



Proposed changes to the Independent Verification Programme

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Submissions

The New Zealand Food Safety Authority seeks submissions from all interested parties on any aspect of the proposed changes to the requirement for dairy manufacturing risk management programme operators to have an independent verification programme (IVP) as set out in the Animal Products (Dairy Processing Specifications) Notice 2006.

The following points may be of assistance in preparing comments:

- Wherever possible, comment should be specific to a particular section of the document. All major sections are numbered and these numbers should be used to link comments to the document.
- Omissions should be clearly and separately indicated.
- Comments should be to the point and, where possible, reasons and data to support comment are requested.
- The use of examples to illustrate particular points is encouraged.
- As a number of copies may be made of your comments, please use good quality type, please make sure the comments are clearly hand-written in black or blue ink.

Please include the following information in your submission:

- The title of the discussion document;
- Your name and title (if applicable);
- Your organisation's name (if applicable);
- Your address;
- The number(s) of the sections you are commenting on.

Please submit your response by 5:00pm on 27th May 2009

Your comments should be sent to:

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Submitters may wish to indicate any grounds for withholding information contained in their submission. Reasons for withholding information could include that information is commercially sensitive or that the submitters wish personal information such as names or contact details to be withheld. NZFSA will take such indications into account when determining whether or not to release information. Any decision to withhold information requested under the OIA may be reviewed by the Ombudsman.

Next Step

The next step in this consultation will be to;

- analyse the submissions received,
- provide a summary of submissions on the NZFSA website,
- consider these submissions to determine whether to proceed with the proposal as presented in this discussion paper, and
- if supported by the submissions, draw on these in developing and implementing the amended independent verification programme.

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1 Executive summary

NZFSA have reviewed the current independent verification programme (IVP) and believe that it needs replacing due to;

- Not being flexible enough to cope with the diversity of dairy industry manufacturing operations.
- Not being centrally monitored by the competent authority. As a result, estimates of compliance or failure rates (as a function of sample numbers or production volumes) cannot be easily determined.
- The current costs are too high relative to the delivered benefits of the programme.

We have reviewed various options and have concluded that to better meet the intended IVP outcomes, the current IVP should be replaced with a scaled down, centrally monitored, regulated control scheme. This would significantly reduce the cost of the IVP programme whilst still retaining market confidence.

2 Introduction

Dairy independent verification programme (IVP) requirements were originally developed under the Dairy Industry Act 1952 as part of the suite of D series standards (D205) issued under the Dairy Industry Regulations 1990. Although the IVP standard specifies the outcome and default criteria to achieve the outcome, a significant number of risk management programmes (RMP's) have alternatives approved by NZFSA.

For further background on the original purpose of the IVP refer to Discussion paper No. 36.

2.1 Purpose of this discussion paper

NZFSA seeks feedback on the proposal to replace the IVP programme with a national programme administered by NZFSA. The proposed programme would only apply to manufacturers of dairy products for human consumption intended for export (excluding Australia).

2.2 Scope of the review

This is limited to the intent and purpose of the current IVP, and consideration of principles for an improved, more effective IVP that would deliver;

- International credibility.
- Robustness sufficient to withstand third party scrutiny.
- Support to the official assurance programme by a statistically valid independent sampling and testing programme.
- Efficiency and effectiveness for the export animal products (dairy) industry.

Synergies with the National Chemical Contaminants Programme (NCCP) have been taken into account. This acknowledges that, there may be opportunities to take one sample of product for multiple purposes.

3 Current IVP programme

The current IVP provides an independent verification of the sampling and testing managed under the operators RMP. This programme supports the official assurance programme. It requires the independent sampling and testing of product for food safety, wholesomeness and standards of identity.

The IVP must include all regulatory parameters required for dairy material or dairy;

- Animal Products Act 1999.
- Animal Products (Dairy) Regulations 2005.
- NZFSA Dairy Specifications.
- Australia New Zealand Food Standards Code/New Zealand Food Regulations 1984 and
- Any official assurances provided by NZFSA, whether explicit or implicit.

