



Dairy National Chemical
Contaminants Programme -
Operational Criteria

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Disclaimer

Important Disclaimer

Every effort has been made to ensure the information in these operational criteria is accurate.

NZFSA does not accept any responsibility or liability whatsoever for any error of fact, omission, interpretation or opinion that may be present, however it may have occurred.

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Explanatory Note

This dairy NCCP Operational Criteria details the technical requirements and expectations for parties fulfilling specified functions under the dairy NCCP. This programme is administered by NZFSA under the Dairy Industry (National Residue Monitoring Programme) Regulations 2002.

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1 Introduction

1.1 Chemical residues

The purpose of the NCCP is to:

- a) determine whether the New Zealand regulatory framework for the management and control of chemical residues and contaminants in dairy material and dairy products is working effectively;
- b) demonstrate the level of conformance achieved within New Zealand; and
- c) identify emerging residue hazards.

The programme is statistically designed to provide an assurance that at least 99% of milk conforms to New Zealand and international requirements and has a confidence limit of 95%.

The programme consists of:-

- random monitoring of raw milk at the farm bulk milk tank;
- directed surveillance of raw milk, dairy material or dairy product at the farm bulk milk tank, milk tanker or dairy premises; and
- surveys.

2 Interpretations

Abbreviations used throughout this document include:

Act means the Animal Products Act 1999

Action limit means a maximum tolerable limit nominated under the NCCP for a specified compound, analyte or attribute. Exceeding the action limit will trigger an action, but may not result in raw milk, dairy material or dairy product being deemed non-conforming (eg failure against an importing country MRL for which the raw milk or product was never intended to be eligible under the risk management programme).

MRL means the maximum residue limit imposed by a competent authority or promulgated by the Codex Alimentarius Commission

LoD means limit of detection

LoQ means limit of quantitation

NCCP means the dairy National Chemical Contaminants Programme, operated and administered by NZFSA under the Dairy Industry (National Residue Monitoring Programme) Regulations 2002.

3 Generic Procedures

3.1 Generic principles

3.1.1 The service provider shall be familiar with the Dairy Industry (National Residue Monitoring Programme) Regulations 2002 and their obligations under those regulations.

3.1.2 Sampling Plan: the annual sampling and testing plan will be distributed (with the minimum required detail) at the start of the dairy season to allow the service provider to procure the required consumables and resources.

3.1.3 Action limits: a list of action limits is provided in Annex A: *NCCP action limits*

3.1.4 Sample anonymity: the anonymity of the samples shall be maintained during storage, transportation, analysis and reporting. An exemption may be provided by the NCCP administrator on a case by case basis for survey samples (for example product samples).

3.1.5 Sample integrity and suitability: sample integrity and suitability shall be maintained during sampling, storage, transportation and analysis.

3.1.6 Records: Any modifications made to any records relating to the NCCP (e.g. worksheets documents used during analysis, etc) shall be signed or initialled, dated and commented by the person performing the modifications. Records shall be maintained in accordance with the quality system operated by the service provider and be available for a period of 3 years.

3.1.7 Documentation: additional systems implemented to meet requirements of these criteria must be documented by the service provider.

3.1.8 Results: the service provider shall provide a summary of results at the conclusion of each dairy season or as requested by NZFSA, and should provide interpretative comments for results only where these are relevant and desirable.

3.1.9 Confidentiality and Data Security: to maintain the integrity of NCCP the service provider must ensure that they have procedures in place to maintain the security and confidentiality of NCCP data and information, and to ensure the provisions of the Dairy Industry (National residue monitoring Programme) Regulations 2002 are complied with as per 3.1.1.

3.1.10 Sample Fitness for Intended Purpose: should any person associated with the sampling, storage, transportation, analysis or reporting of results under the NCCP become aware of any information which impacts on the integrity or fitness for purpose of a sample or result, then the NCCP administrator shall be advised without delay.

3.2 Compliance with criteria

3.2.1 The service provider shall advise NZFSA as soon as it becomes aware that it will be unable to comply with any requirement specified contained within this document.

3.2.2 Non-compliance with criteria identified during external quality systems audit, administrative audit, or technical audit which have the potential to undermine the integrity of the NCCP must be reported to the NCCP administrator and may result in the status of the service provider being reassessed.

