



**Ministry of Agriculture and Forestry**  
Te Manatu Ahuwhenua, Ngaherehere

## DISCUSSION PAPER No. 36

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### Independent Verification Programme

Ministry of Agriculture and Forestry  
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# 1. Executive Summary

Manufacturers of dairy products have for some time operated audit sampling programmes. These programmes are intended to provide verification and assurances to MAF of the information used by manufacturers in determining product conformance.

Discussion Paper No. 33, "Independent Verification Programme" was sent out in May 2001 for industry comment along with a draft Standard (D205) outlining requirements for an independent verification programme (IVP). Feedback from consultation highlighted strong industry concerns with the proposed draft Standard. This resulted in the draft Standard being withdrawn from the group of Standards being presented at the Dairy Product Safety Advisory Council's (DPSAC) July meeting for endorsement.

This discussion paper considers the background, legislation, importing country requirements and issues raised by industry consultation relating to the purpose, design and operation of independent verification programmes.

This paper proposes the following:

- That a MAF Standard relating to independent verification programmes (D205.1) be drafted and provided for industry consultation.
- That this Standard requires:
  - the current audit sampling programme be replaced by the independent verification programme;
  - all manufacturers of dairy products to have an independent verification programme;
  - manufacturers to develop systems for the operation of independent verification programmes;
  - manufacturers obtain the services of a suitably qualified independent sampler;
  - manufacturers to prepare a sampling and testing programme which is evaluated as part of a product safety programme and verified at normal verification audits by MAF Compliance and Investigation Group (CIG)/the Third Party Agency (TPA);
  - the independent sampler to take monthly samples from each packing system and dispatches the samples in a manner that maintains sample integrity to the independent laboratory for food safety and truth of labelling tests;
  - the analysis of the results by the manufacturer;
  - action by the manufacturer and MAF CIG/TPA where non-conforming produce is identified;
  - investigation where discrepancies between independent and routine results are identified.
- Assuming that the Standard is issued on or about January 2002, that it come into force 12 months later.

## **2. Purpose**

This discussion document provides background information about the independent verification programme and summarises industry feedback relating to the drafting of a previous Standard. The independent verification programmes are used to assess the integrity of the New Zealand regulatory system and information provided by manufacturers, which support the official assurances given by MAF.

This discussion document is based on a rethink of the operation of an independent verification programme after consultation with industry and highlights how the document was revised based on industry feedback.

## **3. Background**

### **3.1 HISTORY**

For most of the last twenty years independent verification has existed in various forms in the New Zealand dairy industry. These have been known throughout this time by names such as “official samples”, “audit samples” or “regulatory verification sampling programme”. The actual requirements of such programmes were defined in the 1993 edition of “Dairy Products Safe and True” but not formally defined in later editions or MAF Standards.

The lack of official definition of the requirements for independent verification programmes has resulted in significant differences in the operation of these programmes throughout the dairy industry.

### **3.2 CURRENT STATUS**

All exporting dairy manufacturers have been required to have some form of independent verification programme in place, however as previously noted there are likely to be significant variations in such programmes. Smaller manufacturers have had difficulty in the interpretation of what is required in this area.

There have been two previous attempts at drafting a Standard and initial feedback prevented the drafts being presented to DPSAC for endorsement. The draft prepared as part of the Priority 3 group of Standards was stopped at the internal DPSAC consultation stage before going out to industry on advice that more development was needed. The last draft was prepared as part of the Priority 5A group of documents and withdrawn from the group and DPSAC endorsement as a result of industry feedback.

### **3.3 NEW ZEALAND’S LEGAL REQUIREMENTS**

The *Dairy Industry Act 1952* and the *Dairy Industry Regulations 1990* currently do not contain requirements specifically pertaining to the provision of official assurances or certificates or independent programmes to verify compliance. Developments are under way to amend the legislation relating to the provision of official assurances.

Regulation 56 (1) of the *Dairy Industry Regulations 1990* states:

**Inspection of premises** – Every occupier of any farm dairy, dairy factory, milk station, store, or registered laboratory shall permit an Inspector, or any other person authorised by the Director-General for that purpose, at all reasonable times, to do all or any of the following things for the purposes of these regulations:

- (a) To enter the premises and inspect any part of the premises, and any equipment, process, procedure, or dairy produce on the premises:
- (b) To carry out any examination or test, or to require any demonstration of any processing, testing, or inspection procedure:
- (c) To peruse all charts and other records kept for the purposes of these regulations, and to make copies of any entries in any such chart or record.

