

PAPER 4:

IMPLEMENTATION OF FOOD CONTROL PLANS

Introduction

The Domestic Food Review

This is Paper 4 in a Review of government involvement in the domestic food sector.

The Review is a significant long-term project that is likely to run over at least five years. Its purpose is to put in place a food regulatory programme across all sectors of New Zealand's domestic food industry that promotes and delivers safe and suitable food in New Zealand.

This is only the second time in the last 30 years that the government's role in the New Zealand domestic food sector has been critically examined at official level. The last review was undertaken in the late 1980s, and led to the Food Amendment Act 1996 and eventually the establishment of the New Zealand Food Safety Authority (NZFSA).

This paper covers the implementation of the proposed new food regulatory regime, in particular the registration and subsequent external verification processes for Food Control Plans. The recognition of individuals and agencies undertaking verification and other functions is also discussed in this paper. Other Papers in the series include:

- Paper 1: Introduction and context
- Paper 2: Regulatory roles, responsibilities and structures
- Paper 3: Food Control Plans

Further papers are planned and will be consulted upon.

Food Control Plan registration and external verification

Registration is a mechanism for providing the regulator with information on 'persons' with Food Control Plans – who they are, where they are, the type of food produced and what processes are undertaken. It is also the process by which the regulator gains confidence that the Food Control Plan meets the regulatory requirements and is suitable for the business concerned.

NZFSA intends to standardise, as far as possible, the assessment and registration process for future Food Control Plans across the various food sectors and operations.

Following registration, the business operator is responsible for making sure that the plan is followed, thereby producing safe and suitable food. External verification of Food Control Plans is expected to be undertaken largely by 'third parties'.

This paper discusses:

- the use of approved Codes of Practice
- the degree of evaluation a Food Control Plan will be required to undergo prior to registration to give the regulator confidence that the Food Control Plan will consistently produce food that is safe and suitable for its intended use
- the assessment and registration processes necessary for the regulator to properly administer Food Control Plans (including the decision on whether or not to register the Food Control Plan)
- the application of verification to ensure that operators comply with their registered Food Control Plans
- the required competencies and recognition process for evaluators and external verifiers of Food Control Plans.

A number of principles are proposed in this paper, and it is primarily these on which submissions are sought. These principles will guide the development of the policy to underpin the Domestic Food Review.

Submissions

At the end of public consultation on all of the Papers, NZFSA will analyse all submissions and provide policy advice to Government. Submissions are sought from interested people and organisations on the draft policy principles. A response form is provided, but submissions will be accepted in any format.

The closing date for submissions is 31 December 2004.

Submissions should be sent to:

Submissions – Domestic Food Review
c/o Policy Group
New Zealand Food Safety Authority
PO Box 2835
WELLINGTON
Email: robbie.thomson@nzfsa.govt.nz
Fax: (04) 463 2501

The discussion document will be available on the NZFSA website

www.nzfsa.govt.nz/policy-law/projects/domestic-food-review/index.htm. Following analysis of submissions, a summary of issues raised will be made available on the above website.

All submissions are subject to the Official Information Act 1982, which specifies that information is to be available unless there are grounds for withholding it. If you wish your submission or any part of it to be withheld, please indicate the grounds within the Official Information Act that apply. NZFSA will take your request into account when determining whether or not to release information. Please note that any decision by NZFSA to withhold information is reviewable by the Ombudsman.

Executive Summary

The New Zealand Food Safety Authority (NZFSA) is seeking to make the development and registration processes for getting a Food Control Plan registered as simple and cost-effective as possible, while still ensuring that food is safe and suitable.

Food Control Plan design and development

NZFSA would like to see Codes of Practice to assist with Food Control Plan design and development available for all main types of food business. Where possible a Code of Practice would include a Food Control Plan template or model. All relevant Good Operating Practice, HACCP application and regulatory requirements would be evaluated as part of preparing the Code of Practice. Codes of Practice would have the specified regulatory elements approved by NZFSA.

Food Control Plan evaluation

'Persons' that apply an approved Code of Practice without significant variation should not need a full evaluation of their Food Control Plan prior to registration. They would simply be required to confirm in writing that the Code is applicable and appropriately applied to their business. There will, however, likely remain some types of operations where evaluation prior to registration will be required, for example UHT (ultra heat treatment) processes. If a 'person's' business, or some part of it, is not covered by an approved Code of Practice, evaluation prior to registration will also likely be required.

For some operations, completion of evaluation will not be possible until after the Food Control Plan is registered and the food-processing operation is run for a time to ensure consistent performance. In this scenario, the operator is to prepare, agree with the regulator, and implement a protocol setting out how performance is to be assessed and what will happen to the food processed during this time.

Food Control Plan assessment and registration

Registration of Food Control Plans is necessary to ensure the regulator knows who the operators are, where they are, what type of food is produced and what processes are undertaken. A registration system provides the necessary information, and can ensure that operators can be contacted when necessary. A registration process includes an assessment or decision step in which the regulator decides whether to register a specific Food Control Plan. The system also needs to cover administration requirements such as review of registration decisions, surrender, suspension, withdrawal, and so on.