3.2.3 Remedial actions or conditions imposed as a consequence of the non-compliance will be provided in writing to the service provider. These will include the actions required by the service provider and the time frame for resolution of the problem(s).

3.2.4 Failure to satisfactorily address the issues identified by NZFSA within the stipulated time frame will result in NZFSA review and the potential for removal of NZFSA approval or recognition to provide services under part or all of the NCCP.

4 Sampling and Transportation

4.1.1 Sample identity: a clear, consistent and unique identification system for the samples shall be used and maintained at all times to ensure traceability of the samples.

4.1.2 The service provider shall manage the sampling to achieve the following:

- (i) milk collection companies contacted no earlier than 72 hours prior to the scheduled sampling to confirm the farm is supplying milk without divulging the purpose; and
- (ii) farm dairy operator notified, by reasonable attempt, immediately before entering farm to sample.

4.1.3 The service provider shall arrange for and supervise the documented systems and persons to collect and dispatch samples. The arrangements shall include:

- (i) provision of procedures for sampling activity including the sampling procedures under clause 4.1.4;
- (ii) training of the sampling persons;
- (iii) confirming the competence of sampling persons prior to undertaking sampling unsupervised;
- (iv) confirming that sampling persons have no conflict of interest;
- (v) the provision of on-going training and assessment of sampling person competency and performance;
- (vi) the provision of suitable sampling and transporting equipment;
- (vii) the recording the temperature of the raw milk in the farm bulk milk tank at time of sampling;
- (viii) the provision of an effective tamper proof system to enable sample security to be confirmed; and
- (ix) maintaining records as appropriate for the above.

4.1.4 Sampling procedures are to be based on IDF 50C:1995 and shall include, but not be limited to:

- (i) Sample size/volumes and containers are to be appropriate for the test profiles and laboratory requirements;
- (ii) samples shall be sub-sampled into appropriate containers of sufficient volume and suitability for the analyses required;
- (iii) dispatched to arrive at the designated testing lab within 30 hours of dispatch and within 48 hours of sampling, except that sample dispatch is to be delayed where it would not be possible for the samples to arrive at the laboratory with 30 hours of dispatch (for example weekends and statutory holidays);
- (iv) sampling shall be done within 2 days of the nominated day, unless otherwise agreed with the NCCP administrator;
- (v) samples shall be held at a temperature of 5°C or below during storage and transport for a period of up to 30 hours, or frozen for longer periods; and
- (vi) samples shall arrive at the laboratory in a suitable condition for accurate testing or for further sub-sampling.

4.1.5 The sampling plan will allow for the primary sample selection. For raw milk samples, the sampler will fall back to the nearest farm dairy supplying milk to that of the primary sample that cannot be sampled. For product samples the fall back protocol will be provided with the sampling plan.

4.1.6 The fall-back provisions of 4.1.5 will only apply where the primary source has ceased to supply for legitimate reasons (eg early dry-off due to drought, flooding). In any situation where the farm dairy temporarily has no milk but is expected to resume supply, the sampler must either:-

- (a) return within the sampling period to sample at the bulk milk tank; or
- (b) notify the NCCP administrator who may consult the risk management programme operator, review farm quality performance statistics and confirm that the reason for non-supply was genuine and of no concern to the programme, or may elect to apply directed surveillance in a future round.

4.1.7 The service provider shall notify the NCCP administrator of all sampling persons used for the collection of samples under the National Chemical Contaminants Programme, and shall include:

- (i) any relevant qualification and/or experience;
- (ii) confirmation of the competence of the sampling person as assessed by a suitably qualified person;
- (iii) the nature of sampling for which the person is to be used (eg farm raw milk or dairy product).

4.1.8 NZFSA and/or overseas governmental authorities may audit the technical and administrative aspects of the sampling operations throughout a contractual year. The rate of auditing may increase or decrease depending on the performance of the service provider.

5 Laboratories

5.1 Recognised or authorised laboratories

5.1.1 Laboratories intending to provide analyses under the NCCP must be;

- (i) a dairy laboratory recognised by NZFSA; and
- (ii) agreed by the NCCP administrator.