Regulation 58 of the *Dairy Industry Regulations 1990* states:

**Production of records and test results** – Where an approved safety programme, or these regulations, require the keeping of particular records or the making of particular tests an Inspector, or any person authorised by the Director-General for the purpose, may direct the person in control of the records or the results of the test to produce them for inspection.

These regulations provide MAF with the authority to obtain the information necessary to undertake verification of compliance prior to providing assurances.

### 3.4 IMPORTING COUNTRY REQUIREMENTS

#### 3.4.1 European Union

EC Directive 92/46 states in Article 14 that:

“Member States shall ensure **that the operator or manager** of the treatment and/or processing establishment **takes all necessary measures to ensure that, at all stages of production, the relevant specifications of this Directive are complied with.** To that end, the operator or manager of the establishment must constantly carry out his own checks based on the following principles:

- taking samples for analysis in a laboratory recognised by the competent authority for the purpose of checking cleaning and disinfection methods and for the purpose of checking compliance with the Standards established by this Directive.”

EC Directive 92/46, Chapter VI of Annex C states:

“Establishments shall be **subject to supervision by the competent authority**, which must ensure that the requirements of this Directive are met and in particular:

(a) **check:**

- (i) the cleanliness of the premises and equipment and staff hygiene;
- (ii) **the efficacy of the checks carried out by the establishment**, in accordance with Article 14 of this Directive, notably by examining the results and taking samples;”

The EC/NZ Veterinary agreement does not make any specific reference to carrying out independent sampling and testing of product. However general audit principles are covered.

## **4. Issues**

### **4.1 PURPOSE OF INDEPENDENT VERIFICATION**

The information provided through a manufacturer's product safety programme (PSP) to confirm product conformance is used as the basis for the assurances provided by MAF to consumers of New Zealand dairy products in New Zealand and other competent authorities.

The purpose of an independent verification programme is to independently verify a portion of the information used by the manufacturer to confirm product conformance. The independent verification programme identifies when the decisions relating to product conformance, and therefore MAF's assurances, have been inadvertently or deliberately compromised.

### **4.2 ISSUES RAISED DURING CONSULTATION**

Below is a summary of all issues raised during consultation with industry during the Priority 5A Standards process when Discussion Paper No. 33 and the draft Standard D205 were circulated for comment:

- questions which stem from confusion over the purpose or need of an independent verification programme. Some specific questions were:
  - Why is it necessary for manufacturers who already contract independent laboratories for testing to be involved?
  - Isn't it duplication of the Inter-laboratory Comparison Programme (ILCP) and laboratory accreditation?
  - Why does IVP apply to domestic operations?
  - Is IVP is an Importing Country Requirement (ICR)?;
- concerns around the need for all manufacturers to contract a TPA and why Recognised Service Provider organisations were not able to be involved in IVPs which led to a perception that ORM is compulsory;
- confusion over what the following terms mean:
  - independent laboratories;
  - conflict of interest;
  - packing systems;
  - manufacturer as opposed to packing operation;
  - scope of testing;
- strong message from industry indicating that the draft is not consistent with the philosophy of industry responsibility for demonstration of compliance, i.e. concerns over autonomous system being run and monitored by TPAs;
- potential implementation issues raised, e.g. positive/negative results assessment, potential for alternative proposals and delegation by the accountable person;
- responsibilities of all parties were not clear in the initial draft;

- issues raised about the requirement for annual assessment of samplers and definition of independence;
- concern about the ability of TPAs to resource the operation of an independent verification programme;
- concern about the proposal adding unnecessary steps, time delays and cost;
- concern over a lack of consistency with the systems under the *Animal Products Act 1999*;
- concerns over which laboratory results would be correct in the case of a discrepancy and the limited number of laboratories;
- issues raised over difficulties in sample selection, availability and numbers of samples required.

The above feedback was considered by the Working Group and incorporated into the review of the draft Standard. One of the main changes was the development of a guideline attached to the draft Standard for industry use.

### **4.3 REQUIREMENTS OF INDEPENDENT VERIFICATION**

MAF gives assurances relating to New Zealand's regulatory requirements, i.e. food safety and truth of labelling, as well as importing countries' requirements. Consequently, the programme for independent verification must:

- be an integral part of MAF's official assurance programme;
- support the assurances given by MAF;
- cover New Zealand regulatory requirements, i.e. testing for food safety and truth of labelling;
- be independent of the manufacturer's sampling and testing system; and
- be internationally credible.

#### **4.3.1 International credibility**

For a system to be internationally credible, it must provide equivalent outcomes to similar programmes operated by the competent authorities of the countries to which New Zealand exports dairy products.

