

***Establish Verification Procedures (SEE PRINCIPLE 6)***

(43) Establish procedures for verification. Verification and auditing methods, procedures and tests, including random sampling and analysis, can be used to determine if the HACCP system is working correctly. The frequency of verification should be sufficient to confirm that the HACCP system is working effectively. Examples of verification activities include:

(a) Review of the HACCP system and its records;
(b) Review of deviations and product dispositions;
(c) Confirmation that CCPs are kept under control.

(44) Where possible, validation activities should include actions which confirm the efficacy of all elements of the HACCP Plan.

(45) The internal verification procedures should detail who is to undertake the verification process(es), the frequency of verification, including sampling regimes, what is to be verified and how verification is undertaken.

WITHDRAWN

***Hazard Identification and Analyses or HACCP Plan Validation***

(46) The Hazard Identification and Analyses or HACCP Plan is validated at least when it is first developed and following revision, by a competent, internal or external validator on behalf of the company/operator.

(47) Validation involves obtaining evidence that all steps of the Hazard Identification and Analyses or HACCP Plan are effective in achieving the product outcomes. The Hazard Identification and Analysis or HACCP Plan validation includes:

(a) review of the scope, product description, intended use;
(b) review of the process flow and verification;
(c) review of the hazard identification and analysis;
(d) confirmation the control measure(s) and critical control points eliminate or reduce the hazard(s) to an acceptable level (product outcomes);
(e) review of CCP determination;
(f) review of justification of critical limits, including validation information;
(g) determination of the ability for equipment to deliver the parameters of the critical limit (e.g. heat treatment in accordance with Animal Products (Dairy) Approved Criteria for the Manufacturing of Dairy Material and Products “Dairy Heat Treatments” which may include crack tests, divert checks);
(h) determination of whether monitoring activities, corrective action, record keeping and verification activities are appropriate and adequate for the defined hazard and relative to product outcomes.

(NB. CCP monitoring and CCP corrective action apply to a HACCP Plan only.)

### *HACCP System Audits (Internal Only)*

(48) HACCP system audits should review the actual practices and application of any procedures written in the Hazard Identification and Analyses or HACCP Plans. HACCP system audits may include on-site observations to confirm that events are occurring. These may include confirmation that:

(a) product description and process flow diagram continue to be accurate;
(b) monitoring required by the HACCP Plan at the CCPs is performed;
(c) processes are operating within established critical limits;
(d) where monitoring has indicated a deviation from critical limits, affected product has been controlled as established and corrective actions have been followed;
(e) records are filled out accurately.

(49) The audits may cover the entire Hazard Identification and Analyses or HACCP Plans or selected parts. However a full review is recommended periodically to ensure that the Hazard Identification and Analyses or HACCP Plans continues to meet expected outcomes and remains suitable. Where possible, reviews should be carried out under a formal audit procedure with appropriate follow-up for non-conformances to the Hazard Identification and Analyses or HACCP Plans.

(50) Additionally, a review of the HACCP system should occur when changes that may impact on the Hazard Identification and Analyses or HACCP Plans occur. Examples of changes include:

(a) introduction of a new raw material;
(b) changes to the formulation, processing or packing methods and/or system;
(c) a change to the intended product use;
(d) a significant food safety event, e.g. pathogen or foreign matter contamination.

WITHDRAWN

(51) In addition, a review of the Hazard Identification and Analyses or HACCP Plans may be undertaken following customer complaints.

### *Equipment Calibration*

(52) The calibration of CCP process monitoring instruments needs to be:

(a) at a frequency to assure continuous accuracy;
(b) according to procedures established in the HACCP Plan;
(c) against a recognised standard.

(53) When equipment monitoring a CCP is out of calibration, the CCP is considered to have been out of control since the last documented calibration.

### *Product Sampling and Testing*

(54) The product sampling and testing regime that is used to verify the product outcomes of the HACCP Plan have been met, shall be recorded, validated and available for audit. Guidance for establishing the sampling and testing regime is available in the MAF Dairy HACCP Plans operational guideline located on the MAF Food Safety website http://www.foodsafety.govt.nz.