5.1.2 The requirements under clause 5.1.1 apply to all laboratories providing analyses, including any laboratory providing sub-contracted analyses.

5.2 Analyses required

5.2.1 All samples that are sent to the laboratory and meet the minimum sample acceptance requirements must be tested for the nominated analytes/attributes.

5.3 Sample receipt

5.3.1 Every sample shall be inspected at the time of sample receipt to assess sample integrity, suitability and confirm sample identity. The laboratory shall ensure the NCCP administrator is informed of noncompliant samples and other sample problems. Substitute samples may be provided in such circumstances from controlled sub-samples held by other laboratories.

5.4 Sample integrity and suitability

5.4.1 The assessment of the integrity of the sample consists of checking sample packaging to ensure:

- that samples and outer packaging are appropriately sealed with a tamper proofing mechanism unless an alternative is specified for the particular round (eg survey round); and
- no interference with the sample is evident (e.g. damage to the sample packaging or interference with the tamper proof seal) has occurred.

5.4.2 The assessment of the suitability of the sample includes the following components:

- Identifying the condition of the sample on receipt (eg frozen); and

- identifying any other evidence of deterioration of the sample which may compromise the analysis of the sample (e.g. cross contamination, coagulation) ; and
- checking sufficient sample is provided for the relevant analysis to which the sample is allocated.

5.4.3 Evidence of sample interference or total absence of the tampering mechanism on the sample and outer packaging or evidence of sample deterioration or any other unsuitable characteristics shall be recorded and notified to the NCCP administrator.

5.4.4 Any problems associated with samples shall be reported within 2 working days of the problem being confirmed.

5.4.5 Where the integrity or suitability of the sample has been compromised the NCCP administrator must be informed and will make a decision on the sample disposition, and if necessary, request a replacement sample.

5.5 Sample identity and other details

5.5.1 A clear, consistent and unique identification system for the samples shall be used and maintained at all times to maintain the traceability of the samples.

5.5.2 Sample information contained on the label shall be recorded on receipt.

5.6 Sample storage

5.6.1 The temperature of samples awaiting analysis shall be no higher than -18°C, unless an alternative is specified for a particular sample type/test parameter. Samples shall not be thawed and refrozen for the purposes of sub-sampling unless required as part of the sample preparation step.

5.6.2 During the analytical process the retained sample shall be stored no higher than -18°C.

5.6.3 At all times samples shall be stored in a manner that insures they are secure from contamination or loss of identity.

5.6.4 With the exception of the requirements of clause 5.8, any remaining portion of a sample in which residues have been identified above the action limit for any compound shall be retained at a temperature no higher than -18°C for a minimum period of 3 months following reporting of the results or until approval for disposal is granted by the NCCP administrator.

5.6.5 Where an official investigation may be carried out, NZFSA may request a sample to be securely stored at a temperature no higher than -18°C or, where deemed necessary due to the nature of the sample or analyte, at a temperature nominated by the NCCP administrator.

5.7 Sampling plan and test profile

Where possible, the laboratory will be advised of the sampling plan and test profile at least 3 weeks prior to sampling, but the plan and/or test profile may be amended by agreement between the laboratory and NCCP administrator.

5.8 Methods of analysis

5.8.1 Validation and approval of analytical methods

5.8.1.1 All methods used for the provision of analytical services under the NCCP shall be:

- a) either an approved dairy methods in accordance with the Animal Products (Recognised Agency and Recognised Persons Specifications) Notice 2005 or a method otherwise authorised for use by the NCCP administrator;
- b) validated for the test matrix in accordance with the laboratory's documented method validation procedure; and
- c) agreed by the NCCP administrator.

5.8.1.2 The laboratory shall provide NZFSA with a copy of its method validation procedure and the validation data relating to methods used for the provision of analytical services under the NCCP on request.

5.8.1.3 The laboratory shall inform NZFSA if and when changes to the Limit of Quantitation (LOQ) of the assay is likely to compromise the ability of the laboratory to detect concentrations of a compound at the level originally specified by the laboratory.

5.8.2 Confirmation

5.8.2.1 Unless otherwise directed by NZFSA for specific assays, confirmatory analysis shall be performed (if screening and confirmatory methods are different) on samples which indicate the presence of an analyte at 50% or greater of the action limit for the matrix.