Agreements or memoranda of understanding (MoUs) with international competent authorities, sampling and testing programmes operated at borders by importing countries, international regulatory Standards for laboratory accreditation, and feedback from audits of the regulatory systems of other competent authorities have been used to identify the features of such programmes.

International programmes for testing dairy products for compliance in their country of manufacture have the following features:

- the regulators operate the testing programmes;
- the samples are analysed by the manufacturer's laboratory and a government laboratory;
- the results of the government laboratory are paramount;
- control charts for each analyst in the manufacturer's laboratory are reviewed by a government officer; and
- actions are taken by a government officer if there is a discrepancy.

MAF requires a system which achieves equivalent outcomes, and also:

- provides an independent check of the total system operating in the New Zealand dairy industry that provides product which complies with food safety and truth of labelling Standards;
- is an independent check on the total system which is the basis of assurances;
- generates useful information;
- adds value to the other systems;
- does not require MAF to do the sampling; and
- does not require MAF to operate testing laboratories.

#### **4.3.2 Independence from routine sampling and testing systems**

To enable a programme to successfully identify when decisions relating to product conformance have been inadvertently or deliberately compromised, the programme must operate independently.

##### ***4.3.2.1 Management of the programme***

To maintain independence the programme must be evaluated and verified as part of the PSP by MAF CIG/the TPA who are entirely independent of the manufacturer. MAF CIG/the TPA have the systems in place in order to assess the independence of the programme.

##### ***4.3.2.2 Samplers***

The independent verification programme sampling of dairy product must be independent of the manufacturer. The sampler should be sourced from an officially recognised body (ORB). The ORB is defined as an organisation that has been recognised by MAF as being competent to provide services to the dairy industry in specified categories and includes third party agencies, recognised service providers and MAF-registered laboratories. The sampler must also be competent to take and secure representative samples. It is therefore recommended that the individual carrying out the sampling (henceforth referred to as the 'independent sampler') must meet the minimum requirements outlined below:

- must not be an employee of the manufacturer and is free of any conflict of interest;
- must have satisfactorily completed a NZQA-approved training course or has equivalent experience in correct sampling techniques such as those documented in IDF Standard 50C:1995, "Milk and Milk Products Guidance on Sampling".

These requirements could be met by an approved individual (refer MAF Standard D501, “Technical Competency of TPA Individuals”) or a person who is employed or contracted by the TPA or Category 1 or 2 laboratories specifically set up to deliver independent sampling.

#### ***4.3.2.3 Preparation of the sampling programme***

To ensure that the independent verification check is free from the potential for manipulation, it is important that the manufacturer has no forewarning of the time of sampling, the products to be sampled or the analysis that will be undertaken on the samples. Therefore it is recommended that sampling and testing is undertaken in accordance with a pre-planned programme and samples are selected by the independent sampler.

#### ***4.3.2.4 Frequency of sampling***

It is recommended that the frequency of sampling for independent verification be monthly at every factory, the same as that for the current audit sampling programme.

#### ***4.3.2.5 Content of the sampling programme***

The independent verification programme checks a portion of a manufacturer’s product conformance sampling, testing and decision-making. Accordingly it is not necessary to sample all products and test for all parameters every month. Rather it is more effective to test sufficiently to determine effectiveness of sampling, testing and decision-making and provide a deterrent to fraudulent activity.

It is assumed that error or fraudulent activity in the sampling process is more likely to be determined by the packing system and associated sampling processes rather than the actual product type. Emphasis for independent verification should therefore be placed on the selection of samples primarily based on the sampling line.

Therefore it is recommended that the independent verification programme be designed to meet the following requirements:

- Only specifications/product types may be specified. The manufacturing date, the lot number and/or specific unit numbers within a lot are not to be specified.
- Sampling is to be carried out monthly.
- Product safety tests to be included are:
  - inhibitory substances; and
  - all parameters outlined in MAF Standard D107.1, “Dairy Product Safety”, but excluding those parameters that form part of a National Chemical Contaminants Programme e.g. radionuclides.
- Each month a minimum of two product safety tests and one standard of identity test (as outlined in MAF Standard D103.2, “Labelling of Dairy Products”) are carried out on each sample taken that month.
- All required tests to be carried out at least once over each six months period.
- When there is no production through a packing system, no sampling or testing is required.

The number of samples is based on a sampling matrix outlined in the Standard. This sampling matrix is based on the average lot size per packing system and the number of lots per month per packing system. The purpose of the matrix is to allow more representative sample numbers to be taken for differing production throughputs. The matrix caters for those producing very small amounts of product and for those on a larger production scale also.

