Ministry for Primary Industries
Manatū Ahu Matua

Policy proposals for inclusion in the Food Safety Law Reform Bill

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Growing and Protecting New Zealand

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This publication is available on the Ministry for Primary Industries website at:

www.mpi.govt.nz/news-andresources/consultations/proposals-for-policies-under-the-Food-Safety-Law-Reform-Bill

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1 Submissions

This document sets out policy proposals for potential inclusion in the Food Safety Law Reform Bill. The Ministry for Primary Industries invites interested parties to make **written submissions** on the proposals presented in this consultation document.

Your submissions will help us assess whether, and if so how, we need to amend the proposals to meet the objectives of the legislation.

1.1 How to have your say

The deadline for submissions is 5:00pm on Thursday 7 May 2015

We have included questions throughout this document. If you would like to respond directly to some or all of these, you can download a document that contains these questions from www.mpi.govt.nz/news-andresources/consultations/proposals-for-policies-under-the-Food-Safety-Law-Reform-Bill

The Ministry for Primary Industries will consider all relevant material made in submissions, so you are welcome to provide information supporting your comments. Please make sure you include the following information in your submission:

- the title of this consultation document;
- your name and title;
- your organisation's name (if you are submitting on behalf of an organisation), and whether your submission represents the whole organisation or a section of it;
- your contact details (that is, phone number, address, and email).

Please also:

- make sure your comments can be clearly read, as several copies will be made to help with analysis;
- state the number of the question you are answering; or if you are making a general comment, state the number of the section your comments are referring to.

You can **send your submission** to us in any of the ways below:

Email: FSLRBill@mpi.govt.nz

By post: **Consultation: Policy proposals for the Food Safety Law Reform Bill**
Ministry for Primary Industries
PO Box 2526
Wellington 6140

Hand delivery: **Consultation: Policy proposals for the Food Safety Law Reform Bill**
Ministry for Primary Industries
Pastoral House
25 The Terrace
Wellington

For answers to any **questions you have** about this consultation, please email info@mpi.govt.nz or telephone 0800 00 83 33

Please make sure your submission gets to us no later than 5:00pm on 7 May 2015

1.2 Official Information Act requirements

Under the Official Information Act 1982 (OIA) information held by the Ministry for Primary Industries is to be made available to requestors unless there are grounds for withholding it. The grounds for withholding information are outlined in the OIA.

If you are making a submission you may wish to indicate any grounds for withholding some information contained in your submission. Reasons for withholding information could include that the information is commercially sensitive or that you wish personal information, such as names or contact details, to be withheld. An automatic confidentiality disclaimer from your IT system will not be considered as grounds for withholding information.

We will take your indications into account when determining whether or not to release requested information. Any decision to withhold information requested under the OIA may be reviewed by the Ombudsman.

1.3 What happens next

Once the consultation period has closed we will analyse submissions and make recommendations to the Minister for Food Safety on the proposed content of the Food Safety Law Reform Bill. A summary of submissions will be posted on the Ministry for Primary Industries website.

After Cabinet has approved the final proposals, the Parliamentary Counsel Office (the Government's legislation drafters) will prepare a draft Amendment Bill. The Bill will be introduced to Parliament and considered by a select committee.

2 Summary

The independent Government Inquiry into the Whey Protein Concentrate (WPC) Contamination Incident reported its findings to the Government in 2013 and 2014. The WPC Inquiry examined the causes and responses of the incident, and New Zealand's dairy food regulatory system. It found that New Zealand has a world class regulatory system but that some improvements can be made.

The Government agreed to implement all the recommendations made by the WPC Inquiry. Legislative change is required to implement some recommendations, and the Food Safety Law Reform (FSLR) Bill is the vehicle to achieve this.

Although the WPC Inquiry focused on the dairy sector, which operates under the Animal Products Act 1999, the FSLR Bill will also amend other food safety legislation (that is, Food Act 2014 and Wine Act 2003) where appropriate to align the provisions that apply across the food sector. This approach will make it easier for businesses to comply with the law, and ensures that improvements apply across the whole system.

The proposed amendments to primary legislation (the Acts) discussed in this consultation document apply to the overarching framework for the food safety system. However, most of the WPC Inquiry recommendations are being addressed without statutory change being required. Where future detailed requirements and obligations need to be set in regulations or notices, separate consultation processes will occur.

The priority is to address the WPC Inquiry recommendations in a timely way. However, the FSLR Bill takes the opportunity to make some additional enhancements and to clarify or modify some provisions that are currently unclear.

2.1 What we propose

The changes to primary legislation arising from the recommendations of the WPC Inquiry are relatively modest. Our proposals are summarised below and set out in more detail in chapters 6 to 13 of this document.

Legislative design: Chapter 6

- *Improve the design of the enabling provisions for regulations and notices, by*:
  - providing more direction on whether a notice or regulation should be developed;
  - making the relationship between some regulation- and notice-making provisions clearer;
  - removing inappropriate duplication.

The proposal looks broadly at the WPC Inquiry concern with delegated legislation, particularly the proliferation of notices under the Animal Products Act. Legislative practice is always developing. We are therefore exploring ways to guide the use of the legislative tools (regulation and notices) that will support best practice.

Risk management programmes (and, as relevant and appropriate, Food Control Plans, Wine Standards Management Plans): Chapter 7

- *options for limiting risk management programme (RMP) content to food safety and related regulatory matters:*

Three options are presented:

i) fully implement the WPC Inquiry recommendation by prohibiting inclusion of material other than food safety and related regulatory matters in custom RMPs (and potentially custom food control plans and wine standards management plans). This option would streamline and focus the content of RMPs, but would have the highest change costs.

ii) require clear separation of RMP regulatory requirements in custom RMPs, either through having a detachable section of the document or via other means. This option would implement the spirit of the WPC Inquiry recommendation, but not all current custom RMPs would necessarily need to be amended so the change costs would be lower than in option i).

iii) case-by-case approaches to allow the Ministry for Primary Industries to intervene to ensure that RMP requirements are clearly identifiable, easy to understand and readily verifiable. This option would not fully address the WPC Inquiry recommendation, but would have the lowest change costs.

- *receive and maintain records of up to date programmes:*

The proposals are to ensure the regulator and verifying agencies are kept up to date with RMPs and changes made to them, by requiring:

i) operators to: hold a full copy of all their RMPs in a readily accessible form; provide a full copy electronically to the Ministry for Primary Industries when applying for registration and on request; send copies of all amendments to their verifiers within a specified timeframe; and

ii) the Ministry for Primary Industries to retain full copies of RMPs it registers; and

iii) verifying agencies to hold a full copy of the RMPs of the businesses they verify.

Traceability and recall: Chapter 8

- *be more explicit about traceability and recall:*

The proposal addresses the WPC Inquiry recommendation by adding appropriate provisions to ensure the visibility of traceability in the Acts. The provisions will signal that traceability and recall requirements (to be set subsequently in regulations and notices) will in future apply to all food and wine businesses.

- *ensure appropriate regulation- and notice-making powers for traceability:*

This proposal links to the one above; it will ensure there is an ability in the statutes to make regulations and notices for traceability and recall requirements.

Alignment of compliance and enforcement tools: Chapter 9

This proposal implements the WPC Inquiry recommendation by aligning compliance tools so all three food safety Acts will have the same provisions for improvement notices, infringement notices, a penalty based on commercial gain, and compliance orders.

Proposals related to improving food safety responses: Chapter 10

- *align the purposes of Director-General Statements:*

The three food safety Acts will be aligned so they all permit Director-General Statements to be made for the purposes of both "informing" and "protecting" the public.

- *compel information disclosure when identifying and responding to food safety incidents:*

Implementing the WPC Inquiry recommendation by providing a power to require information from parties providing services to or contracted by a food business (such as the laboratory involved in the WPC contamination incident) when identifying or responding to a food safety incident.

- *provide statutory oversight for food safety contingency planning:*

Implementing the WPC Inquiry recommendation by clarifying that the Ministry for Primary Industries has a role in planning responses to food safety incidents, in addition to the existing role of coordinating the response at the time of an incident.

Verification: Chapter 11

- *clarify that verifiers owe their duties primarily to the regulator:*

Addressing the WPC Inquiry recommendation about perceived conflicts of interest for recognised agencies and persons by a declaratory 'avoidance of doubt' provision.