### *Establish Documentation and Record Keeping (SEE PRINCIPLE 7)*

(55) Efficient and accurate record keeping is essential to the application of a HACCP system. HACCP procedures should be documented. Documentation and record keeping should be appropriate to the nature and size of the operation.

(56) Documentation examples are:

(a) Hazard analysis;
(b) CCP determination;
(c) Critical limit determination;
(d) Record examples are;
(e) CCP monitoring activities;
(f) Deviations and associated corrective actions;

(g) Modifications to the HACCP system.

(57) Records are essential for reviewing the adequacy of the HACCP Plan and the compliance of the HACCP system to the plan. As a minimum the following documentation should be kept:

(a) HACCP Plan and the support documentation used to develop the Plan e.g. data used to establish the adequacy of the critical limits in ensuring the safety of the product or data used to establish sampling and testing rates.
(b) hazard identification and analysis data;
(c) CCP determination process;
(d) CCP monitoring records e.g. temperature, time etc;
(e) Corrective Action Records (including product disposition records);
(f) verification activity records e.g. sampling and testing regimes;
(g) verification records e.g. audit reports, etc.

(58) Documentation and record keeping should be undertaken in accordance with the requirements detailed in "Reporting Requirements" and Animal Products (Risk Management Programme Specifications) Notice 2008.

***Implementation***

(59) There are a number of ways that a Hazard Identification and Analyses or HACCP Plan can be implemented. This will depend on the size and complexity of the operation and resources available. The company must decide the best way to introduce the Plan to the workplace.

(60) For the Hazard Identification and Analyses or HACCP Plan to be successful, it should be effectively implemented. The first stage of effective implementation is to ensure that effective training has been undertaken.

WITHDRAWN

(61) Training of personnel in industry, government and academia in HACCP principles and applications, and increasing awareness of consumers are essential elements for the effective implementation of HACCP. As an aid in developing specific training to support a HACCP Plan, working instructions and procedures should be developed which define the tasks of the operating personnel to be stationed at each Critical Control Point.

(62) Cooperation between primary producer, industry, trade groups, consumer organizations, and responsible authorities is of vital importance. Opportunities should be provided for the joint training of industry and control authorities to encourage and maintain a continuous dialogue and create a climate of understanding in the practical application of HACCP.

(63) Then the following points are recommended:

(a) external assessment of the Hazard Identification and Analyses or HACCP Plans.
(b) evaluation of Hazard Identification and Analyses or HACCP Plans

(64) The validated Hazard Identification and Analyses or HACCP Plan is evaluated by the recognised agency when it is first developed and following all significant changes. The technical competencies of evaluators are detailed in Animal Products (Dairy) Approved Criteria for Recognition of Agencies and Persons.

***Reporting***

Records and reporting should be undertaken as required by clause 7 "Reporting Requirements" and sub clause (58) above.

## 14 Management of Non-Conforming Dairy Material or Dairy Product

(1) All dairy raw materials that fail to meet the requirements of Animal Products (Dairy) Approved Criteria for Farm Dairies “Raw Milk Acceptance” is to be identified as non-conforming.

(2) All dairy material or dairy product supplied or manufactured, since the last recorded demonstration of conformance is to be identified as non-conforming.

(3) Where dairy material or dairy product is produced, stored, transported or manufactured using common premises or equipment, all dairy material or dairy product passing through that common premise or equipment since the last recorded demonstration of conformance and suspected of also being non-conforming is to be identified as non-conforming.

(4) All dairy material or dairy product identified as non-conforming must be isolated, appropriately labelled and recorded and secured against use, sale or export.

(5) All instances of non-conforming dairy material or dairy product are to be reported in accordance with “Reporting Requirements”.