4 The need for change

4.1 Key issues

The following issues with the current IVP have been noted;

- Not flexible enough to cope with the diversity of dairy industry manufacturing operations.
- Not centrally monitored by the competent authority. As a result, estimates of compliance or failure rates (as a function of sample numbers or production volumes) cannot be easily determined.
- The current cost to industry of approximately \$1,052,000 is too high relative to the delivered benefits of the programme.

4.2 Requirements of an IVP

An IVP must have the ability to independently verify a portion of the product information used by the manufacturer. The IVP can identify issues with routine sampling or testing.

The programme must;

- Be an integral part of NZFSA's official assurance programme.
- Support the assurances given by NZFSA.
- Cover New Zealand regulatory requirements.
- Be independent of the manufacturer's sampling and testing system and
- Be internationally credible.

4.3 Legal requirement

The Animal Products (Dairy Processing Specifications) Notice 2006 states;

Part 5, 29

A risk management programme for manufacturers of dairy products intended for human consumption must include an independent verification programme that provides independent sampling and testing

of product to confirm the accuracy of routine monitoring used for the determination of dairy material or dairy product conformance under the programme.

5 Assessment of options

NZFSA have considered three options, two of which are discussed in detail below;

- i. Status quo
- ii. Replace the current programme with an NZFSA centrally administered programme or
- iii. Withdraw the programme without replacement.

5.1 Status quo

NZFSA have reviewed the current independent verification programme (IVP) and believe that it needs replacing due to;

- Not being flexible enough to cope with the diversity of dairy industry manufacturing operations.
- Not being centrally monitored by the competent authority. As a result, estimates of compliance or failure rates (as a function of sample numbers or production volumes) cannot be easily determined.
- The current costs are too high relative to the delivered benefits of the programme.

5.2 National programme administered by NZFSA

Under this option the current IVP programme will be replaced with a national programme covering all premises manufacturing human consumption dairy products for export (excluding Australia).

This is the preferred option and has been set out in detail under section 6 of this document.

Impact

The key features of this option are;

- Withdrawal of the specific IVP requirements set out under clause 29 of the Animal Products (Dairy Processing Specifications) Notice 2006 and clause 13 and appendix 2 of the DPC3: Animal Products (Dairy) Approved Criteria for Dairy Manufacturing.

- Issue of an export notice under section 60 of the Animal Products Act 1999 which establishes the requirement for participation in a regulated control scheme (RCS) by dairy processors who manufacture human consumption dairy products intended for export.
- Issue of a Regulated Control Scheme (RCS) under part 3 of the Animal Products Act 1999, which describes the NZFSA administered programme.
- Amending the Animal Products (Dairy Fees and Charges) Regulations 2007 to include a provision to recover the costs incurred from the beneficiaries of the programme.

Withdrawal of the current IVP is expected to have a significant impact on most dairy processors as;

- The independent IVP sampling role will be assumed by recognised agency (RA) verifiers.
- No operator IVP samples need to be handled, dispatched and analysed by industry.
- No special handling of results, analysis of trends or reporting of routine results and observations to the recognised agency.

Benefits

- Manufacturers and evaluators will no longer have the task of establishing the appropriate limits for the purpose of comparing IVP results with the operators own results.
- The programme will be centrally monitored by NZFSA and hence, more credible to auditors and will more readily gain recognition from competent authorities of importing countries.
- Actual cost to industry will be reduced considerably.

While there may be additional commercial advantages, these are not the primary drivers for the proposed change.

Costs

The actual cost of the programme would be determined year to year, based on the minimum level of activity required to meet the programme objectives. The following provides an indication of the likely cost to NZFSA to operate the IVP as a national programme. In time, if compliance is consistently demonstrated it is likely that the costs indicated would reduce further. The total cost will be recovered from across all export manufacturers on a volume basis.