- *provide verifiers' accreditation reports directly to the regulator:*

A proposal that bodies that accredit verifiers and evaluators against international standards must provide their reports to the Ministry for Primary Industries (which formally recognises persons and agencies to perform verification and other functions).

Enhance electronic transactions: Chapter 12

Amendments to align the Animal Products and Wine Acts with the Food Act 2014 provisions to allow the Ministry for Primary Industries to use automated electronic systems for its statutory functions including decision-making; and a proposal to allow the Director-General to require information to be provided electronically and in a particular format.

Technical amendments and enhancements: Chapter 13

Minor and technical amendments that harmonise similar requirements across the three Acts, clarify legislative inconsistencies, and make minor enhancements.

Harmonising and aligning similar requirements

- align the limitation periods for bringing criminal proceedings: all three Acts will align with the Food Act 2014 provision for a 4 year limitation period;
- reliance on superior officer's reasonable belief;
- completion of matters by other officers;
- align incorporation by reference provisions: the same provisions should apply across the system.

Clarifying intent

- clarify there is no right of review of a delegated decision to suspend an operation: the deregistration decision is reviewable, but the decision to suspend while the investigation is carried out should not be;
- clarify the process for and finality of review decisions made under delegated authority;
- clarify which provisions Overseas Market Access Requirements can be made under;
- clarify the definition of "retail butcher" in the Animal Products Act;
- clarify regulatory regime for dual operator butchers' premises;
- clarify the definition of "dairy processor" in the Animal Products Act: the current definition could be read to include people or businesses that should be regulated under the Food Act;
- clarify the scope of section 60B of the Animal Products Act.

Minor enhancements

- provide a notice-making power to notify levy formula components;
- make references to "part-business" consistent in the Animal Products Act.

2.2 Terms used in this document

Term	Meaning
Animal Products Act	the Animal Products Act 1999
custom RMP	a risk management programme that is customised to the needs of the individual business (compare template RMP below)
DG	Director-General (of the Ministry for Primary Industries)
Food Act	the Food Act 2014, which comes fully into effect from 1 March 2016 (to differentiate from the Food Act 1981, which remains in force until that date)
Food Control Plan (FCP)	under the Food Act 2014, a high-risk food business's plan to identify, control, manage and eliminate or minimise hazards or other relevant factors for the purpose of achieving safe and suitable food
food safety Acts	the three Acts that cover food safety, namely the Animal Products Act 1999, Food Act 2014, and Wine Act 2003
FSLR Bill	the Food Safety Law Reform Bill
MPI	the Ministry for Primary Industries (the main regulator of the food safety and assurance system)
notice	a legal instrument issued by the Chief Executive of the Ministry for Primary Industries that specifies particular requirements under authority of a food safety statute
operator	in relation to an animal product or food business, means the owner or other person in control of the business
recall	the act of removing potentially unsafe or not fit-for-purpose food, wherever it may be in the supply chain
recognised agency or person	under the law, the Director-General recognises persons or agencies to carry out specified functions or activities (for example, verification)
RMP	risk management programme under the Animal Products Act (see chapter 7)
safety	a condition in which food, in terms of its intended use, is unlikely to cause or lead to illness or injury to human life or public health

Term	Meaning
template RMP	a risk management programme that uses a template issued by the Ministry for Primary Industries (compare custom RMP above)
traceability	ability to track forward the movement of a product through the supply chain, or to trace back the history and location of a product
verification	applying methods, procedures, tests and other checks to confirm an operator's ongoing compliance with legal requirements
verifying agency	verifying agency means a recognised agency whose specified functions and activities include managing and carrying out verification functions and activities
Wine Act	the Wine Act 2003
Wine Standards Management Plan (WSMP)	under the Wine Act, a business's plan to identify, control, manage, and eliminate or minimise hazards and other risk factors related to the making of wine, to ensure the wine is fit for its intended purpose
WPC	whey protein concentrate
WPC Inquiry	the independent Government Inquiry into the Whey Protein Concentrate Contamination Incident

3 Context

Our food regulatory system has an excellent international reputation and underpins the high standing of New Zealand's food products in overseas markets. New Zealand's system has been recognised by both the European Union and the United States via mutual recognition arrangements that few other countries have achieved.

We must continuously adapt our system to meet new challenges and opportunities, both here and overseas. Every year brings new food technology, new products and processes, new diagnostic techniques, and new scientific knowledge about food safety and risk. The food safety scene is constantly evolving.

Part of this change is due to growth in New Zealand's food exports to new and developing markets such as China and India, which have different expectations and requirements to our traditional trade partners (for example, England or the European Union). There is also continuous change in consumer expectations about food, its quality, and its source.

3.1 The WPC Inquiry

In August 2013, Fonterra notified the regulator (the Ministry for Primary Industries) that three batches of whey protein concentrate were contaminated with *clostridium botulinum*. Although the contamination subsequently proved to be a false alarm, this "botulism scare" made global headlines, and had enormous consequences for New Zealand's international reputation as a supplier of safe food.

Its impact led the Government to establish an independent Government Inquiry into the Whey Protein Concentrate Contamination Incident. The WPC Inquiry investigated the causes of, and responses to, the incident and examined New Zealand's dairy food safety regulatory system.

The WPC Inquiry found that the incident was not the result of any failure in the regulatory system, and that New Zealand's food safety regulatory model is consistent with international principles. The Inquiry considered that its recommendations should renew confidence (both internationally and domestically) in New Zealand's food safety system and encourage all participants to work together to ensure that our system continues to be among the best in the world.

The WPC Inquiry consulted widely during its deliberations, using formal submissions and interviews, including with dairy companies, regulators, accreditors, verifiers, customers, laboratories and others. It also consulted regulatory and expert organisations around the world, before reporting its findings to the Government and making its recommendations.

The Inquiry's 38 recommendations to improve New Zealand's food safety and assurance system fall under the themes of:

- the wider view;
- regulatory design;
- role of the regulator;
- role of verifiers;
- testing: quality and integrity;
- implementation of food safety standards;
- traceability, recall and contingency planning;
- infant formula.

The Inquiry's reports can be found here: http://www.dia.govt.nz/Government-Inquiry-into-Whey-Protein-Concentrate-Contamination-Incident

3.1.1 Government's response to the Inquiry

The Government accepted all of the recommendations. A list of the recommendations is provided in Appendix 2. They aim to ensure that the food safety and assurance system remains fit for purpose to address risks and to meet future challenges. Some recommendations were also made on aligning provisions that should apply consistently across the system.

A large number of the recommendations are already being implemented, for example (among other things):

- the Ministry for Primary Industries has increased its audit capability and programmes including unannounced visits;
- all of the working groups and advisory panels recommended have been established and some have reported;
- a Food Safety Science Centre has been established;
- the Ministry for Primary Industries has increased its ground presence in key overseas markets including China.

The responses to the WPC Inquiry recommendations can be found here: www.mpi.govt.nz/news-andresources/consultations/proposals-for-policies-under-the-Food-Safety-Law-Reform-Bill

3.2 Existing legislation

The WPC Inquiry focused on the dairy sector, which is regulated under the Animal Products Act 1999. The two other main Acts that govern food safety are the Food Act 2014 and Wine Act 2003. The Agricultural Compounds and Veterinary Medicines Act 1997 completes the system, indirectly impacting human food safety.

Animal Products Act

The Animal Products Act applies to the production and processing of animal material and products, and has a trade facilitation role that extends beyond purely food safety matters. The objects of the Act are to:

- ensure that traded animal products are fit for their intended purpose; and
- facilitate the entry of animal products into overseas markets through giving official assurances to foreign governments.

Food Act 2014

The Food Act focuses on ensuring that food for sale is safe and suitable. The Food Act applies to food produced for the domestic market and for export but does not include provisions for official assurances. This consultation document applies to the Food Act 2014 that will come fully into force incrementally from 1 March 2016, and not the Food Act 1981.