5.8.2.2 Where the batch control values are outside standard control parameters the sample shall be reanalysed.

5.8.2.3 Confirmation or repeat analysis may be requested by NZFSA where official investigations are required.

5.9 Reporting results

5.9.1 Results shall be reported in a manner acceptable to NZFSA.

5.9.2 The format of a written Analytical Test Report when required by NZFSA shall be consistent for all methods used within the laboratory and shall contain the following elements:

- sample identification;
- dairy material type analysed;
- attribute or analyte(s) assayed;
- method;
- unit of measure;
- result;
- IANZ authorised signatory name and counter signature; and
- date of reporting.

5.9.3 DDT (total) residue analysis shall include the concentration of individual metabolites (when positive) and the sum of the metabolites.

5.10 Exception results

5.10.1 Where any residue result exceeds the action limit the details must be advised by email to the NCCP administrator without delay.

5.10.2 For results that exceed the action limit, the laboratory shall provide the confidence interval to the NCCP administrator on request.

5.10.3 Where any residue result exceeds 50% of the action limit, the results must be advised by email to the NCCP administrator within 5 working days.

5.11 Turnaround time

5.11.1 Unless otherwise specified, the confirmed results shall be reported to the NCCP administrator within:-

- (i) 10 working days of sample receipt for Inhibitory Substances results; and
- (ii) 20 working days of the full sampling round batch being received by the laboratory for all other analyses.

The three business days between Christmas and New Year do not apply as working days in respect of the turnaround time required for any sample.

Commentary: historically residues of Inhibitory Substances, most notably beta-lactams, pose the highest risk to dairy product action limit/MRL conformance. For this reason analyses of Inhibitory Substances must be completed without undue delay and any violation notified to enable timely investigations to be initiated tracing back to the farm and forward to all recipients of the dairy material or product.

5.11.2 An extension to the turn around time requirement may be given by the NCCP administrator in cases where analyses routinely require longer periods, or where complicated confirmatory procedures make a definitive time period hard to estimate, or where technical failure has been encountered. Any such occurrence shall be documented and a written request forwarded to NZFSA that includes:

- analysis type; and
- sample number(s); and
- circumstances requiring extended turnaround; and
- revised turnaround time (total days); and
- actions initiated to resolve problem (if applicable).

6 Laboratory Performance Standards

6.1 Assay performance standards

6.1.1 The laboratory shall maintain systems which confirm either;

- (a) the LoD /LoQ of each method and the coefficient of variance centred around the action limit; or
- (b) an agreed equivalent to (a)

and provide these on request.

6.2 External audits

6.2.1 NZFSA shall be provided with a copy of the laboratory's accreditation schedule and any subsequent amendments on request.

6.2.2 NZFSA and/or overseas governmental authorities may audit the technical and administrative aspects of the laboratory throughout a contractual year. The rate of auditing may increase or decrease depending on the performance of the laboratory.

6.3 Inter laboratory quality assurance programmes

6.3.1 Participation Criteria

The laboratory shall participate in a suitable proficiency testing programme provided such a programme is available. NZFSA may require, as a condition on the provision of any specified analyte or attribute, participation in a programme specified by the administrator.

6.3.2 Testing Criteria

6.3.2.1 All proficiency samples shall be handled, prepared and analysed in the same manner as any NCCP sample.

6.3.2.2 Where possible proficiency samples are to be analysed with NCCP samples.

6.3.2.3 Proficiency test samples shall be analysed by the analyst who routinely performs the same analysis in the NCCP.

6.3.2.4 All aspects of the methodology used in analysing a proficiency test sample shall be the same as those used in the NCCP programme.

6.3.2.5 The laboratory shall have a procedure to ensure that within 15 working days of receipt of an unsatisfactory proficiency test result, an investigation will be undertaken into the reasons why the aberrant result occurred, and the intended corrective action(s) to prevent a recurrence will be documented.