Overheads	28,000
Administration	78,000
Analytical	90,000
Total	\$196,000

Regulated control schemes (RCS)

Part 3 of the Animal Products Act provides for RCS. The objective of this part is to provide for RCS which are special regulatory regimes to provide for cases where;

- It is inappropriate or impracticable to manage risk factors under risk management programmes, or
- Risk factors may need to be addressed in relation to the production of animal material or the processing of animal product that is not required by this act to be covered by a registered risk management programme, or
- Special provision is required for the purposes of overseas market access requirements.

Regulated control schemes may be imposed by way of regulation, or in the case of matters relating to overseas market access requirements, by way of a notice issued by the Director-General.

Appendix 2 details the matters considered in relation to sections 38 and 39 of the Animal Products Act.

5.3 Remove current IVP requirement without replacement

Under this option, the current IVP requirements would be withdrawn. Dairy manufacturers would cease sampling. Operators would then be required to review the appropriateness of their routine monitoring programmes, with particular emphasis on parameters monitored less frequently and currently covered by the IVP.

Impact

The removal of IVP requirements would have an immediate direct financial benefit due to the removal of the sampling and testing requirements. However, IVP provides confidence to NZ's trading partners by demonstrating that;

- Sampling activities are executed with integrity.
- Operator monitoring programmes are appropriate and sufficient to identify and correct non-compliances.
- Official assurances are supported by an operator administered programme which is subject to verification by the recognised agency.

Complete removal of the IVP without replacement is seen by NZFSA as weakening the official assurance programme. IVP has been consistently represented to overseas authorities as a component of NZ's regulatory verification programme, and complete removal would have adverse market access consequences, unless there is sound justification that existing controls are sufficient. Information is not currently available which supports such assertions.

While the impact of overseas market perception is difficult to quantify, NZ trades on the basis of being a "trusted supplier of dairy products". Verification programmes support official assurances and ensure that trust is earned. Complete removal of the IVP would potentially lower the level of confidence in NZ's regulatory systems currently held by our trading partners and therefore is not a viable option at this time.

6 Proposed IVP programme

6.1 Principles

The following principles will be applied to the proposed replacement IVP programme;

The programme will;

- Be centrally administered and directed by NZFSA.
- Independently verify the sampling and testing performed by the operator, giving integrity to the systems they operate.
- Be internationally credible.
- Utilise RA controlled samples and independent, contracted laboratory services.

6.2 Scope

The proposed programme will include;

- Sampling of finished product for human consumption.
- Product intended for export (excluding Australia) at the time of sampling.

- Routine, random monitoring of microbiological parameters relevant to food safety (sampling with or without replacement will be determined at the time the plan is designed, with consideration given to the number of samples required relative to the number of premises available).
- A sampling plan design determined by NZFSA.
- A response to unfavourable results that is commensurate to risk.
- NZFSA oversight of any traceback or follow up in response to unfavourable results and any consequential actions.

The programme may also include;

- Periodic, random monitoring of wholesomeness and standard of identity as considered appropriate (sample selection method determined at the time based on the population to be sampled).
- Periodic surveillance and surveys as considered necessary (e.g. to assess the degree to which a particular kind of process or product may be affected by an emerging hazard or issue).

The programme will not include;

- Follow-up sampling and testing of unfavourable results to confirm control has been restored (this is an operator responsibility in conjunction with their RA). Once advised of an unfavourable result the operator will respond as if the result had been identified as part of the operators own monitoring programme.
- Monitoring of suspect product (operator responsibility).
- Providing assurances regarding the performance of individual operators (this is the role of wider programme verification activities).
- Investigations into suspected food-borne outbreaks or complaints.
- Chemical residues and contaminants subject to monitoring under the national chemical contaminants programme (NCCP) are not required to be included under an operator's IVP. Monitoring may be required in the case of additives or where contaminants are introduced via ingredients.