Food Control Plan verification

It is proposed that third-party external verifiers check the suitability of the Food Control Plan and compliance with it. Wherever possible the verification audits will be contestable, provided by recognised agencies and individual verifiers who meet set competencies. Verification will be performance-based: businesses that consistently comply with their registered Food Control Plan can gain reduced frequency of verification. Verifiers will not have the legal authority of a regulator, but mechanisms are proposed to allow prompt action in response to serious non-compliance.

Competencies of evaluators and verifiers

The regulator (NZFSA) will recognise agencies and individuals and will set criteria and standards for

performing the functions of evaluation and verification. The regulator needs to be confident that these third-party agencies and individuals:

- meet the appropriate international standard, namely ISO 17020¹
- meet organisational and individual criteria
- use appropriate quality systems
- have appropriate mechanisms to manage conflicts of interest, and to achieve impartiality and independence.

Objectives

NZFSA's objectives for the processes around the registration and external verification of Food Control Plans are to:

- have a registration system that ensures that Food Control Plans meet regulatory requirements and are applicable to the business concerned
- have a verification system that ensures ongoing compliance with the registered Food Control Plans
- apply the regulatory model to ensure that suitable competencies are met by those performing verification or evaluation functions
- make the process of registration as simple as possible, in particular by providing for the use of Codes of Practice
- achieve consistent processes and outcomes across all food sectors and operations, thus removing any duplication of requirements
- minimising administrative costs for both industry and the regulator.

Background

Registration

The current systems for the registration of risk-based management plans in New Zealand are provided under the Dairy Industry Act 1952 (product safety programmes), the Food Act 1981 (food safety programmes) and the Animal Products Act 1999 (risk management programmes).²

In all cases, the preparation of these plans is the responsibility of the 'person'. Specific requirements for these plans are set out in the respective legislation, and supporting Codes of Practice, templates and models are available in some industry sectors.

In all of the above cases, the plan is evaluated before it can be registered. Under the Dairy Industry and Animal Products Acts, the application for registration must include a report from an independent evaluator recognised by NZFSA. Under the Food Act, evaluation is undertaken by the regulator as part of the registration process.

The formal application process is similar under all the Acts:

- Application is made in writing to NZFSA, along with documentation as required in the respective legislation.

¹ ISO (International Organization for Standardization) standards are available for purchase through Standards New Zealand (www.standards.co.nz) or direct from ISO (www.iso.org)

² This paper does not comment on other systems of registration that are in use, such as that used for premises operating under the Food Hygiene Regulations 1974.

- Under the Dairy Industry and Animal Products Acts, additional information may be sought from the applicant. If it is not provided within a specified time, the application lapses.
- In all cases, registration details are recorded in a database. In the case of the Food Act and Animal Products Act, elements of the Register are required to be available to the public.
- Costs associated with registration are payable by the applicant, although the basis of the fees varies among the three Acts.
- Under the Animal Products Act and the Food Act, registration may be subject to start-up conditions. Under the Food Act, a cleared external verification report is required.
- These Acts provide for administration powers such as the ability to surrender, suspend, or withdraw a registration.

Verification

External verifiers (third parties who verify compliance with risk-based management programmes) are used currently under the various Acts that regulate New Zealand's domestic food supply, but the provisions are different under each of those Acts. In summary:

ANIMAL PRODUCTS ACT 1999

Under the Animal Products Act, external verification of risk management programmes is a contestable function that can be performed by third parties. This enables domestic operators to engage third-party verifiers; however, the current regulatory requirements of overseas countries demand that verification for export markets must be done by a government agency. External verification under this Act focuses on the operator's internal monitoring, corrective action and internal verification activity.

The extent or intensity of external verification required is performance-based; that is, operators who perform well can expect to be subject to less verification.

AGRICULTURAL COMPOUNDS AND VETERINARY MEDICINES ACT 1997

Under the Agricultural Compounds and Veterinary Medicines (ACVM) Act, external verifiers are appointed as Authorised Persons to carry out assessments of manufacturers' compliance with the ACVM Standard and Guidelines for Good Manufacturing Practice. Authorised Persons also assess approved traders of Prescription Animal Remedies (PAR) veterinary medicines (and vertebrate-toxic agents) for their compliance with the trading section of the ACVM Standard for PAR Veterinary Medicines. MAF Quarantine Service officers are appointed as Inspectors under the Act for the control of imported agricultural compounds and veterinary medicines at the border.

DAIRY INDUSTRY ACT 1952

Under the Dairy Industry Act, buildings and equipment are expected to be inspected prior to premises registrations, with inspections covering international Good Hygiene Practice standards and environmental issues. Following premises registration but prior to commencing operations, a Product Safety Programme (PSP) must be approved and is mandatory for businesses who manufacture and store dairy products. Under the Dairy Industry Act:

- External verification of the PSP must take place within three months of operation commencing, and again within 12 months of start-up.
- Verification audits are generally conducted annually. The verifier recommends audit frequency to the regulator and the regulator makes the final decision.
- Monthly reporting to the verification agency on the operation of the PSP is a mandatory requirement.

- Reporting of critical incidents is required. Such incidences are unusual and significant events that have either compromised or will potentially compromise food safety. Truth in labelling critical incidents are also required to be reported.