Wine Act

The Wine Act applies to wine produced for the purposes of trade or export. Like the Animal Products Act, the Wine Act has a trade facilitation role that extends beyond purely food safety matters. The purposes of the Wine Act extend to matters such as:

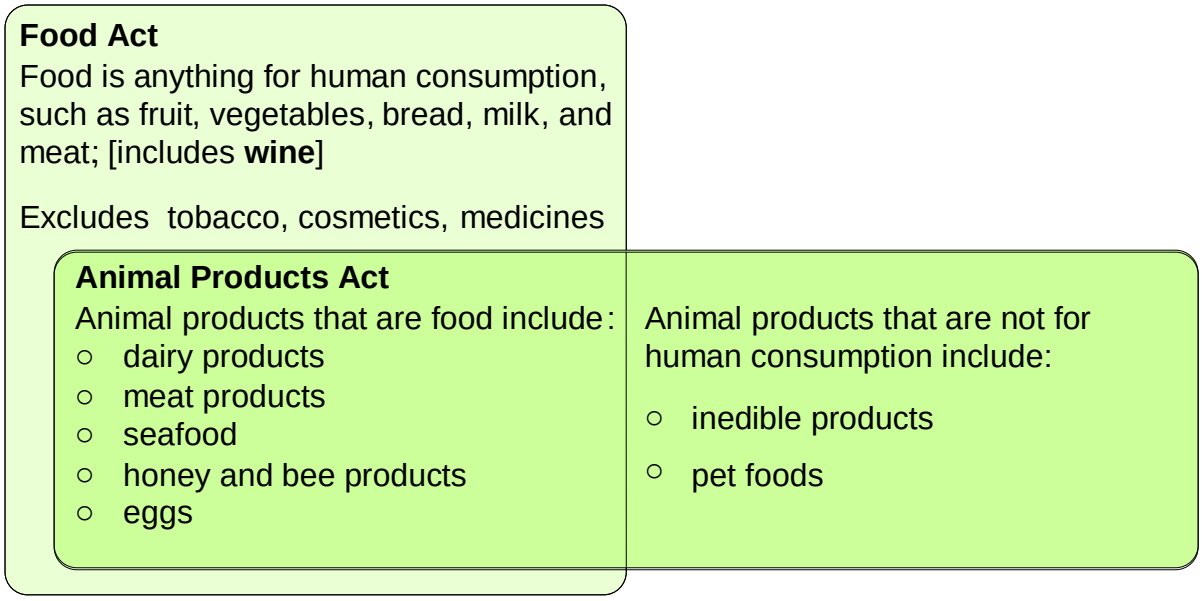
- setting standards for identity and truthfulness in labelling;
- setting export eligibility requirements to safeguard New Zealand's reputation in overseas markets.

Agricultural Compounds and Veterinary Medicines Act

This Act covers agricultural compounds including products such as fertilisers, animal feed, and veterinary medicines. It regulates these compounds to manage risks to public health, trade, animal welfare, and agricultural security. The FSLR Bill is not proposing to amend this Act.

3.2.1 Overlap of Animal Products Act, Food Act, and Wine Act

There is some overlap between the food types regulated by the Food Act and Animal Products Act as illustrated below.



The Food Act 2014 that comes fully into effect from March 2016 has a similar risk-based regulatory model to the Animal Products Act, which provides better consistency between the regimes. A relationship also exists between the Food Act and the Wine Act as the definition of food in the Food Act includes wine. This relationship is explicitly recognised in the legislation. Many of the legislative changes proposed in this document therefore aim to apply across these Acts, where it is appropriate that the provisions align.

3.2.2 The regulatory model

The Animal Products Act, the Food Act and the Wine Act all apply a similar regulatory model under which:

- food businesses are responsible for managing food safety risks and meeting the standards set by government;
- the compliance of food businesses with their risk management plans is audited by recognised verifiers;
- the Ministry for Primary Industries is responsible for setting the standards that food businesses must meet and for recognising the verifiers (in addition to other roles as the lead agency for food safety).

A central principle of the regulatory model is that food businesses are required to operate under a risk management tool. These tools are either RMPs (or regulated control schemes in some instances) under the Animal Products Act, or risk-based measures under the Food Act, or wine standards management plans under the Wine Act. In some cases businesses can choose which risk-based tool they wish to operate under.

4 The problem/opportunity

New Zealand's good food safety reputation was tested by the WPC contamination incident. As noted in chapter 3, the Government has accepted all of the WPC Inquiry recommendations.

Implementing some of the recommendations first requires changes to the primary legislation. Cabinet therefore agreed an omnibus Food Safety Law Reform Bill will be the vehicle through which those recommendations can be implemented.

The legislative changes provide the opportunity to demonstrate New Zealand's commitment to preserving and maintaining our excellent food safety reputation by addressing the identified improvements and continuing to adapt our regulatory system to meet new challenges.

The opportunity presented by the FSLR Bill also allows us to ensure key provisions in the three main Acts that cover food safety are harmonised where appropriate. Having similar obligations across the Acts assists businesses to know and comply with the law, and helps ensure a consistent approach by the regulator to similar situations. We can also address some other minor issues. However, the priority of the FSLR Bill is to respond to the WPC Inquiry in a timely way, in line with government assurances to the public and overseas trading partners.

4.1 Scope of this consultation

Purpose

The purpose of this consultation is to:

- communicate key messages and proposals for statute change to all stakeholders;
- ensure that stakeholders can understand how the proposals would impact on them, and have the opportunity to submit comment.

Proposals

The proposals in this consultation document address only those WPC Inquiry recommendations that need changes to the primary legislation to implement, and some other enhancements.

Most proposals are by their nature high level and enabling. The proposals are at the policy intent level. Decisions on which specific provisions would be amended in each Act and how they should be drafted are matters for the Parliamentary Counsel Office in consultation with the Ministry for Primary Industries, once Cabinet has approved the policy.

The WPC Inquiry recommendations that require legislative change are very specific. Therefore, for most proposals set out here there is no alternative approach, other than not fully implementing the WPC Inquiry recommendation. We are interested in receiving comment if you think the status quo (that is, no change) should apply.

Future changes to detailed obligations or requirements that need to be implemented via regulations or notices will have separate and subsequent consultation processes.

Other work underway:

The Ministry for Primary Industries has an ongoing food safety policy work programme. Problems or issues identified or raised during this public consultation that are outside the scope of the FSLR Bill will be evaluated in the context of that broader work programme.

What do you think?

1. **Do you agree with the way the problem/opportunity that the Food Safety Law Reform Bill is aiming to address has been described? If not, why not?**
2. **Are there any areas covered in the proposals in this document where you think the status quo (no change) should apply? Please provide evidence to support your views.**

5 Objectives

The main objective of the Food Safety Law Reform (FSLR) Bill is to help protect New Zealand's reputation as a supplier of safe and suitable food that is fit for its intended purpose, by making improvements to the food safety regulatory system.

The related objective is to ensure all the recommendations of the WPC Inquiry are implemented, both to protect human health and provide assurance to New Zealand's overseas trading partners that all steps have been taken to address the issues identified in the system.

The FSLR Bill proposes to achieve these objectives by:

- implementing the recommendations made by the Government Inquiry into the Whey Protein Concentrate Contamination Incident that need legislation change;
- enabling the implementation of the recommendations made by the Dairy Traceability Working Group (established on the recommendation of the WPC Inquiry) that have legislative implications;
- aligning and harmonising the compliance and enforcement tools (as recommended by the WPC Inquiry) so that similar tools are available to the regulator under the three main food safety statutes;
- making enhancements to enable the use of automated electronic systems for statutory functions;
- harmonising and aligning similar requirements across the food system where appropriate, clarifying some existing provisions, and making other minor enhancements within or between the food safety Acts.

The final proposals will be assessed against (among other things) the relevant food safety principles agreed by Cabinet during the development of the Food Act 2014. These principles include:

- government involvement and compliance costs imposed on the food sector will be minimised, consistent with the need for food to be safe and suitable;
- any government involvement and regulatory controls will be risk-based and science-based as far as possible;
- the food regulatory programme will be seamless and coherent;
- "persons" will take responsibility for producing safe and suitable food;
- regulatory requirements will be applied consistently and equitably across sectors and groups.

What do you think?

3. Have all the objectives of the FSLR Bill been identified? If not, what other objectives for the Bill should the Ministry for Primary Industries consider?

6 Legislative design proposals

Context

The food safety Acts enable delegated legislation to be made through regulations or notices to address particular matters.