## 15 Traceback for Non-Conforming Dairy Material or Dairy Product

(1) When dairy material or dairy product is identified as non-conforming, a team of people with appropriate knowledge, skill and experience is to complete a traceback and prepare a written report.

(2) The traceback examines all relevant records to:
- (a) determine the extent of the defect,
- (b) identify and isolate all non-conforming material or dairy product including current production,
- (c) identify the cause(s),
- (d) define the necessary corrective actions to ensure the current risk is effectively managed, and
- (e) define the necessary corrective actions to ensure that future dairy material or dairy product is protected against the defect.

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## 16 Sampling and Testing for Non-Conforming Dairy Material or Dairy Product

(1) Information to support the proposal for disposition is obtained from sampling and testing as follows:
- (a) Dairy raw materials — Sampling and testing of the raw materials is undertaken as prescribed by MAF on a case-by-case basis.
- (b) Dairy products:
  - (i) Unregistered premises — Where dairy product has been:
    - (A) manufactured or stored in premises not registered for the class or description of product concerned, or
    - (B) in breach of a condition of registration of the premises, sampling and testing of the product is undertaken as prescribed by MAF on a case-by-case basis.
  - (ii) Risk management programme coverage — Where there are gaps in risk management programme coverage, sampling and testing of the product is undertaken as prescribed by MAF on a case-by-case basis.
- (c) Safety:
  - (i) Risk management programme control systems — Where there has been a failure of a risk management programme control system, or the control limits have been exceeded, the non-conforming product is sampled and tested to assess the level of the hazard in the batch or lot of product.
  - (ii) Where finished product sampling and testing has identified that product fails to conform to the product safety standards specified in “Dairy

Product Safety," product is sampled and tested to assess the level of the hazard in the batch or lot of product.

(d) Truth of labelling:

(i) Risk management programme control systems — Where there has been a failure of a risk management programme control system or the control limits have been exceeded, finished product is sampled and tested to assess the level of the attribute(s) in the batch or lot of product.

(ii) Finished product sampling and testing — Where sampling and testing of the finished product has identified that product fails to conform to the labelling standards specified in Animal Products (Export Requirements – Dairy Products) Notice 2005 the finished product is sampled and tested to assess the level of the attribute(s) in the batch or lot of product.

***Sampling and Testing Conditions***

(2) Samples taken for the purposes of finished product testing are representative of the non-conforming product being sampled and remain representative. The portion of the sample that is tested is also representative of the product. Guidance on sampling techniques can be obtained from IDF Standard 50C: 1995 "Milk and Milk Products Guidance on Sampling."

(3) All testing for the purposes of the determination of safety is undertaken using a MAF-approved test method for the attribute. A list of MAF-approved test methods can be obtained from the MAF Food Safety website http://www.foodsafety.govt.nz

(4) All dairy material or dairy product testing for food safety and truth of labelling is undertaken in a MAF-registered laboratory accredited/recognised in the appropriate category for the required test refer Animal Products (Dairy) Conditions for Recognition and Animal Products (Dairy) Approved Criteria for Recognition of Agencies and Persons.

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(5) Resampling and retesting of product does not occur except:

(a) in accordance with the requirements for control of non-conforming testing and/or calibration work specified in ISO Guide 25/ ISO Standard 17025, and

(b) for the purposes of gathering information for the traceback.

**17 Disposal of Non-Conforming Dairy Material or Dairy Product**

(1) The Director-General will provide written consent for the disposition of all non-conforming dairy material and dairy product. The owner of the non-conforming dairy material and dairy product obtains this consent by submitting a detailed written proposal for disposition to MAF or the recognised agency. This proposal addresses the hazard, the level of risk associated with the proposed disposition and provides all relevant information relating to the dairy material and dairy product concerned.

(2) The options available for the disposal of non-conforming dairy material and dairy product are:

(a) sale as dairy product,
(b) use as dairy raw materials,
(c) use as animal feed or ingredients thereof,
(d) sale for non-food and non-feed uses, or
(e) destruction.