FOOD ACT 1981

Under the Food Act, initial external verification of a Food Safety Programme (FSP) usually occurs within 28 days after approval. In some cases an external verification may have occurred prior to approval of the FSP. The subsequent frequency of external verification is set as a condition of approval, according to relative risks and other relevant circumstances, with annual verification being the norm. More frequent verification is typically imposed when a verification or other investigation identifies a significant deviation.

Verification and Evaluation Competencies

The Animal Products, Food and Dairy Industry Acts and the Official Organic Assurance Programme (OOAP) each set out criteria that must be met by an applicant who wants to become an external verifier. There is a significant level of similarity between the criteria with all including impartiality, independence and a 'good character' test. The key elements of the application process are also similar (made in writing, accompanied by a fee and relevant documentation). The detail of the standards to be met and the application process are set out in tertiary legislation. administrative standards or other documentation.

Applications from external verifiers under the Animal Products and Dairy Industry Acts, as well as for OOAP recognition, must include an assessment from the accreditation body against ISO 17020. An accreditation assessment is not compulsory for a Food Act applicant, but it is an acceptable method of demonstrating technical competence. For evaluators under the Animal Products Act, the competency and assessment process is run administratively by NZFSA.

Each Act provides for some form of appeal or complaint process where an application is declined.

When recognition is granted, in all cases the regulator lists the specific activities, functions or classes of business that the applicant is recognised to verify, along with any conditions that apply. Recognition under the Food and Animal Products Acts and OOAP includes a renewal or expiry date. Processes for surrender or revocation of recognition are provided for under the Animal Products, Food and Dairy Industry Acts, and are similar under each.

Food Control Plan design and development

It is proposed that Food Control Plans will be required of all 'persons' to ensure that the food is safe and suitable for its intended purpose. The development of a Food Control Plan is the responsibility of the relevant 'person'.

NZFSA wants to make it easier for 'persons' to develop and implement a Food Control Plan by having available approved Codes of Practice that specify how the applicable food safety and suitability requirements can be met. It will not be mandatory to use a Code of Practice to develop a Food Control Plan.

It is intended that NZFSA will sign off on the food safety and suitability components of Codes of Practice – that is, those components that deliver on the regulatory requirements. This will ensure that there is a sound legal basis for the Food Control Plan based on a particular code.

Codes of Practice

A Code of Practice is a document that sets out the regulatory requirements and acceptable or agreed practices or processes for meeting those requirements. Codes of Practice are often industry-specific, and can include general guidance and information relevant to the purpose and scope of the Code, including industry-agreed practices.

Codes of Practice for Food Control Plans will have a strong focus on 'Good Operating Practice' to ensure that businesses have a solid foundation of hygienic practices and operational procedures and HACCP principles will be applied as appropriate when developing the Code. Depending on the scope of the Code of Practice other components may be included.

It is intended that the Codes will clearly identify:

- regulatory requirements, ie those set out in legislation and which the operator must meet or comply with
- recommended approaches or processes, these are likely to be industry agreed or recognised processes but alternative ways of doing things will be allowed
- other guidance and general information.

NZFSA proposes that, wherever possible, Codes of Practice will incorporate a template or model that can be used to develop an individual operator's plan, recognising these as a valuable tool to assist operators and to reduce development time and costs.

The advantages to an operator in following an approved Code of Practice are that it will:

- ensure that the operator complies with current best practice or acceptable industry practices and procedures
- ensure that the operator meets the relevant regulatory requirements
- reduce the costs of developing and evaluating the Food Control Plan.

Registration and External Verification Principle 1:

Codes of Practice, templates and models to support the implementation of Food Control Plans will be approved by NZFSA.

Food Control Plan evaluation

Evaluation of a Food Control Plan is an assessment to determine whether or not the plan complies with regulatory requirements and is appropriate for the business to which it is to apply. This process needs to be undertaken by someone independent of the business to which the plan will apply.

Evaluation when directly applying a Code of Practice

In developing a Code of Practice, NZFSA would ensure all food safety and suitability regulatory requirements set out in the code are correctly described and the approaches or processes identified to deliver those regulatory requirements are valid. The Code could be applied to a specific business with no need for independent evaluation of the 'person's' Food Control Plan, provided there is no significant variation from the approved Code. NZFSA would provide information to determine what constitutes a significant variation.

To provide NZFSA with some assurance that a Food Control Plan submitted for registration conforms to an approved Code of Practice, is applicable to the business, and contains no significant variations, a written confirmation will be required from the 'person'. This confirmation may take the form of a declaration

to be made within the Food Control Plan registration application form. This confirmation process places responsibility on the business operator to identify significant variations from the Code of Practice, and to have any such variations properly evaluated.

ON-SITE CHECK

The purpose of on-site visits is to satisfy the regulator that the business operation does in fact exist at the location claimed in the Food Control Plan, is able to perform the operations claimed, and is able to process the categories of food products claimed. For some high-risk type operations, it is likely that an on-site visit of the confirmed Food Control Plan would precede registration. But for the majority of businesses, the on-site visit would simply be done at the initial verification visit by the contracted verifier.