#### ***4.3.2.6 Sample taking***

Decisions regarding sample taking and the products and manufacturing lots to be sampled must be based on the sampling and testing programme and be taken by the independent sampler. In the past there has been discussion about whether independent samples should be taken from sealed packages or whether samples can be taken during filling/packing.

To ensure the integrity and independence of the verification programme it is recommended that:

- The independent sampler selects, using their own discretion, the actual lot to be sampled.
- Samples are taken from previously unopened final packages. Where appropriate, to protect the integrity of the sample, final packages may be dispatched as discrete samples, e.g. ice cream, liquid milk, consumer packs of butter and cheese.
- For bulk fill lines sampling may be carried out during packing.

#### ***4.3.2.7 Sample handling***

Samples taken by the independent sampler must be secured in a manner sufficient to prevent tampering, substitution or loss during dispatch, transfer and receipt by the laboratory. The normal process for ensuring this is to have the samples remain in the independent sampler's custody until the samples are off site and then dispatching in a manner which ensures the sample security. It is recommended that the sampler is responsible for securing the samples in a manner that ensures sample integrity and dispatching the consolidated samples to the independent laboratory. It is also recommended that other systems for dispatch be acceptable provided that it can be demonstrated that the system can maintain sample integrity.

#### ***4.3.2.8 Sample analysis***

To maintain independence and prevent conflict of interest, the laboratories doing the testing of the independent samples would be required to be independent of the manufacturer concerned. This means that samples from one dairy company would be analysed at either an independent laboratory or a laboratory of another company. It would be the manufacturer's responsibility to organise and pay the laboratory for these analyses. The laboratory would report the results of the analysis to the manufacturer.

Laboratories doing the analyses are required to be registered by MAF in accordance with MAF Standard D302.1, "Registration of Dairy Laboratories" for the required tests. Furthermore as the conformance decisions checked by the independent verification programme relate to food safety and truth of labelling, it is recommended that only Category 1 laboratories are used for the independent analyses by the verification programme.

#### **4.3.2.9 Handling of analytical results**

One area that is important is in the consideration of the analytical results and the decision regarding product conformance. Controls are required to prevent alteration of and/or the ignoring of unfavourable analytical results.

It is recommended that the results be checked to ensure that the results comply with the limits for food safety and also compared with the manufacturer's own results. This is the responsibility of the Accountable Person and will be checked when the IVP system is assessed during the PSP audit.

Where the results indicate that food safety may be compromised, the manufacturer advises the TPA and then manages the non-conformance in accordance with MAF Standard D108, "Non-conforming Dairy Produce".

During the Verification Audit the TPA obtains a copy of the manufacturer's own test results and compares both sets of results. This ensures that information from either source is not altered or ignored.

The manufacturer determines the limits of the independent verification programme which include:

- test method reproducibility (as defined by Test Methods and/or ISO 17025, "General Requirements for the Competence of Testing and Calibration Laboratories"); and
- sampling reproducibility, which is determined by the manufacturer with supporting information available for audit purposes.

Where there is a discrepancy between the results that exceeds the independent verification programme limit the accountable person initiates investigation and corrective actions and reports the outcome in the regular report to MAF CIG/the TPA in accordance with MAF Standard D102, "Product Safety Programme Reporting Requirements".

#### **4.3.2.10 Reporting to MAF CIG/the TPA**

It is recommended that reporting be managed in the following manner:

- Food safety issues identified are reported under MAF Standard D102, "Product Safety Programme Reporting Requirements",
- The manufacturer's Accountable Person reports the outcomes from the comparison of the results and conformance decisions to MAF CIG/the TPA in the event of an exception.
- MAF CIG/the TPA then checks to confirm that the appropriate decisions and actions have been taken. If not, a non-compliance is issued by MAF CIG/the TPA.
- The TPA notifies MAF CIG if the accountable person's comparison was incorrect or if they have not initiated the required follow-up actions in response to discrepancies.

## **4.4 RELATIONSHIP WITH ICLP**

Independent verification programmes are designed to check the integrity and accuracy of all systems relating to the confirmation of product conformance by the manufacturer. These systems include sampling, testing, data handling and conformance decision making.

The independent verification programme is not designed to measure a laboratory's testing accuracy. A laboratory's testing accuracy is checked by participation in Inter-laboratory Comparison Programmes (ILCP) which are a mandatory component of laboratory operation (refer MAF Standard D302, "Registration of Dairy Laboratories"). As the test results from the independent verification programme are only one data point from different samples, they provide considerably less information about laboratory performance than the results of the ILCP. Where the independent verification programme identifies a difference in the results between laboratories further investigation will be required, including consideration of the laboratories' performances in ILCP.