The WPC Inquiry referred in both its reports to the way delegated legislation, particularly notices under the Animal Products Act, has been used. It noted the numerous instruments of different types, which run to about 12,000 pages in the tertiary layer of dairy regulation. Submitters to the WPC Inquiry said this layer is "difficult to navigate", "inaccessible", and "a bit of a nightmare".[1]

Ministry for Primary Industries' operational approach

The Ministry for Primary Industries has been improving its business processes to ensure tertiary legislation is effective, efficient, equitable, clear and transparent.

It is running an internal programme that aims to ensure that tertiary legislation and associated guidance is developed in a clear and consistent way, is easier to find, and easier to understand.

New processes, guides and templates have been developed to ensure that the tertiary legislation is presented consistently, is written in plain English to aid understanding, and is legally robust. A consolidated online repository for tertiary legislation is also under development.

However, this programme does not consider wider matters of legislative design such as whether a regulation or a notice is the most appropriate legislative vehicle in a given circumstance.

Problem

Although the Ministry for Primary Industries is addressing issues operationally (as outlined in the box above) the current primary legislation does not always provide a clear division between delegated notice- and regulation-making powers.

There are some very broad empowering provisions under the Animal Products Act that enable notices to be issued on a wide range of matters. There are also a number of examples where the relationship between the regulation- and notice-making provisions is unclear or where the enabling provisions duplicate each other. This may have contributed to more requirements being set at the notice level than was anticipated when the legislation was drafted.

The Wine Act and Food Act also have enabling provisions drafted in a similar manner.

[1] *Report on New Zealand's Dairy Food Regulatory System* Government Inquiry into the Whey Protein Concentrate Contamination Incident, December 2013, p.31

Examples of unclear legislative design

Wide notice-making powers: Section 44 of the Animal Products Act provides a power to make regulations for a variety of matters in relation to animal product standards and requirements. Section 45 enables notices to be made that set requirements in relation to the regulations. However, section 45 is so wide that it has supported a proliferation of notices, when regulations may have been a better option.

Unclear relationship: The Animal Products Act has regulation-making powers that refer to prescribing requirements, criteria, *specifications* and so forth for risk management programmes (RMPs). It also has notice-making powers to set *specifications* in relation to RMPs. It is not clear how these provisions fit together.

Duplication: The Wine Act and Animal Products Act have regulation- and notice-making provisions that are the same for prescribing competencies, qualifications, experience or other requirements that must be met for a recognised person. There is therefore no guide as to which material is better suited to which delegated instrument.

6.1 Provide more direction in the primary legislation

Proposal

We propose that adjustments be made to some of the regulation- and notice-making provisions in the food safety Acts. These adjustments will provide more guidance and direction on when a regulation or a notice is the appropriate mechanism to use. For example, where delegated legislation is setting policy outcomes it may more appropriately be provided for in regulations, while more technical detail may be provided for in notices.

How it would work in practice

The adjustments will build upon the examples of clear legislative design in the current enabling provisions, some of which are set out below. They will also clarify unclear relationships between regulation- and notice-making provisions and remove duplication.

Examples of good legislative design

Appropriate notices: The Animal Products Act in some situations provides a clear legislative design to allow the making of notices. For example, notices can be made in one-off situations or where there is a need to respond quickly to changing circumstances; such as:

- exemptions from the requirement to operate under a RMP;
- exemptions from the requirement that food for export meets certain domestic standards;
- export requirements (Overseas Market Access Requirements).

Clear relationship: For some subject matters, what must be in regulations and what can be in notices is clear. For example, with game estates under the Animal Products Act the regulations must cover the procedures and requirements for the listing of game estates and the notices can cover particulars to be shown on the register and specify the animals to be treated as game estate.

Transitional provisions

We propose that appropriate transitional provisions be provided to ensure that existing regulations and notices stay in effect. The existing stock of regulations and notices would be reviewed over time to be aligned with the new regulation- and notice-making enabling provisions.

What do you think?

4. Do you support the proposal to provide more guidance and direction for the delegated notice and regulation-making powers under the food safety Acts?

7 Improving risk management programmes (RMPs)

Context

The WPC Inquiry noted that New Zealand's food regulatory system is world class. Many participants in the Inquiry referred to there being a "good balance" in the system between prescription, outcome-based, and process regulation. One participant was cited as saying "the current risk management programme approach to food safety is very powerful and in the best interests of consumers and industry...". [2]

However, the Inquiry also noted where improvements could be made. It recommended that there should be a new requirement that RMPs be limited to food safety and related regulatory matters. It also recommended that the Ministry for Primary Industries should receive and maintain records of full and up-to-date programmes.

The WPC Inquiry focused only on the dairy sector. However, we are also examining whether it is appropriate for any changes to RMPs to be reflected in the risk-based plans under the Food Act 2014 and Wine Act.

This chapter discusses:

- the WPC Inquiry recommendation to limit the content of RMPs to food safety and related regulatory matters, covering the following options:
  - prohibit inclusion of material in a custom RMP other than that which directly addresses the requirements specified in the Act, regulations and notices
  - clearly separate food safety matters;
  - case-by-case interventions;
- the WPC Inquiry recommendation for the Ministry for Primary Industries to receive and maintain records of full and up-to-date RMPs.

Purpose of a food risk management programme or risk-based plan

A risk-based plan or programme is the key tool that a business uses to manage its food safety and suitability risks. These tools aim to ensure food is safe, and suitable for human consumption or its intended purpose. These programmes and plans are legally binding documents specific to an individual operator's business.

The Animal Products Act states that a RMP is designed to identify, control, manage, and eliminate or minimise hazards and other risk factors in the production and processing of food so that the food is fit for its intended purpose.[3] Operators set out in their RMPs how they will do this. The RMP must also set out the actions necessary when products do not conform to legal requirements, including the method of notification of food safety issues and product recall.

RMPs are similar to food control plans under the Food Act 2014.[4] Food control plans are designed for a particular food business to identify, control, manage, and eliminate or minimise hazards or other relevant factors for the purpose of achieving safe and suitable food. The Food Act prescribes the coverage, content, and registration requirements for food control plans, and the sanctions that apply for breaches.

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[2] *Report on New Zealand's Dairy Food Safety Regulatory System* Government Inquiry into the Whey Protein Concentrate Contamination Incident, December 2013 p.29
[3] See Animal Products Act 1999, section 12
[4] Food Act 2014, see sections 35 to 72

The analogous tool in the Wine Act is a Wine Standards Management Plan. These plans are designed to identify, control, manage, and eliminate or minimise hazards and other risk factors related to making wine, to ensure the wine is fit for its intended purpose.[5]

All of these risk-based tools manage the hazards, wholesomeness, and labelling of food products. They should:

- be relatively simple for the business to develop and use, and easy to amend as needed (a "living" document);
- adequately set out all the legal requirements the business must meet in ensuring the food is safe, and suitable for its intended purpose;
- illustrate clearly how the business will meet those requirements – this includes identifying all the relevant risks and stating how they will be addressed;
- be able to be readily evaluated and verified. Operational compliance with legal obligations needs to be able to be demonstrated and measurable.

Who must have a RMP under the Animal Products Act

In general, all primary processors of animal material and products for human or animal consumption are required to operate under a registered and independently verified RMP. Certain dairy processors and secondary processors (for example, dual operator butchers) also need a RMP.

The Ministry for Primary Industries has created RMP templates for some sectors, which businesses in those sectors can use. Operators can, however, choose to develop a RMP that is customised for their individual business (called a custom RMP). At present, around 400 custom RMPs exist across all animal product sectors.[6]

Problem

Many custom RMPs have become unwieldy and very complex. The WPC Inquiry noted that "some have grown to thousands of pages, made up of dozens of individual documents".[7] Some contain extensive material that is not related to food safety regulatory obligations, such as commercial specifications and matters related to staff safety.

The increased complexity has come about partly because some businesses are ascribing dual purposes to RMPs; that is, using them to fulfil both the statutory purpose of an RMP (as above) for compliance purposes, and as a food business risk management tool that is used constantly by the operator. The RMP requirements are often scattered throughout a business's operating manual. This makes it difficult for the operator of the RMP to maintain awareness of which parts of the document are the requirements of the RMP and which are not. It is not always clear how the regulatory requirements will be met, and therefore is harder to evaluate and verify.