Evaluation where there is no Code of Practice or there is a significant variation

A significant proportion of businesses should be able to apply a Code of Practice without significant variation, but some businesses will want to tailor parts of a Code of Practice to meet their particular process variations or to develop their own specific Food Control Plan. Where a Food Control Plan is developed without a Code of Practice or has significant variation from the relevant Code, it will be the responsibility of the 'person' to arrange for an independent evaluation of the entire Food Control Plan or the process variation as appropriate.

In some cases, it will not be possible to complete the evaluation until after the Food Control Plan has been registered and the operations are actually run for a time. For example, it may be necessary to obtain additional information based on practice, and to make adjustments, before completing evaluation. In this scenario a protocol is to be used to describe what needs to be done to complete evaluation. The protocol would also need to cover what will be done with any food produced under the protocol, as it may not be possible to ensure that the food produced during this time is fit for its intended purpose. A protocol should be bound to a specified time period. The time period should be agreed via the registration process.

Registration and External Verification Principle 2:

Independent evaluation of a Food Control Plan is required where the Plan is developed individually without the basis of an approved Code of Practice, or a significant variation from the Code is employed.

High-risk operations or processes

NZFSA will identify high-risk operations or processes (for example, ultra-heat treatment or UHT) where evaluation prior to registration is required regardless of whether a Code of Practice has been developed.

Food Control Plan assessment and registration

In 'Paper Three – Food Control Plans' Principle one stated *All 'persons' will have and implement a documented Food Control Plan unless agreed alternative mechanisms are in place.* As noted earlier in this paper registration is the mechanism for providing the regulator with information on who has Food Control Plans. It is proposed that all 'persons' will require a registered Food Control Plan prior to commencing operations, unless a specific exemption applies.

Registration Process

The registration process is expected to be similar to that which currently occurs, but will be applied consistently across all food sectors:

- NZFSA will establish clear criteria for assessing applications, including disclosure by the applicant of any previous food-related convictions.
- The responsibility for making an application for registering a Food Control Plan will rest with the 'person'.
- Applications will be in writing.
- Additional information may be sought from the applicant or the evaluator and will need to be provided within a specified time.
- A standard fee will apply to recover costs of processing the application, but where an application requires specific assessment, a separate fee (likely based on an hourly rate) may apply.

The registration process requires that the regulator make a formal decision on the application. Elements in this decision will include:

- whether the application and the applicant meet the regulatory requirements set out for the operation to which the Food Control Plan applies
- the recommendation in the evaluation report (if required)
- whether start-up conditions, if any, should apply to the Food Control Plan.

It is proposed that the regulator be able to impose relevant conditions on its registration of a Food Control Plan. For example, verification of a particular process or piece of equipment may be required once the operation is under way. If verification later shows that any conditions have not been met, the operation will probably be interrupted while the issues are addressed. The costs of other than routine follow-up are likely to be recovered from the 'person'.

Triggers for re-registration

Food Control Plans are living documents. Technology and scientific knowledge improve over time, and the circumstances of 'persons' change. It is the responsibility of the 'person' to review and revise the Food Control Plan as and when necessary. It is not intended that the regulator will hold a full copy of every Food Control Plan, but the regulator will need to hold sufficient information to maintain the Register (see section on *Public Registers* below) and have access to a full copy on request.

It is not necessary or appropriate to re-register a Food Control Plan for every minor change that occurs in the operation. It is proposed that re-registration will only be required when:

- there is a change of ownership of the business
- a significant change in the Food Control Plan is to take place or is proposed
- a series of minor changes in the Food Control Plan together constitute significant change
- the registration has lapsed or is about to lapse.

Re-registration times are likely to vary among 'person' types, and may be determined according to factors such as their risk profile, the specific products or processes involved, or to ensure that minor amendments to the Food Control Plan are consolidated regularly.

Consistency is important and minimising compliance costs and removing unnecessary burdens is a priority. Therefore, when a 'person' can assure the regulator that no significant change to the Food Control Plan is necessary, the re-registration process should be simple and administrative.

In defining a 'significant' change to a Food Control Plan that requires a more in-depth re-registration process,

the following examples have been suggested:

- major alterations to facilities or equipment
- relocating to a new physical address (except where this is already permitted, e.g. mobile premises and vessels)
- processing a product that is not covered by the Food Control Plan, except:
 - where a hazard identification and analysis has shown that all hazards associated with the new product are adequately addressed by the existing Food Control Plan
 - on a trial basis where the affected product is not offered for consumption.
- incorporating new legislative requirements into the Food Control Plan, where this has been determined by the regulator to be a significant amendment
- changes that introduce new hazards or affect existing factors to the extent that the Food Control Plan is no longer effective
- changes to a critical control point and its associated requirements.

**Registration and External Verification
Principle 3:**

All registrations of Food Control Plans are to be time-limited and only a significant change to the plan will trigger re-registration before the end of the set time-limit. Other conditions may apply to the registration of Food Control Plans when appropriate.