By monitoring final product and its intended use/markets, the programme will indicate that the product either:

- Meets process hygiene and food safety criteria of all intended uses/markets for each parameter that it is tested against, or
- Has been identified as not fully conforming and has already had restrictions of an appropriate nature applied by the operator, or
- There is a potential non-conformance that warrants further investigation.

It will also independently demonstrate that the sampling and testing programme as operated by the manufacturer under their RMP is adequate and complies with regulatory requirements.

Unfavourable findings will be the subject of further investigation which may include:

- Determining if the result is within a level of uncertainty (particularly relevant to microbiological sample/lot determinations). A finding considered to fall within the bounds of uncertainty to be recorded as an unfavourable result, but not a failure or non-compliance.
- Additional sampling and testing (by the operator) across the batch and adjacent batches (without compositing) to quantify the extent any non-conformance.
- Comparison between the operators own determination of lot conformance and the programme finding.
- Examining historical results from the operators' own monitoring programme and confirmation that unfavourable results have been handled correctly.

Throughout this process there is an opportunity for the RMP operators to quantify the level of uncertainty associated with any particular parameter.

Unfavourable results or potential product classification conflicts will;

- Require investigation and review of:
 - Sampling procedures and handling.
 - Sampling frequency.
 - Sampling plan design relative to process/product variability.
 - Operator response to unfavourable results from the self monitoring.
- Accommodate uncertainty in findings (including apparent low frequency microbiological failures).
- Be reported to the RA and may influence verification frequency decisions.

At the time of sampling, the operator can request a supplementary sample for submission to a lab of their choosing or to retain for their own purposes. The results of any supplementary sample will be for general interest only and would not change the outcome from the primary sample. However if the supplementary sample were to give an unfavourable result, the operator would be obliged to notify the result to the RA and take appropriate actions per any other non-conforming result.

7 Implementation

7.1 Changes requirement for implementation

7.1.1 By NZFSA

- Amendment of DPC3 and the Animal Products (Dairy Processing Specifications) Notice 2006 to remove current IVP requirements.
- Issuing an export notice under section 60 of the Act and a Regulated Control Scheme under part 3 of the Act.
- Establishing administration mechanisms for the programme.
- Issuing operational criteria applicable to the operation of the programme and including;
 - The duties and obligations of contracted parties.
 - Processes for the receipt and analysis of the data.
 - Procedures for timely reporting and publishing of results.
- Contracting laboratory services according to government guidelines.
- Amending cost recovery as set out in the Animal Products (Dairy Industry Fees and Charges) Regulations 2007.

7.1.2 By manufacturers

- Reviewing and revising of current procedures, documentation and the RMP to remove IVP provisions and to ensure routine monitoring (sampling and testing) programmes to ensure they remain adequate, and if not amending the RMP as may be necessary.

- Arranging evaluation and registration of significant amendments (such as changes to sampling and testing) to the RMP.
- Discontinuing any arrangements for independent sampling and testing of IVP samples.

7.1.3 Recognised agencies

- Receipt of sampling plan and confidential distribution to relevant Recognised Persons (RP).
- Including provision for obtaining any required samples as part of scheduled premises visits (typically during RMP verification audits).
- Documenting procedures for;
 - Observing sampling.
 - Confirming the identity and authenticity of the samples.
 - Securing the sample.
 - Ensuring dispatch in accordance with the notice and RCS.

7.2 Proposed implementation period

Given the current economic environment and the significant cost saving to industry, NZFSA see no impediment to revoking the current requirements and having the proposed changes take effect as of 1st July 2009. This will coincide with the new dairy season and will ensure benefits are captured immediately.

8 Appendix 1: Proposed regulated control scheme for IVP.

8.1 Process

NZFSA will obtain annual production information from all manufacturing premises registered with NZFSA to manufacture for export. From this NZFSA will design an annual plan taking into consideration products/parameters of interest, market requirements and volumes produced by product type. Initially the plan will cover 300 random samples per season.