The ability under the Act for businesses to provide only an outline RMP to the Ministry for Primary Industries (rather than the whole document) has resulted in the Ministry losing some oversight over the detail of the specific processes the operator proposes to use to address identified risks.

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[5] Wine Act 2003, see sections 8 to 29

[6] There are expected to be around 400 food control plans under the Food Act 2014 once it is fully in effect

[7] *Report on New Zealand's Dairy Food Safety Regulatory System* Government Inquiry into the Whey Protein Concentrate Contamination Incident, December 2013, p.33

In addition, the Animal Products Act requires RMP operators to apply to the Ministry for Primary Industries to register significant changes to RMPs. The Ministry considers these applications using a similar process to the initial registration process. RMP operators must periodically notify the Ministry of changes that are not significant, but the Ministry does not need to approve and register these amendments. This means that many versions of the document can be created, and the RMP operator and regulator may hold and refer to different versions. This situation creates confusion and makes compliance difficult.
The shift to a risk-based approach to food safety occurred with the passage of the Animal Products Act in 1999. Most businesses that use custom RMPs have undergone much development and change since then. It is timely to reconsider how these RMPs have evolved and how they can be improved to better meet their object under the Animal Products Act.[8]

7.1 Limiting the content of custom RMPs to food safety and related regulatory matters

This discussion focuses on custom RMPs. RMP templates have been developed for only some sectors, so many processors have no choice but to have a custom RMP. Other businesses whose food products and processing procedures are more complex may also choose to use custom, rather than template, RMPs. Guidance is provided to help operators develop custom RMPs.[9]

The addition of material not directly related to food safety legal obligations becomes an issue when it makes a RMP too difficult to understand and to verify. The intent of the WPC Inquiry's recommendation (above) was to ensure RMPs focus specifically on how the business will meet its *food safety* and other product traceability (and market access-related if applicable) obligations.[10]

Streamlining RMP content will focus businesses on the core requirements, thereby helping to foster the necessary food safety culture. It will support the fundamental principle of the regulatory model, where a business must take responsibility for identifying all its own food safety hazards and risks, and develop appropriate solutions to prevent and manage these on an ongoing basis.

There are options for how limiting RMP content can be achieved, and these are discussed below. The options are not mutually exclusive – a combination could be selected.

7.1.1 Option: Prohibit inclusion of material in a custom RMP other than that which directly addresses the requirements specified in the Act, regulations and notices

The WPC Inquiry report considered that the key requirements for the content of a RMP are those in the Animal Products Act[11] and related specifications notice,[12] plus any notification and reporting requirements. Under this option, information that does not directly relate to these obligations would not be able to be included in a RMP.

[8] See Animal Products Act 1999, section 11, Object of this Part
[9] Including in codes of practice and other models
[10] Note that many animal product business operators have their market access requirements outside their RMPs
[11] See Animal Products Act 1999, section 17
[12] Animal Products (Risk Management Programme Specifications) Notice 2008; however, other relevant notices will also apply

How it would work in practice

The legislation would make clear that only food safety and related regulatory requirements could be included in a RMP. The prohibition on including non-food safety material would be applied to custom food control plans under the Food Act 2014, and potentially to wine standards management plans under the Wine Act. A potential model for making the exclusion clear is the provision in the Food Act 2014[13] that relates to template food control plans.

Content requirements for RMPs are currently set out in the Animal Products Act, regulations, and notices, with guidance being provided in a manual. Under this option, regulations and notices would specify the content that must be included in a RMP and what must not.

RMPs that currently have additional material (such as commercial specifications or employee health and safety processes) would need to be re-designed to remove such content. The new documents would have to be independently evaluated and submitted to the Ministry for Primary Industries for registration.

If this option is preferred, the change would need to occur over a period long enough for businesses to be able to make the required changes and evaluation to be carried out, and to spread the cost. The Ministry for Primary Industries would also need time to register the revised RMPs.

Advantages

- Implements the WPC Inquiry's recommendation and aligns with the original intent of the legislation.
- A more-concise document is easier for everyone to understand and comply with.
- Easier to check that the RMP is complete and addresses all the regulatory requirements.
- Will be simpler to change when necessary.
- Easier to verify RMPs; may reduce verification costs for businesses.
- Will enable the Ministry for Primary Industries to better identify breaches, and to pursue enforcement action against breaches.
- Makes comparisons of RMPs easier.

Disadvantages

- Depending on the systems they use, operators who have fully integrated food safety with other business requirements may have difficulty separating these, and doing so may impact on their food safety performance.
- Imposes re-design, re-evaluation and re-registration costs on all businesses; high cost to implement the change. Many custom RMPs that incorporate other material are not complex or currently hard to understand and verify.
- May be less used by businesses in their day-to-day operations if no longer a 'one-stop-shop' document; could lead to a risk of less 'ownership' of the document, and therefore reduced compliance or less food safety focus.
- Businesses are likely to need to develop more than one document to cover all of their operational processes and requirements, and customer obligations. Maintaining more than one document risks staff confusion about requirements, and increases staff training costs.
- Current lack of document development and evaluation capacity in the sector will dictate the timeframe over which this option can be implemented.

[13] See Food Act 2014, section 38

7.1.2 Option: Require clear separation of food safety matters:

Stipulate that RMP requirements must be readily identifiable and distinct from any other content that is included in a custom RMP, either through separating the food safety requirements into a specific section of the document or via other means

This option would apply to all custom RMPs. The acceptable ways this requirement could be met would be specified in regulations. If this option is selected, minor changes to the provisions in Part 2 of the Animal Products Act would be made to support it.[14] Transitional arrangements would be needed, and a time period by which the change has to be made would need to be set.

There are different ways to make food safety regulatory requirements separate from other business processes within a single document. For example, the RMP requirements could be made detachable, or RMP requirements could be in a different colour from other material in the document. There might be a road map for all RMP requirements specifying where they are covered in the document. Today's technology enables documents to be multi-purpose.

Advantages

- Builds on the existing system – this option mandates the expectations already set out in guidance material, so the obligation is not totally new.
- Facilitates operator flexibility to bundle food safety elements in business risk management documentation.
- Would implement the spirit of the WPC Inquiry recommendation.
- Not all custom RMPs would need to be amended, re-evaluated, and re-registered.
- Less cost to businesses than prohibiting inclusion of non-food safety material.

Disadvantages

- Would not fully address the WPC Inquiry recommendation.
- Some re-design and re-writing of custom RMPs (and potentially, some re-evaluation and re-registration) required, with attendant costs.
- Relative to option 7.1.1 it would be more difficult to find the regulatory food safety requirements.

7.1.3 Option: Case-by-case intervention:

i) enable the Director-General to decline to register a RMP or a significant amendment if the regulatory elements of the document are not easily identified and understood or readily verifiable,

and

ii) give the Director-General a power to direct an operator to amend a RMP in which the regulatory requirements are not easily identified and understood or readily verifiable.

This option would allow RMPs with problematic content to be addressed on a case-by-case basis. Both proposals go together as a package.

[14] For example, Animal Products Act 1999 sections 12, 16, and 17

The first proposal would provide a new ground on which the Director-General of the Ministry for Primary Industries could refuse to register a RMP. Section 22 of the Animal Products Act provides that the Director-General *must* register a RMP *if satisfied that* [emphasis added] the content complies with the requirements imposed by or under the Act. There is no current legislative requirement that a RMP must be clear enough to be readily understood.

Registration of a RMP may be subject to such reasonable conditions as the Director-General may specify,[15] but it is not explicit that "can be readily understood" is one of those conditions. This option would make explicit the requirement for a RMP to be clear and readily understood. Note that there is precedent for this kind of discretion in the Biosecurity Act.[16]

The requirement would apply to RMPs at the time of registration and will improve the RMPs of the future. However, on its own it would not deal with existing RMPs that have problematic content.

The second part of the proposal would enable the Ministry for Primary Industries to require changes to individual problematic RMPs, either when they are submitted for registration of a significant amendment or when the Ministry becomes aware that a particular document is proving difficult to verify because its content is hard to understand.

Advantages

- Tailored approach would allow problems with individual RMPs to be addressed without applying content restrictions to all RMPs.
- Targets costs to the operators with problem RMPs.
- Builds on the existing statutory provision that permits conditions to be placed on registration.