(3) A flowchart is provided in Figure A1.2 to assist in selecting the appropriate disposal option.

(4) The owner of the dairy material and dairy product is responsible for obtaining the approval of any other authorities, e.g. the regional council, which is necessary for the disposal of the non-conforming dairy material and dairy product.

## 18 Labelling of Mislabelled and/or Unsafe Dairy Material or Dairy Product

(1) Where dairy produce fails to meet the requirements of Animal Products (Export Requirements - Dairy Products) Notice 2005 any MAF devices appearing on the product must be defaced.

(2) Where dairy material and dairy product fails to meet "Dairy Product Safety," the following are to be completed:
- (a) any MAF devices appearing on the product are defaced, and
- (b) all packages and associated documentation bear the words "Not for Human Consumption".

(3) Where dairy raw materials fail to meet the requirements any MAF devices appearing on the raw materials are to be defaced.

(4) The HACCP plan for maintaining the safety of dairy material during collection and transportation is to be developed in compliance with Animal Products (Dairy Risk Management Programme Specifications) Notice 2005 and requirements for dairy HACCP Plans contained in Animal Products (Dairy) Approved Criteria for General Dairy Processing. Where dairy raw materials fail to meet "Dairy Raw Materials Safety," the following are completed:
- (a) any MAF devices appearing on the raw materials are to be defaced, and
- (b) all packages and associated documentation must bear the words "Not for Human Consumption".

***Disposal***

(5) The owner of the dairy material or dairy product must dispose of the dairy material or dairy product in accordance with MAF's consent and any conditions that have been specified by MAF, the recognised agency, and any other authority.

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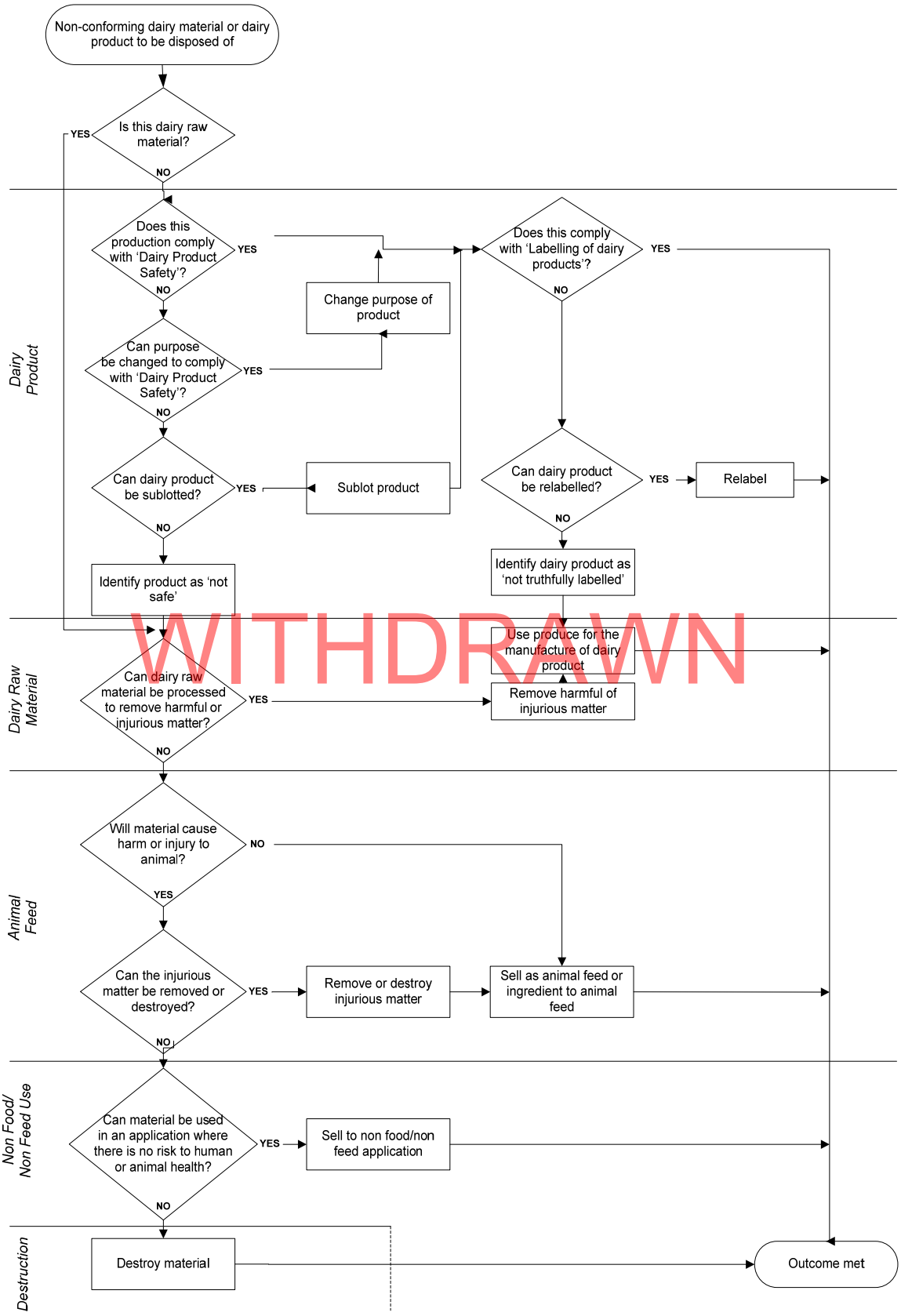
(6) The owner bears all costs associated with disposal of the dairy material or dairy product.