Appeal and Review Process

It is intended that an appeal and review process will continue to be available where an application is declined.³ The key elements of such a system are:

- The review is undertaken by the Director-General or by a delegated person who was not involved in the original decision.
- The application for a review must be in writing, state the grounds for the review, and be lodged within a specific time period.
- The review must be concluded within a specific time period and the applicant notified in writing of the outcome and the reasons for the decision.
- If additional information is requested from the applicant, the time taken to respond is not included in the time allowed for completion of the review.
- The original decision remains in force unless and until it is altered or ruled invalid.
- The decision of the review is final, unless determined otherwise by a court of law.

Public Register

It is intended that NZFSA will maintain a Register of 'persons' operating Food Control Plans, which will be a 'public register' under the Privacy Act 1993.

The purposes of the Register will be clearly specified in the legislation, along the lines of the following:

- to enable members of the public to know what 'persons' are subject to Food Control Plans, and who is responsible for the plan
- to enable the Director-General to ensure that all domestically traded foods are safe and suitable, and in particular to manage any emergency situation
- to facilitate the compliance, audit and other supporting and administrative functions of the regulator under the legislation.

It is intended that the Register will be open for public inspection, without fee, during business hours at the regulator's head office. It is also likely to be accessible on the NZFSA website. Copies of all or part of the

³ *The appeal and review process set out in the Animal Products Act 1999 provides a good example of the process that will continue into the future (see <http://www.nzfsa.govt.nz/animalproducts/legislation/apa/apa.pdf>)*

Register will be available on payment of a reasonable charge for copying. It is expected that the Register will contain such details as the name, contact details, physical location, and type or category of business to which the Plan applies.

**Registration and External Verification
Principle 4:**

Basic details of the 'person' and scope of the Food Control Plans will be held on a public register.

Powers on the administration of registration

Inherent in the power to register a 'person' is the regulator's ability to refuse registration. Other powers are needed in order for the Food Control Plan registration process to be administered properly. An operator must be given the ability to surrender the Food Control Plan without cost. The regulator also requires the power, to be exercised subject to clear criteria and procedure, to suspend and if necessary withdraw registration and these too will be provided for in any empowering legislation. It may also sometimes be appropriate to recover the costs associated with the suspension and withdrawal of registration, and this should also be provided for.

Food Control Plan verification

New Zealand's future food regulatory programme will be based on the following regulatory model:

- The government sets the regulatory framework and standards, registers Food Control Plans and recognises third-party service providers such as external verifiers.
- Third-party external verifiers check the suitability of the Food Control Plan and compliance with it.
- Each 'person' – i.e. every organisation and individual with legal responsibilities within the food chain – takes responsibility for developing, implementing and where necessary amending the relevant Food Control Plan.

Using recognised third-party verifiers allows central and local government to focus on its role as manager of the regulatory system, rather than as a deliverer of regulatory services. Under this approach, the government retains overall control and responsibility, but can deliver the regulatory services if necessary or desirable.

External verifiers work on behalf of the regulator, and must be independent of the 'person' whose Food Control Plan is being verified. External verifiers must be recognised by NZFSA to ensure their competency. Once recognised, external verifiers will be subject to specified performance requirements and duties.

The primary responsibility for meeting the costs of external verification falls on the 'person' who operates the Food Control Plan. While external verification is a legal requirement, it is not the responsibility of the regulator; rather, it is part of the cost of being in the food business.

**Registration and External Verification
Principle 5:**

External verification will be performed by recognised agencies and individuals, with the verification costs borne by the 'person'.

Performance-based verification

Performance-based verification is based on the concept that a 'high performer' (i.e. an operation that maintains a consistent level of compliance with the Food Control Plan and other legal requirements) undergoes less frequent or less intensive external verification. NZFSA anticipates there will be three levels of external verification within a performance-based system:

- 'standard' or 'entry-level' frequency
- reduced frequency or intensity
- increased frequency or intensity.

Different types of food businesses will have appropriately different intervals and intensity of verification at each level. NZFSA intends to work with industry organisations to identify the requirements for each sector and the various types of operation. Factors to be taken into account include:

- the level of risk associated with the relevant products and processes
- any quality-control systems that are in place
- if the product is exported as well as sold domestically do any market-access requirements apply for the export product.

Businesses can expect increased or more intensive external verification when a corrective action is ordered after non-compliance.

**Registration and External Verification
Principle 6**

Operations that demonstrate high levels of compliance with Food Control Plans will undergo less frequent or less intensive external verification than those with a lower level of compliance.

Dealing with non-compliance

External verifiers have a responsibility to exercise professional judgement when they identify deficiencies in procedures or practices. It is envisaged that a hierarchy of responses be available to address the range of possible outcomes, and that these should be suitable for each industry and operation. Accordingly, NZFSA intends to work with industry organisations to develop appropriate requirements for each sector. In general, it is expected that minor non-compliance identified by the external verifier will be dealt with directly by the 'person'.

Major or repeated non-compliance can be expected to trigger more serious action. Examples of such non-compliance might be:

- A problem not identified by the 'person' has resulted in exposure of humans or animals to an unacceptable level of hazard.
- The 'person' has failed to identify or address repeated problems,
- Internal verification systems are not being implemented appropriately.
- Records are insufficient to confirm compliance or repeatedly inaccurate.