7 Exception Results

7.1 Tracing material and identification of non-conforming product

Upon receipt of a confirmed result that exceeds the action limit, the NCCP administrator will advise the Risk Management Programme (RMP) Operator without delay and:-

- (i) determine whether an MRL has been breached, should there be any doubt (ie to confirm that the dairy material or product was intended to be eligible for a market to which the MRL applied);
- (ii) request that the farm dairy operator be advised and a farm traceback undertaken to determine the source and cause of the residue, with the outcome reported back to the NCCP administrator; and
- (iii) advise that the material must be traced forward and any dairy product found to be non-conforming managed in accordance with the requirements of the Animal Products (Dairy Processing Specifications) Notice 2006 and the Animal Products (Dairy) Approved Criteria for General Dairy Processing, and that any recipients of non-conforming dairy material be immediately advised.

7.2 Suspension of certification

For any dairy product result that is confirmed to exceed an applicable MRL, the NCCP administrator will advise the NZFSA Programme Manager (Verification), Export Standards Group, so that the affected product can be identified and certification suspended without delay.

8 The NCCP Monitoring Programmes

8.1 Random monitoring

The assays, sample matrices and number of samples to be analysed in the routine monitoring programmes for each NZFSA financial year will be supplied to the service provider by NZFSA in conjunction with the annual sampling plan.

8.2 Directed surveillance

The surveillance programme specifically targets dairy material for testing which pose a higher risk of containing chemical residues.

Samples submitted under the surveillance programme shall be sampled and analysed in accordance with the requirements for random monitoring samples unless specified otherwise by the NCCP administrator.

8.3 Surveys

Residue surveys are designed to assess the chemical residue status of a specific population for an emerging or potential residue issues. Samples may be specifically targeted or may be randomly selected within the specified population of interest.

The variable factors which may comprise the design of a survey include such things as; time of year, geography, animal population and agricultural/industrial practices.

The number of surveys and their specific requirements are generally factored into the NCCP prior to the commencement of an analytical year. However, for a number of reasons, survey data may be required at short notice within a year, in which case the parameters pertaining to a particular survey will be provided to the service provider at that time.

There will be, when possible, prior notification of proposed surveys to interested laboratories.

Unless other wise specified in the contractual arrangements pertaining to a particular survey, the requirements applicable to random monitoring samples shall apply.

9 Residue Limits for Dairy Material and Products

9.1 Maximum residue limits for raw milk and dairy products

9.1.1 New Zealand Maximum Limits (MRLs) for chemical residues and contaminants are specified in the following:

- a) The New Zealand (Maximum Residue Limits of Agricultural Compounds) Mandatory Food Standard 2005;
- b) Food Standards Code 2002;
- c) DPC1: Animal Products (Dairy) Approved Criteria for General Dairy Processing; and
- d) DPC2: Animal Products (Dairy) Approved Criteria for Farm Dairies.

9.1.2 Raw Milk and Dairy Products intended for export must meet the following:

- a) Codex Alimentarius (2005) List of Codex Maximum Residue Limits for Veterinary Drug residues in Food;
- b) Codex Alimentarius (2006) List of Codex Pesticide Residues in Food: Extraneous Maximum Residue Limits;
- c) Export requirements issued under Part 5 of the Animal Products Act (including market specific requirements);
- d) DPC1: Animal Products (Dairy) Approved Criteria for General Dairy Processing; and
- e) DPC2: Animal Products (Dairy) Approved Criteria for Farm Dairies.

9.2 Action limits

Because a range of MRLs may apply to dairy material depending upon the scope of the risk management programme under which it is processed and the intended market, nominal action limits have been established based upon the MRLs of New Zealand, Codex and major export markets. The schedule of NCCP action limits is set out in Annex A and will be updated as required.

Appendix I: Monitored Residues and Contaminants

The residues that may be monitored under this programme include:-

- (i) Registered and licensed agricultural compounds and veterinary medicines;
- (ii) Unregistered or prohibited agricultural compounds and veterinary medicines;
- (iii) Radionuclides;
- (iv) The following environmental contaminants:-
 - Organochlorines;
 - Organophosphates;
 - Dioxin and dioxin-like PCBs;
 - Mycotoxins; and
 - Potentially toxic elements
- (v) Any chemical compound or its metabolite that, via risk assessment or profiling, is considered to have the potential to adversely affect dairy material or product.
- (vi) Any other chemical of national or international interest.

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Annex A: NCCP Action Limits

NCCP action limits are published as part of the annual sampling plan, with any amendments advised as they occur.