NZFSA will then contract laboratory services to conduct the testing. Consideration will be given to laboratory capability as well as cost.

Action limits will be determined by parameter, by product and by market requirements. There will be two tiers of limits;

- Action limit 1 being the limit as applied by the tightest applicable standard.
- Action limit 2 being the limit plus the level of measurement uncertainty associated with the particular parameter (test and sampling).

8.1.1 Recognised agency and laboratory roles

The confidential plan will be advised to the RA prior to the start of the season (noting that the plan will be dynamic and will be shaped by experience over time). The RA will be advised of requirements (location/product) at least 1 month before the start of each sampling period. There will be between 2 to 4 sampling periods per season, each period being 2 to 6 months in duration. The verifiers will observe sampling (thus no recognition of official samplers required). The plan will include fall back provisions for substitute samples. The RA will be required to advise NZFSA of the sample details and intended eligibility.

The contracted laboratories will be advised at least 1 month before the start of each sampling period. The laboratory will be required to advise NZFSA of receipt of samples and of the corresponding test results. The premises identity will not be made available to the laboratory.

8.1.2 Sample requirements

The verifier will observe the sampling, secure the sample using an official label (tamper evidence required) and will advise the tests required. The verifier will maintain control of the samples through to dispatch to the laboratory.

In addition the verifier;

- May require sampling on demand.
- Will observe the sampling person in operation and confirm;
 - The competence of the sampling person to sample.
 - The competence of the sampling person to operate and maintain sampling equipment.
 - The suitability of any sampling equipment used.

Temperature loggers may be used to maintain a record of sample storage and transport conditions. If the lab indicates that the sample is or may be compromised a replacement sample may be required.

8.1.3 Market eligibility

The intended market eligibility of the product will be taken into consideration at the time of sampling.

8.1.4 Analysis of results

No comparison will be made against individual company results unless the result is non-compliant. Conformance/non-conformance will be based on action limits, with further assessment against the limits applicable including the nature of the product, intended use and market eligibility. Tiered approach with actions defined.

Low impact failure - result exceeds action limit 1 but does not exceed action limit 2:

- For the purposes of the programme the finding is considered a RMP failure (and not a regulatory failure as the result is open to challenge i.e. within margin of uncertainty).
- Repeat sample to be submitted for testing but original result stands.
- The operator is required to;

- Follow exception reporting/product disposal process as if the result was from their own testing programme.
- Confirm the suitability of the intended use (as per normal non-conforming product process).
- Demonstrate that appropriate corrective actions taken

Low impact failure - result exceeds action limit 2 AND the RMP operators own programme identifies the failure and appropriate control has been initiated (per the RMP):

- Product is non-conforming (but already detained & RA advised).
- The finding is not considered a regulatory failure but is reported as part of the programme report.
- The operator is required to;
 - Follow exception reporting/PD process as if the result was from their own testing programme.
 - Confirm the suitability of the intended use (as per normal non-conforming product process).
 - Demonstrate that appropriate corrective actions taken.

High impact failure - result exceeds action limit 2 without the RMP operators own programme identifying the failure:

- Product is non-conforming and the finding is considered a confirmed regulatory failure.
- The operator is required to;
 - Follow exception reporting/PD process as if the result was from their own testing programme.
 - Confirm the suitability of the intended use (as per normal non-conforming product process).
 - Demonstrate that appropriate corrective actions taken.
- The verifier would review operator monitoring programme and review verification frequency.

8.1.5 Reporting results

Information relating to specific operator/premises will remain confidential. NZFSA will report, or make available, the results to the RMP operator and their RA within 30 days of receipt. Any results exceeding action limits will be reported to the RMP operator and the RA without delay.

8.1.6 Surveillance sampling

This is the follow-up sampling required as a result of a failure (action limit 1 or 2). This will apply across all products and parameters for the premises concerned, and will be a stepped frequency based on historical performance. All programme costs will be invoiced to the individual operator (i.e. sample dispatch and testing). The operator can elect to use any independent recognised dairy laboratory for the surveillance testing. Some surveillance sampling visits may need to be un-notified.