Disadvantages

- Some re-design and re-writing of the RMPs of individual operators would be needed, with resultant change costs (including re-evaluation and re-registration) for those businesses.
- Could be difficult for the Ministry for Primary Industries to set the expectations for what is "able to be readily understood." Guidance material would be necessary.

What do you think?

5. Which of the options for limiting the content of RMPs (and potentially FCPs and WSMPs) to food safety and related regulatory matters, as recommended by the WPC Inquiry, do you support? Please give reasons.

6. What would the impact be on your business from each of these options? What costs might your business incur? Please give details.

[15] See Animal Products Act1999, section 22(2)
[16] See Biosecurity Act 1993, sections 62(k), 71(j), 82(k), 91(j)

For separate consultation:

The WPC Inquiry recommended that the key requirements to be included in a RMP should be placed in regulations. This will be progressed through a separate project. Implementing that recommendation necessitates bringing together requirements that are currently in more than one notice. Depending on the option chosen from the above proposals, additional requirements may also be placed in regulations. The proposed regulations will have their own (separate) consultation process.

7.2 Make sure the regulator is kept up to date with RMPs and changes made to them

Context

The WPC Inquiry recommended that the Ministry for Primary Industries should receive and maintain records of full and up-to-date programmes.

The current legislation permits a business to choose whether to provide the Ministry for Primary Industries with an outline only of its RMP or a full copy, when it applies for initial registration or for registration of a significant amendment.

When a food safety incident occurs, the regulator should be able to readily access the latest RMP. The current obligation for a business to be able to provide its RMP within two working days of any request is contained in a notice (tertiary level regulation).[17] As recommended by the WPC Inquiry, this and the other RMP requirements are to be placed in regulations (under the project noted in the "for separate consultation" box above).

Problem

The WPC contamination incident demonstrated a particular problem with sourcing Fonterra's full RMP. The situation was compounded because the Ministry for Primary Industries had registered an outline only.[18]

An outline does not allow the Ministry for Primary Industries to know the specific and detailed processes that the business has agreed to follow. The WPC Inquiry suggestion that the Ministry should retain the RMP document would mean a record of what the operator agreed to do at that point in time (when it was registered) would always be available.

The result of the current process is that the regulator's oversight of many of these documents has reduced over time.

Verifiers are also not currently obliged to hold a copy of the full RMP. A verifier must, on behalf of the regulator, judge whether the operator is complying with all their food safety legal obligations. Keeping up to date with all amendments to the documents is essential to robust verification.

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[17] Animal Products (Risk Management Programme Specifications) Notice 2008, clause 19(4); allows the Director-General, verifiers, and Animal Product Officers to request a copy of a RMP and for it to be supplied within two working days.
[18] No significant amendments had been registered since 2007.

Proposals

The proposals below link to the options in section 7.1 to limit the content of RMPs, because more streamlined documents will make it easier for the proposals below to be implemented. Note that an "electronic copy" may simply be a scanned version of the original.

7.2.1 Require operators, MPI, and verifying agencies to hold copies of RMPs

Under this proposal, we would require:

a) operators to:

- **i hold a full copy of all their RMPs, in a readily-accessible form**
- **ii provide the full RMP electronically to the Ministry for Primary Industries at the time of registration (both initial and for subsequent significant amendments)**
- **iii provide the full RMP to the Ministry for Primary Industries on request within two working days**
- **iv send copies of all amendments to their verifying agency, either before the next verification visit or within 6 months of the amendment being made, whichever is the sooner;**

b) the Ministry for Primary Industries to retain a full copy of a RMP it registers;

c) verifying agencies to hold a full (electronic) copy of the RMPs of the businesses they verify.

The elements of this proposal are a package that would work together to ensure the regulator and verifiers have access to the most recent version of a RMP.

Under this proposal the provision in the Animal Products Act[19] that permits a business to choose to provide only an outline RMP to the Ministry for Primary Industries would be removed.

The proposal is not expected to be a big change for businesses because they are already required to be able to supply their RMP within two working days.

Where a document is not able to be provided electronically, a charge will be made for processing a paper copy. Now that technology allows most RMPs to be developed and saved electronically, storage and sharing of these documents is less of an issue than it was when paper copies were the norm.

Advantages

- Ensures the regulator has access to the full copy of the RMP it has approved, allowing better oversight.
- Ensures the verifier always has up-to-date versions of the RMPs of the businesses they verify, thereby assisting the verification process.

[19] Animal Products Act 1999, section 20(2)(a)(ii)

Disadvantages

- Some cost to businesses that do not have their RMP in electronic form.
- RMP approval and registration may take longer, which will be a cost to industry.
- Verifiers will need to have the capacity to store the documents securely (may need to invest in IT improvements). May pass these costs on to businesses.
- Increased cost for businesses that operate multi-site RMPs.

What do you think?

7. Do you agree that this proposal will adequately address the WPC Inquiry recommendation to ensure better access to full and up to date RMPs? If not, why not?

8. What impacts might there be from implementing this proposal?

8 Traceability and recall

This chapter discusses proposals to:

- be more explicit about traceability in the legislation;
- ensure there are explicit regulation-making and notice-making powers for traceability and recalls.

Context

Traceability and recalls are critical factors in the food safety system. Traceability facilitates the rapid identification of the quantity and location of food (including ingredients) to allow effective recalls of products if they are unsafe or not fit for purpose.[20] Traceability can be defined as the ability to track forward the movement of a product through the supply chain, or to trace back the history and location of a product (and its ingredients).

Recalls are the act of removing potentially unsafe or not fit-for-purpose food, wherever it may be in the supply chain – including food held by consumers. They help ensure that consumers are protected from unsafe food. Mandatory recalls are recalls that the Ministry for Primary Industries compels a business to undertake by use of a statutory power. Voluntary recalls are those undertaken by businesses where the Ministry for Primary Industries has not used a statutory recall power.

New Zealand needs to have robust traceability and recall processes for all food products to maintain its domestic and international reputation as a trusted supplier of safe and suitable food.

The WPC Inquiry

The WPC Inquiry found that during the contamination incident frequent changes to traceability information greatly contributed to confusion during the response, and it took three weeks before the Ministry for Primary Industries received full traceability information.

In reviewing New Zealand's regulatory requirements the WPC Inquiry found the traceability requirements to be broadly comparable with those in similar countries, although there were differences in the degree of precision. The Inquiry concluded that New Zealand's traceability processes for dairy foods can and should be improved.

The WPC Inquiry recommended that a working group be convened to consider: first, the most appropriate regulatory provisions for traceability of dairy products; and secondly, a code of practice or similar to guide industry in implementing such provisions. The Dairy Traceability Working Group (the Working Group) was established in April 2014 and has now provided its advice to the Director-General.[21]

Strengthening traceability of food

The Dairy Traceability Working Group noted that New Zealand needs to ensure its dairy traceability regulatory requirements and processes are consistent with international best-practice, cost-effective, technically feasible, and able to handle increasingly complex supply chains.

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[20] Note that traceability is useful for other purposes too, such as adding commercial value, product integrity, and anti-fraud purposes.

[21] Report A: *Proposed Regulatory Requirements for Traceability,* December 2014. Report B: *New Zealand Dairy Industry Best-Practice Guide to Proposed Regulatory Requirements for Traceability,* December 2014

Traceability systems that meet these requirements will provide enhanced food safety and assurance to consumers of New Zealand food products. The Working Group's recommendations include several new dairy traceability requirements and indicate what is required to future-proof the system.

Traceability is important for the entire food safety system. We are therefore considering how the Working Group's recommendations would apply across all food sectors. The proposals in this document relate to changes to the primary legislation. Separate consultation will occur on proposals for regulations.

For separate consultation:

The Ministry for Primary Industries is considering the Dairy Traceability Working Group's reports and exploring whether, and how, the regulatory requirements for traceability that the Working Group proposed should best be applied to the dairy sector and other food sectors. Detailed requirements will be set in regulations and notices. Progression and implementation of this work will include separate consultation later in 2015. If these proposals were to be implemented, potential costs will be analysed and consulted on at that time.