A significant non-compliance, or a series of minor non-compliances, could indicate a failure in the Food Control Plan, and may therefore warrant a response, such as a follow-up external verification or a directive from the regulator.

**Registration and External Verification
Principle 7:**

The level of response to an adverse external verification will be commensurate with the nature and degree of the non-compliance.

Reporting and record-keeping responsibilities of verifiers

The normal reporting avenue for the external verifier will be to the 'person' of the business. It is expected that the report should cover incidents of non-compliance, the result of the external verification, and any changes to the business's performance rating.

In cases of significant non-compliance, for example a potential threat to the public health, the external verifier will be required to report immediately to the regulator. In line with the provisions of the Food Control Plan, the 'person' will be expected to begin corrective action as soon as the external verifier advises that a significant non-compliance has been found.

Corrective action is the responsibility of the 'person'. Any failure to follow corrective procedures as laid out in the Food Control Plan will be viewed by the regulator as a serious failing. The regulator will have the power to direct 'persons' to take corrective actions, including recall of product; but waiting for instructions from the regulator does not fit with the philosophy that 'persons' are responsible for correcting failures.

It is expected that the reporting responsibilities of external verifiers will be set out in the relevant legislation, as will the responsibilities of Food Control Plan 'persons'.

The keeping of records is a key component of Food Control Plans. It is expected that external verifiers will keep records of verification visits and outcomes. Such records will need to be accessible by the regulator, on an as-required basis. Businesses will also be expected to keep current and historical records.

**Registration and External Verification
Principle 8:**

In cases of significant non-compliance with a Food Control Plan, the external verifier will be required to report immediately to the regulator.

Review process

It is intended that a review or complaints-resolution process will be available if a 'person' disagrees with the outcome of an external verification. In the first instance, a 'person' will be expected to raise any concerns with the relevant external verification agency. Each external verification agency is expected to have a review and complaints resolution process based on a recognised standard. It is intended that NZFSA will provide a further level of review if required.

The costs of a complaint resolution process will likely be covered by a component of the registration fee (for NZFSA involvement) or the external verification charges (when dealt with between the 'person' and verifier). Information from complaints can be an important indicator of the 'quality' of external verifiers and the effectiveness of the food-control system, and a no-fees approach is likely to reduce barriers to operators making a complaint. However, frivolous, vexatious, vindictive, or delaying complaints are likely to result in costs being recovered from the complainant.

Accreditation and recognition

Under New Zealand's regulatory model, the functions of Food Control Plan evaluation and verification can be performed by independent third parties recognised by the regulator. There will likely be specific requirements that only the regulator will consider, such as whether the individual applicant meets the regulatory requirements to perform the function. Otherwise, assessment will generally be done by external providers.

Both the agency and the individuals performing verification and evaluation will need prior recognition by NZFSA. The regulator will want to be assured that applicants (both agencies and individuals):

- meet applicable international standards
- use appropriate quality systems

- met organisational and individual criteria
- have appropriate mechanisms to manage conflicts of interest, and to achieve impartiality and independence.

NZFSA considers that to be assured about these factors and to ensure that the process has integrity, is transparent, and is consistently applied, accreditation to a documented standard is best. While no specific food control evaluation or verification standard has been agreed internationally, NZFSA considers that several international standards contain the vital core elements.

Given the general nature of international standards, it is recognised that secondary (e.g. function specific) criteria will need to be developed by NZFSA. The intention is to keep supplementary criteria to a minimum in order to avoid excessive specialisation and the associated costs.

The scope of the functions that an agency can undertake will be based on the competency of the individual(s) within the agency. Where necessary these competencies will be specified by the regulator.

Powers of refusal to recognise, suspension and withdrawal of recognition

Implicit in the power to 'recognise' agencies and individuals is NZFSA's ability also to refuse, suspend and if necessary withdraw recognition. It may also often be appropriate to recover the costs arising from the suspension and withdrawal of recognition, and this would be provided for in the empowering legislation.

Accreditation to an international standard

New Zealand is somewhat unique internationally, in that accreditation of agencies to international standards can be carried out by two accreditation bodies:

- International Accreditation New Zealand (IANZ), a Crown entity
- the Joint Accreditation System of Australia and New Zealand (JAS-ANZ), a non-profit bi-national body established by Treaty that operates in both Australia and New Zealand.

It is Government policy to have both these accreditation bodies operate within New Zealand, and for them to compete in the accreditation of certain standards. NZFSA has Memoranda of Understanding with both these accreditation bodies to ensure that NZFSA as regulator and the accreditation bodies understand their respective roles, responsibilities and expectations.

Two international standards appear to have potential application for New Zealand's needs in external verification and evaluation agency accreditation. International Organization for Standardization (ISO) Guide 65 sets out standards for accreditation of 'product certification bodies', and ISO 17020 sets out standards for accreditation of 'inspection bodies'⁴. These standards focus on the assessment of processes, systems, and the competence of the individuals. In choosing between these standards, NZFSA considers that the critical factors are:

- the ability to apply technical knowledge and make a professional judgement about the effectiveness of the process being assessed and its on-going appropriateness to meet regulatory requirements
- the ability to assess the on-going competence of the relevant business and its systems
- the ability to effectively manage the correction of non-compliance, including having a sound understanding of when it is necessary to alert NZFSA of real or potential problems
- the ability of the agency's systems to provide on-going assurances to NZFSA.