8.1.7 Periodic review

NZFSA will review results at least annually and earlier if results indicate a potential lack of control within the overarching regulatory programme.

The outcome of the review may include any or all of the following;

- Additional random monitoring in the current and/or subsequent season.
- Amendments to NZFSA standards.
- Additional guidance information (operators or evaluators).
- Higher verification frequency for a particular operator.
- Other forms of intervention where most appropriate.

8.1.8 Publishing results

Summary data will be published in a format that ensures individual operators cannot be identified. The summary results will be presented in categories such as Safety Parameters, Standard of Identity, and Trade.

8.1.9 Cost recovery

Cost for verifier on-site involvement will be covered by the operator as part of the routine verification audit (rationale – includes verification of sampling procedures with minimal additional effort required for sealing samples, designating as official and providing details to NZFSA).

All other costs incurred for the random monitoring covered by the programme will be recovered across all export manufacturing RMPs (based on production volume per premises) but subject to consultation via the Animal Products (Dairy Industry Fee and Charges) Regulations 2007.

9 Appendix 2: Matters relating to sections 38 and 39 of the APA

9.1 Section 38 of the APA, nature of regulated control schemes

The object of a regulated control scheme is to impose risk management measures in circumstances where;

- It is not feasible or practicable for the relevant risk factors to be managed by individual animal product business operators, or
- Having regard to considerations of economic efficiency or to legal considerations that may require the exercise of statutory authority for the successful management of risk factors, it is necessary or appropriate that the measures be imposed generally rather than being dealt with by way of individual risk management programmes, or
- The measures are additional to those normally required to meet New Zealand animal product standards, and are necessary to meet access requirements of overseas markets as notified to made available under section 60 of the Animal Products Act

A regulated control scheme may be imposed;

- In the case of measures required to meet access requirements of overseas markets that have been notified or made available under section 60, by way of specifications and requirements set by the Director-General under section 40.

9.1.1 Considerations

By managing IVP under a RSC, the programme will be centrally monitored by NZFSA and hence, more credible to auditors and will more readily gain recognition from competent authorities of importing countries. In addition the actual total cost to industry will reduce from approx \$1,052,000 to approximately \$196,000.

9.2 Section 39 of the APA, scope of regulated control schemes

In determining whether or not to recommend the making of a regulated control scheme, or the content of such a scheme regard should be given to;

- The need to protect the health of consumers and the users of animal products.
- The most effective way of handling the relevant risk factors.
- The desirability of facilitating market access.
- The desirability of maintaining consistency between New Zealand animal product standards and any relevant standards, requirements, or recommended practices that apply or are accepted internationally.
- The relative costs of having the scheme or not having it, who bears the cost, and any positive and negative impacts on consumers and users.
- Whether the scheme option proposed or selected is the most cost effective way of achieving its prime purpose.

9.2.1 Considerations

The IVP provides an independent verification of the sampling and testing managed under the operators RMP. The IVP can identify issues with routine sampling or testing. This programme must;

- Be an integral part of NZFSA's official assurances programme.
- Support the assurances given by NZFSA.
- Cover New Zealand Regulatory requirements.
- Be independent of the manufacturer's sampling and testing system and
- Be internationally credible.

As detailed in the assessment of options section of this discussion document, the most cost effective way of achieving the desired outcomes of an internationally recognised IVP programme is to put into place a RSC. By using a RCS the cost to industry of the IVP programme would reduce significantly whilst still retaining market confidence.

The RCS would include routine, random monitoring of microbiological parameters relevant to food safety and may include periodic, random monitoring of wholesomeness and standard of identity as considered appropriate.

The RCS will be flexible enough to cope with the diversity of the New Zealand dairy industry manufacturing operations and would enable NZFSA to more effectively determine estimates of compliance or failure rates industry wide.