(7) The owner of the dairy material or dairy product is to provide the recognised agency with written confirmation of the disposal.

***Records***

(8) The owner of the non-conforming dairy material and dairy product keeps appropriate records to demonstrate compliance with these requirements, for as long as is necessary for traceback and verification purposes.

## Figure A1.2: Flowchart for Considering Disposal Options

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## 19 Conditions for Disposal

(1) The conditions of disposal are provided below for each option for disposing of non-conforming dairy material and dairy product.

(2) All dairy product sold must comply with the following:
- (a) Animal Products Act 1999; and
- (b) Animal Products (Dairy) Regulations 2005; and
- (c) MAF Dairy Specifications; and
- (d) Australia New Zealand Food Standards Code/New Zealand Food Regulations 1984; or
- (e) official assurances provided by MAF.

(3) In addition, where dairy product is sold in New Zealand or Australia, it must also comply with the following:
- (a) Food Act 1981, and relevant subordinate legislation made under the Food act 1981.

(4) Where product is to be exported to any country, with the exception of Australia, it must also comply with the requirements of the importing country.

(5) Dairy product may have its purpose changed, be sublotted or relabelled provided it meets these requirements.

(6) Where dairy product does not comply with the above requirements it is considered to have the same status for use as dairy raw materials. For the disposal options and conditions of dairy raw materials, refer to “Use as dairy raw materials.”

***Change of Purpose***

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(7) In two situations, the purpose of a dairy product may be changed to enable it to meet the requirements “Dairy Product Safety.” These situations are as follows.
- (a) Product fails to meet the importing country requirements of an importing country but meets the New Zealand standard or the importing country requirements of another importing country.
- (b) Product fails to meet the requirements specified in “Dairy Product Safety” for the intended use, e.g. infant formula, but meets the requirements for another use.

(8) In both situations, product is labelled, before sale, in accordance with Animal Products (Export Requirements – Dairy Products) Notice 2005.

***Sublotting***

(9) A non-conforming batch or lot of dairy product may be split, provided all of the following conditions are met:
- (a) The batch or lot has not been split previously.
- (b) The batch or lot conforms to the limits for pathogenic micro-organisms specified “Dairy Product Safety.”
- (c) The batch/lot is only split in one of the following ways:
  - (i) good/defective,
  - (ii) defective/good, or
  - (iii) good/defective/good.
- (d) Clear evidence exists which demonstrates that:
  - (i) the process differed in some way which has caused some product to be defective; and
  - (ii) clear separation exists between the defective and “good” product.
- (e) Each of the “good” sub batches/lots must be sampled and tested as a single batch/lot.