The Working Group has proposed the following high-level traceability requirements for the dairy sector:

- providing for full chain traceability from farm gate through to consumer through an inter-operable "one up, one down" system, where RMP operators must maintain records of the food products they receive from each supplier and the products they dispatch to each customer;
- requiring traceability information to be provided electronically on demand in a standard data format to the Ministry for Primary Industries or an independent verifier; and that this be provided within 24 hours or as specified;
- an explicit requirement that companies hold practical tests of traceability processes to supply the information required for mock recall and these be independently verified or audited where a product recall has not taken place in the past 12 months.

Recall provisions

The WPC Inquiry recommended multiple improvements to the recall provisions in the Acts that cover food safety. The passing of the Food Act 2014 implemented the first of these – aligning mandatory recall provisions across the food safety Acts.

The Inquiry also recommended that the circumstances in which businesses undertake voluntary recalls should be contained within regulations, rather than in their individual risk-based plans. This approach will promote consistency in when New Zealand businesses must undertake recalls of unsafe or not fit-for purpose food.

Another recommendation was that regulations should require industry to simulate recalls and that these simulations be audited by independent verifiers. The Dairy Traceability Working Group recommended that companies should hold practical tests of traceability processes; that is, companies will need to demonstrate their ability to undertake the practical steps of recalling product (for example, contacting customers). These two recommendations are complementary.

Problem

Framework for traceability and recalls

The three food safety Acts do not contain the explicit framework for traceability and recalls that could be expected, considering their critical importance to food safety. The Animal Products Act and the Wine Act do not use the term "traceability" and the Food Act 2014 only references it specifically in relation to import requirements. There are references in the legislation to records and returns, and to corrective actions including recalls, and traceability falls under general risk management or risk measures – but it is not given the prominence it requires.

The Acts need to be clearer about traceability obligations. They also need to anticipate and explicitly enable the types of requirements for all food sectors that will be set out in regulations and notices.

The circumstances for voluntary recalls are determined by individual businesses as a part of their risk-based plans. This creates potential inconsistencies in when recall are undertaken because the trigger for one business is not necessarily the same as for another. The voluntary recall obligations within the food safety regime need to be clearer, to establish consistent recall thresholds.

8.1 Be more explicit about traceability in the Acts

Proposal

We propose to strengthen the primary legislation to clearly outline industry's responsibility to have robust systems that ensure ingredients and products can be traced. The traceability requirements will apply to every food and wine business, whether that business operates under a risk-based programme or plan, is an importer, or is an exporter.

Why we are proposing this change

Traceability in food safety is important enough to merit the legislation explicitly focusing on it. This approach would clearly let food and wine businesses know that they must have a robust traceability system and it must be integrated as a fundamental part of their food safety management systems.

How it would work

This proposal is to amend the provisions in the food safety Acts relating to risk-based programmes and plans, importing, and exporting, to clarify that they can include traceability requirements that must be met.

What do you think?

9. Do you agree that the Food Act 2014, Animal Products Act, and the Wine Act should be clearer about traceability requirements? If not, why not?

10. Are the amendments proposed sufficient to enable traceability systems for ingredients and other inputs? If not, please identify what else is needed, and explain why.

8.2 Ensure there are explicit regulation- and notice-making powers

Proposal

We propose to amend the regulation- and notice-making provisions, or any other empowering provision required to enable implementation of policy decisions, in the food safety Acts to explicitly enable:

- traceability requirements;
- simulated traceability and recall exercises that are independently verified;
- the circumstances for voluntary recalls to be set in regulations.

Why we are proposing this change

We need to ensure any future regulations or notices about traceability and recalls are enabled in the legislation.

Advantages and disadvantages of both proposals

Advantages

- Clearer obligations and responsibilities are placed on food businesses to operate robust traceability systems.
- Would highlight and elevate the critical importance of traceability in producing safe and suitable food. The proposals will help make clear that all food businesses operating under a risk-based tool or importing or exporting food must have a robust, integrated traceability system as a fundamental part of their respective food safety management systems. In turn, this will drive sector behavioural change.
- Would lay the foundation for the upcoming regulatory requirements for traceability, and signal that specific proposals on traceability requirements will be forthcoming.
- Will improve the consistency of how food safety legislation treats traceability.
- Will improve the consistency of voluntary recalls across New Zealand food businesses.

Disadvantages

- Businesses may incur costs from meeting subsequent regulatory requirements for traceability and recall, an issue that will be explored in detail when the regulations are developed.

What do you think?

11. Do you agree with the proposal to widen the regulation- and notice-making powers for traceability and recalls in the three food safety Acts? If not, why not?

9 Alignment of compliance and enforcement tools

Context

The VADE compliance model

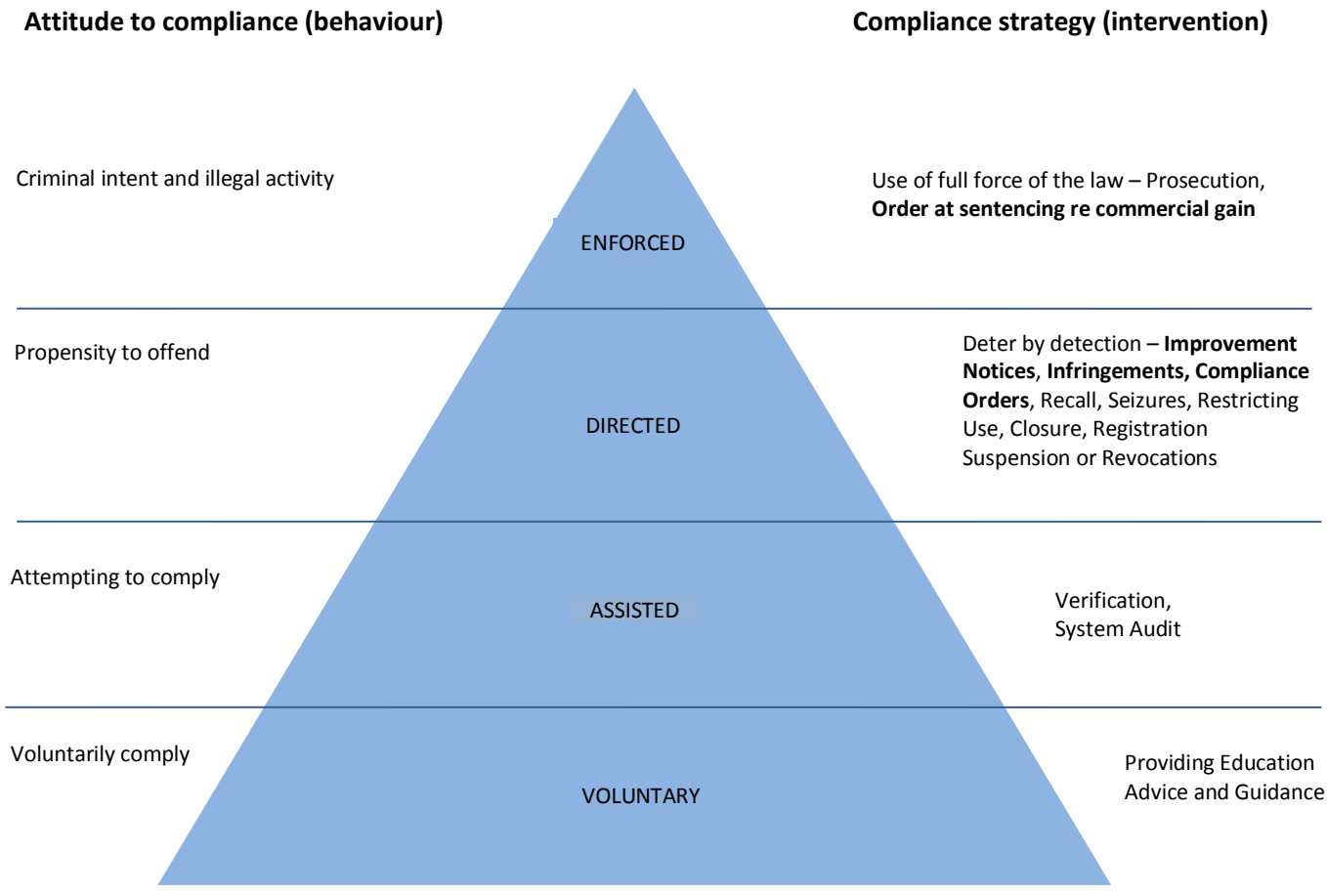
The Ministry for Primary Industries' compliance model adopts a graduated and proportionate approach to non-compliance by food businesses. This approach is supported by the Voluntary, Assisted, Directed and Enforced (VADE) model. VADE provides a framework for regulators to evaluate the behaviours of those they regulate and match an appropriate intervention to the level of non-compliance. It focuses on using the earliest intervention to avoid the risks associated with non-compliance.