Based on these factors, it is NZFSA's view that the most appropriate international standard for accreditation

⁴ ISO (International Organization for Standardization) standards are available for purchase through Standards New Zealand (www.standards.co.nz) or direct from ISO (www.iso.org)

of external verification and evaluation agencies is ISO 17020. Accreditation to ISO 17020 is provided by both IANZ and JAS-ANZ.

Frequency of review and reassessments

The integrity of the food-safety system relies on maintaining confidence in the individuals and agencies recognised to undertake verification and evaluation functions. The system must therefore include robust provisions for review and reassessment of the individuals and agencies who act as external verifiers or evaluators. NZFSA may establish the required frequencies and criteria for review, which can be expected to be based on an international standard or guideline. NZFSA sees the performance of the agency or individual as a key element in determining matters such as the frequency of review of accreditation and recognition.

It is also important to link recognition by the regulator and accreditation to ensure that recognition is discontinued if accreditation is lost or lapses.

Verifier and Evaluator Competencies

NZFSA proposes to set minimum requirements for the qualifications and experience of those undertaking external verification and evaluation. The basic requirements will be the same for both functions, and are likely to fall under the following four headings (see Appendix C for examples of each):

- verification qualifications and experience
- Hazard Analysis Critical Control Point (HACCP) and supporting systems qualifications and experience
- technical skills, qualifications and experience
- regulatory knowledge.

It is expected that the assessment of personnel within the agency, the agency accreditation process, and NZFSA's checks will provide continuing oversight of individuals' experience. Maintaining and updating skills and competencies is a key element in ensuring that external verifiers and evaluators work at the level expected by Government and consumers – thus the regulator's proposed links to the training and education of potential applicants.

It is proposed that the regulator's role be to identify competencies, set criteria and indicate acceptable evidence of attainment or maintenance of competency. Where competencies or criteria relate to new or emerging skills for which current training or educational programmes do not exist, the regulator may be involved in the initial design or establishment of training or education programmes. It should not be necessary, and it may be undesirable, for the regulator to maintain a continuing involvement in education and training of external verifiers and evaluators.

In any instance where IANZ and JAS-ANZ may not have the technical competency in-house to undertake an assessment of certain verifiers and evaluators, NZFSA may provide technical expertise directly or may identify technical experts that can be used.

Registration and External Verification Principle 9:

NZFSA's recognition of third-party agencies performing external verification and evaluation will be based on accreditation to ISO 17020 and relevant secondary criteria set by NZFSA.

Assessment of Individuals

ISO 17020 provides for the assessment of individuals as 'signatories' who can supervise the staff actually undertaking the verification or evaluation. This approach means that not all individual verifiers or evaluators

need be externally assessed by an accreditation body, thus substantially reducing the overall accreditation costs borne by third-party agencies.

How this approach will be applied to a particular agency needs to be agreed on a case-by-case basis among NZFSA, the accreditation body and the applicant organisation. This proposal recognises that different requirements can apply across different sectors, and that an element of flexibility in, for example, the setting of staffing ratios can be allowed given the wide range of processes and products (and thus differing associated risk profiles) that will be covered by food control plans. A shortage of external verification agencies offering services to a particular sector or sub-sector of industry can in turn have cost implications for 'persons' operating in that sector.

Factors to be considered include:

- the ratio of supervisors to staff
- training and calibration systems within the agency
- how the supervision will occur (on-site versus other options)
- whether the supervised staff are assessed by the regulator.

Costs

The imposition of costs associated with gaining accreditation and recognition has been debated in the past. The conclusion reached was that accreditation and recognition gives a third-party agency the ability to earn income, and that the costs of achieving recognition and accreditation are a routine cost of setting up that business. Therefore, it is proposed that the costs incurred by the accreditation body and the regulator will continue to be met by the applicant.

Responsibilities, roles and duties

It is important to specify the verifier's and evaluator's functions, since they act on behalf of the regulator and play a critical role in the success of New Zealand's food-safety system. For individuals the following duties are proposed:

- only undertake functions or duties for which they are recognised by NZFSA
- comply with relevant requirements, regulations and specifications and any directions from the regulator
- maintain an appropriate degree of impartiality and independence
- maintain confidentiality, except to the extent reports to the regulator are required
- report to the regulator as required.

For third-party agencies, the following duties are proposed:

- ensure all recognised individuals under their control are not placed in situations that compromise their impartiality and independence
- ensure the agency is adequately resourced and its systems are adequately maintained to ensure its functions and activities are carried out properly and in line with regulatory requirements.

Registration and External Verification Principle 10:

Duties will be applied to recognised individuals and agencies that undertake external verification and/or evaluation functions.

Overcoming barriers to entry by new agencies

NZFSA is committed to ensuring that a sufficient pool of external verifiers and evaluators is established to support the implementation of Food Control Plans.

NZFSA is also aware that barriers to entry may affect potential new agencies when:

- the entire system or approach is new
- the system or approach is relatively new and there are very few other agencies operating in an existing system (i.e. the market has not reached a point of equilibrium between service providers and clients)
- a monopoly provider is established in the market place.