## **5. Implementation**

### **5.1 MECHANISM FOR IMPLEMENTING**

The changes proposed above would be implemented by preparing a MAF D-series Standard for independent verification programmes.

The Standard would outline the outcomes for independent verification of information generated by manufacturers' programmes to confirm product conformance and acceptable criteria for product safety programmes.

### **5.2 CHANGES REQUIRED FOR IMPLEMENTATION**

#### **5.2.1 By MAF Dairy and Plant Products**

- no changes required.

#### **5.2.2 By manufacturers**

- reviewing and revising of current procedures, documentation and the PSP to ensure that an independent verification programme is operating and delivering the outcomes of the Standard;
- arranging evaluation and approval of revisions to the PSP;
- validating and verifying of PSP in normal cycle; and
- contracting an independent sampler and laboratory.
- establishing the independent verification programme limits.

#### **5.2.3 Officially Recognised Bodies**

- developing systems for the development and management of independent samplers.

#### **5.2.4 By MAF Compliance and Investigation and Third Party Agencies**

- revising evaluation and verification criteria to include requirements of the new Standard; and
- evaluating revisions to PSPs.

### **5.3 PROPOSED IMPLEMENTATION PERIOD**

A 12-month implementation period is usually used for MAF D-series Standards unless there is some specific reason otherwise. Assuming that the Standard is issued on or January 2002, then the Standard will come into force on January 2003.

## 6. Proposal

With regards to independent verification programmes, the following are proposed:

- That a MAF Standard relating to independent verification programmes (D205.1) be drafted and provided for industry consultation.
- That this Standard requires:
  - the current audit sampling programme be replaced by the independent verification programme;
  - all manufacturers of dairy products to have an independent verification programme;
  - manufacturers to develop systems for the operation of independent verification programmes;
  - manufacturers obtain the services of a suitably qualified independent sampler;
  - manufacturers to prepare a sampling and testing programme which is evaluated as part of a product safety programme and verified at normal verification audits by MAF Compliance and Investigation Group (CIG)/the TPA;
  - the independent sampler to take monthly samples from each packing system and dispatches the samples in a manner that maintains sample integrity to the independent laboratory for testing of food safety and truth of labelling tests;
  - the analysis of the results by the manufacturer;
  - action by the manufacturer and MAF CIG/TPA where non-conforming produce is identified;
  - investigation where discrepancies between independent and routine results are identified.
- Assuming that the Standard is issued on or about January 2002, that it come into force 12 months later.

## 7. Draft Standard

Draft MAF Standard D205.1, “Independent Verification Programme”, has been drafted based on the findings and recommendations of this discussion document. Copies of the draft Standard can be obtained from MAF’s website ([www.maf.govt.nz/Dairy](http://www.maf.govt.nz/Dairy)) or by contacting MAF Food: Dairy and Plant Products.

## 8. Consultation

The draft Standard is of concern to all manufacturers operating under a PSP in the New Zealand dairy industry and third party agencies. Internal and external consultation will be conducted according to the MAF Food: Dairy & Plants Consultation Policy. The deadline for submissions is **2 November 2001**. Instructions for making submissions are provided with the draft Standard.

## 9. References

- Agreement between the European Community and New Zealand on sanitary measures applicable to trade in live animals and animal products. Agreement 297A0226(02), Official Journal L 057, 26/02/1997, p. 0005 - 0059. [http://europa.eu.int/eur-lex/en/lif/dat/1997/en\\_297A0226\\_02.html](http://europa.eu.int/eur-lex/en/lif/dat/1997/en_297A0226_02.html).
- Council Directive 92/46/EEC of 16 June 1992 laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products. [http://europa.eu.int/eur-lex/en/lif/dat/1992/en\\_392L0046.html](http://europa.eu.int/eur-lex/en/lif/dat/1992/en_392L0046.html).
- *Dairy Industry Regulations 1990*.
- “Dairy Products Safe and True” MAF Regulatory Authority (Dairy) Issue 1, 1993.
- IDF Standard 50C:1995, “Milk and Milk Products Guidance on Sampling.
- ISO 17025, “General Requirements for the Competence of Testing and Calibration Laboratories”.
- MAF Standard D108, “Non-conforming Dairy Produce”. MAF Food: Dairy and Plant Products.
- MAF Standard D102, “Product Safety Programme Reporting Requirements”. MAF Food: Dairy and Plant Products.