### *Relabelling for Sale as Dairy Product*

(10) Where dairy product meets the requirements above and is able to be relabelled to comply with Animal Products (Export Requirements – Dairy Products) Notice 2005 it may be relabelled and sold as dairy product.

### *Use as Dairy Raw Materials*

(11) All raw milk and dairy raw materials are to be satisfactory for use or sale as dairy raw materials.

(12) All dairy raw materials must comply with the following:
- (a) Animal Products Act 1999
- (b) Animal Products (Dairy) Regulations 2005
- (c) MAF Dairy Specifications
- (d) New Zealand (Milk and Milk Products Processing) Food Standards 2002 and
- (e) official assurances provided by MAF.

(13) Satisfactory dairy raw materials may be used for the manufacture of dairy products, provided the resulting dairy product complies with the requirements for dairy products, including reprocessing and repacking.

(14) Where unsatisfactory dairy raw materials can be processed or reprocessed to remove all harmful and injurious material, this may be done, provided the resulting dairy product complies with the requirements for dairy products.

(15) Where dairy raw materials do not comply with these requirements they are considered for use as animal feed. For the options and conditions for disposal as animal feeds, refer to “Use as animal feed.”

WITHDRAWN

### *Use as Animal Feed*

(16) All material sold as animal feed or used as an ingredient for the manufacture of animal feeds must comply with the following:
- (a) Agricultural Compounds and Veterinary Medicines Act 1999,
- (b) Animal Products Act 1999,
- (c) Fair Trading Act 1986,
- (d) Pest management strategies made under order of the Biosecurity Act 1993, and
- (e) “Standard for Oral Nutritional Compounds Offered for Sale in New Zealand,” MAF: ACVM Group.

(17) Material that meets the requirements for animal feeds may be used for animal feeds or the manufacture of animal feeds, provided the resulting animal feed complies with the requirements above.

(18) Where material that is unsatisfactory for animal feed can be processed or reprocessed to remove all harmful and injurious material, this may be done, provided the resulting material complies with the requirements for animal feeds above.

(19) Where material is disposed of in this manner, its use is supervised by MAF/ recognised agency, to ensure that all material is used and that none enters the human food chain.

(20) Where material does not comply with these requirements, it is considered as material for non-food and non-feed use. (For the options and conditions for disposal as material for non-food and non-feed use, refer to “Sale for non-food and non-feed uses” below.)

### *Sale for Non-food and Non-feed Uses*

(21) There must be complete assurance that material used for non-food or non-feed uses cannot enter the human or animal food chain.

(22) All material sold for use in non-food and non-feed applications must comply with the following:
- (a) Fair Trading Act 1986, and
- (b) Sale of Goods Act 1908.

(23) Where material is disposed of in this manner, its use is supervised by MAF or the recognised agency to ensure that all material is used and that none enters the human or animal food chains.

(24) Where material does not comply with these requirements, it must be destroyed.

**20 Destruction of Unsafe Dairy Material or Dairy Product**

(1) Dairy material or dairy product to be destroyed is to be buried in a controlled landfill or similar operation.

(2) This destruction must comply with:
- (a) Animal Products Act 1999
- (b) Animal Products (Dairy) Regulations 2005
- (c) MAF Dairy Specifications
- (d) New Zealand (Milk and Milk Products Processing) Food Standards 2002
- (e) official assurances provided by MAF
- (f) Hazardous Substances and New Organisms Act 1996,
- (g) Pest management strategies made under order of the Biosecurity Act 1993, and
- (h) Resource Management Act 1991.

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(3) Where material is destroyed, its destruction is to be supervised by MAF or the recognised agency to ensure that all material is destroyed and that none enters the human or animal food chains.

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