One of the key elements of gaining accreditation is the requirement to have experience and to have been supervised by an accredited person while gaining that experience. Each of the situations above presents newcomers with challenges or barriers to entry in this respect.

Entry when the entire system or approach is new: In this case there are no existing agencies or recognised individuals available for the applicant to observe, or who can provide the supervision of an actual on-site verification that is required as part of gaining ISO 17020 accreditation. To overcome this it may be necessary for the regulator to identify those elements of ISO 17020 that must be met prior to an agency undertaking an actual on-site verification as a recognised agency, on condition that full accreditation is gained within a specified period of time (i.e. allow a preliminary recognition system to get things started).

Entry to an existing system with limited existing agencies: In this case there is only limited competition and choice. The limited number of providers will likely be able to set their charges above what the market would pay if more providers were available. Because the co-operation of existing providers is necessary to allow newcomers to gain the necessary experience, market equilibrium may be slower to develop or may not develop at all.

Some possible options to address these difficulties may be:

- establishment of a 'buddy system' where existing agencies are 'encouraged', perhaps through financial incentives, to provide assistance to new entrants
- establish a training system with bonding, where an individual enters an existing agency and works to gain accreditation on the understanding that they will not leave to establish their own agency for a specified period of time
- negotiation with a 'person' seeking to register a Food Control Plan to provide design or evaluation services in the development of the Plan, or assistance in meeting the costs of an on-site verification for the Food Control Plan, in exchange for the opportunity to observe the on-site verification
- preliminary recognition, where time is allowed for an agency to complete full accreditation.

Other implementation issues

The cost of gaining accreditation, particularly for those outside Auckland or Wellington, can be high. For example, the applicant must also meet the travel and accommodation costs of the accreditation agency's technical adviser(s).

NZFSA intends to work with the accreditation bodies to look at how the costs of accreditation can be kept as low as reasonably possible. Another cost-related component that will need to be addressed is how to meet the costs of monitoring and compliance verification for external verifiers and evaluators.

Appendix A

Summary of Principles for Implementation of Food Control Plans

Implementation Principle 1	Codes of Practice, templates and models to support the implementation of Food Control Plans will be approved by NZFSA.
Implementation Principle 2	Independent evaluation of a Food Control Plan is required where the Plan is developed individually without the basis of an approved Code of Practice, or a significant variation from the Code is employed.
Implementation Principle 3	All registrations of Food Control Plans are to be time-limited and only a significant change to the plan will trigger re-registration before the end of the set time-limit. Other conditions may apply to the registration of Food Control Plans when appropriate.
Implementation Principle 4	Basic details of the 'person' and scope of the Food Control Plans will be held on a public register.
Implementation Principle 5	External verification will be performed by recognised agencies and individuals, with the verification costs borne by the 'person'.
Implementation Principle 6	Operations that demonstrate high levels of compliance with Food Control Plans will undergo less frequent or less intensive external verification than those with a lower level of compliance.
Implementation Principle 7	The level of response to an adverse external verification will be commensurate with the nature and degree of the non-compliance.
Implementation Principle 8	In cases of significant non-compliance with a Food Control Plan, the external verifier will be required to report immediately to the regulator.
Implementation Principle 9	NZFSA's recognition of third-party agencies performing external verification and evaluation will be based on accreditation to ISO 17020 and relevant secondary criteria set by NZFSA.
Implementation Principle 10	Duties will be applied to recognised individuals and agencies that undertake external verification and/or evaluation functions.

Appendix B

Examples of Qualification and Experience Requirements

SKILLS	QUALIFICATIONS	KNOWLEDGE & EXPERIENCE
VERIFICATION	NZFSA-recognised Lead Verifier course such as: <ul style="list-style-type: none"> • Stebbing • NZQA (lead Auditor certificate, min. Level 4) • SGS • AgriQuality 	3 years' recent experience
HACCP & supporting systems (e.g. water, cleaning equipment, chemicals, pest control)	NZQA HACCP unit standard (min. Level 4) No specific qualification for supporting systems	Demonstrate competence by way of observed verification and interview
TECHNICAL SKILLS 1. Underpinning (Specified Sectors) 2. Specialised – e.g.: a) low-acid canned food b) other heat treatment c) ante mortem & post mortem in mammals	<ol style="list-style-type: none"> 1. Level 4 equivalent in food, public health, animal health, or relevant science degree, or demonstrated expertise in the area 2a. Massey University thermal, DNC (Aust.) or equivalent 2b. Relevant tertiary qualification or demonstrated equivalence as a technical professional in food processing engineering (e.g. registered engineer or equivalent); relevant process knowledge or experience; adequate knowledge of food safety; NZQA-registered unit standard for validation/evaluation/ verification of dairy heat treatments 2c. National Certificate in meat inspection from a recognised service provider or veterinary degree 	<ol style="list-style-type: none"> 1. Should have some relevant experience working in food-related area 2. Demonstration of competence by way of observed verification and interview
Regulatory requirements	NZFSA to provide framework (unit standard to be developed)	Demonstration of competence by way of observed verification and interview