Having an appropriate range of tools for addressing a variety of behaviours and non-compliance is critical to the success of this approach.

The WPC Inquiry agreed with the concept of the VADE model. It recommended that the compliance and enforcement tools in the Animal Products Act should be aligned with those in the Food Act 2014. The Food Act contains a wider range of enforcement tools than either the Animal Products Act or the Wine Act and is more consistent with the VADE model. Its regime includes improvement notices, an infringement regime, court-ordered compliance orders, and an order at sentencing to pay a penalty based on commercial gain.

The diagram below sets out where these tools may be applied to achieve the desired behavioural change and compliance.

Compliance Operational Delivery Model
VADE – Voluntary, Assisted, Directed, Enforced



Voluntary compliance interventions are focused on the regulator clearly communicating its expectations and obligations to ensure it is easy for the people being regulated to understand what they must do, and why they must do it.

Assisted compliance interventions are focused on monitoring activities that reinforce legal obligations through verification and systems audit. This stage is also where the Ministry for Primary Industries gathers information that is assessed and fed back to stakeholders and used to inform where to focus its regulatory effort.

Directed compliance is about managing non-compliance using a range of interventions to encourage a desired behaviour change. Interventions here require some power under legislation, and so are issued by compliance officers.

Enforced compliance is where the regulator is required to use the full force of the law as a consequence of no noticeable behavioural change despite Voluntary, Assisted, and Directed interventions, or where lesser intervention is inappropriate.

Proposal

9.1 Align the enforcement tools in the three Acts

It is appropriate that similar food-related offending under the different food safety Acts can be responded to in a consistent, graduated, and proportionate manner. It is therefore proposed to amend both the Animal Products Act and the Wine Act to include the following enforcement tools that are contained in the Food Act 2014.

9.1.1 Improvement notices

A compliance officer will be permitted to issue an improvement notice to direct a person to comply with the requirements of the Act, with non-compliance being an offence. This response sits above a warning, and when an operator complies with the improvement notice that is the end of the matter. Such a notice may be suitable to use for a breach of a risk-based plan or programme (for example, equipment cleaning or food handling) or for non-compliance identified during an audit.

9.1.2 An infringement regime

An infringement regime enables a compliance officer to quickly and effectively deal with minor offences that warrant more than a warning but less than the full sanction of criminal law. The objective of an infringement scheme is to change behaviours to reduce harm caused by relatively minor offending. Infringement offences are dealt with by way of a fixed financial penalty, served by an infringement notice. A person who commits an infringement offence must pay the fee but does not receive a criminal conviction. They may challenge the infringement notice in court.

Like the Food Act 2014, the maximum infringement fee will be $1,000. The infringement offences would be identified in regulations, which would have their own public consultation at a later date. Infringements are used as an enforcement tool for relatively minor offences that involve straightforward issues of fact. The Food Act 2014 regime currently proposes infringements for offences such as failure to register food control plans and national programmes, and for failure to comply with specific labelling requirements in the Food Standards Code.

For separate consultation: infringement regime

It is proposed that the Animal Products Act and the Wine Act will provide a regulation-making power to enable the infringement offences and their respective infringement fees to be specified in regulations.

Any proposed infringement offences and fees will have their own public consultation at a later date.

9.1.3 A penalty based on commercial gain

If a person is convicted of a specified offence and it was committed in the course of producing a commercial gain, it is proposed that at sentencing the court may make an order for payment of an amount up to 3 times the gain if it can be determined, or up to 10 percent of the turnover of the company.

Such an order would be useful, for example, where the offending is in relation to wrongful or misleading labelling (for example free-range or health claims) that could potentially give a company a significant market advantage that lasts beyond the duration of the offending. We propose using the specified offences in the Food Act as a guide.

9.1.4 Compliance orders (add to Wine Act only)

The Food Act 2014 and the Animal Products Act both currently contain compliance orders that can be imposed by the court and require someone to take action or prevent someone from taking action. The court may also order a person to pay the costs of remedying any adverse effect. The order can apply to an action that a person intends to do, so there is no need to wait until there is an actual breach.

Advantages and disadvantages of this proposal

Advantages

- A full range of enforcement tools across the three Acts allows a graduated, proportionate, and consistent approach to non-compliance by food businesses.
- An infringement regime has benefits for all parties: the Ministry for Primary Industries would have an option for incentivising behaviour change other than taking a prosecution; the offender would not receive a conviction; and the justice system would not become involved unless the infringement fee is unpaid or the infringement notice is challenged.

Disadvantages

- An infringement regime also has trade-offs: the offender has reduced legal rights (unless they challenge the notice), and the justice system is involved when the fee is unpaid or the notice is challenged.

What do you think

12. Do you agree that the enforcement and compliance tools should be aligned between the Food Act 2014, the Animal Products Act, and the Wine Act? If not, why not?

13. Do you agree that the Animal Products Act should include:

- **a improvement notices**
- **b an infringement regime**
- **c a penalty based on commercial gain?**

If not, why not?

14. Do you agree that the Wine Act should include:

- **a improvement notices**
- **b an infringement regime**
- **c compliance orders**
- **d a penalty based on commercial gain?**

If not, why not?

10 Proposals to improve responses to food safety incidents

The WPC Inquiry placed high importance on the need for planned, coordinated, and risk-based responses during food safety emergencies. It made recommendations on ways to improve responses. Most action for responding to a food safety incident takes place at the operational or business process level.

This chapter discusses:

- aligning the purposes of Director-General Statements;
- compelling disclosure of information during a food safety incident;
- statutory oversight for food safety contingency planning.

10.1 Align the purposes of Director-General Statements

Context

The Animal Products Act, Food Act 2014 and Wine Act allow the Director-General of the Ministry for Primary Industries to publish privileged statements (DG Statements). During a food safety incident these statements may be issued to protect, and in some cases to inform, the public about risks associated with animal products, food, and wine. DG Statements are a distinct statutory power, and can be used separately from or in addition to a mandatory or voluntary recall of food products. This power cannot be delegated by the Director-General.

The provisions for issuing a DG Statement include protection from liability for making the statement. "Qualified privilege" attaches to DG Statements under the Animal Products Act and the Food Act 2014. The "qualified privilege" protects the Director-General against legal proceedings for defamation over the contents of the statements. This privilege means that a person could bring defamation proceedings against the Director-General only if it can be proved that the Director-General acted with "ill will" or otherwise "took improper advantage" of the situation.

The purpose of this privilege is to ensure the Director-General has the freedom to publish a statement that may protect or inform the public in the interests of public health, without having his or her actions constrained by the threat of legal action. Often a level of risk exists with making DG Statements during food safety emergencies because they must, by their nature, be based on the information known or available at the time. The release of information through DG Statements is part of ongoing risk assessment and management during a food safety incident, and is designed to function alongside other powers (also see section 10.2 on compelling disclosure of information).

The WPC Inquiry noted that there is currently no obligation for the Director-General to supply underlying scientific or test results to affected parties (for example, businesses) when making a DG Statement. However, existing provisions are sufficient to permit the disclosure of information as appropriate, and no legislative change is required to implement that part of the recommendation.

Use of DG Statements during the WPC incident

During the WPC contamination incident the Director-General published statements where consumers (namely the parents of infants being fed formula) needed authoritative and clear information from a trusted source, but in circumstances where the information needed to be adjusted as better, more refined information became available.

The WPC Inquiry recommended that "the circumstances in which privileged statements can be made should be clarified"[22] while stating that the power to issue DG Statements both to protect and inform the public in cases of a food safety risk is appropriate.

Problem

The statutory provisions in the food safety Acts for the use of privileged statements do not align.

The Food Act 2014 and the Wine Act allow DG Statements to be issued for the purposes of both "protecting" and "informing" the public.

But under the Animal Products Act, a DG Statement is only for the purpose of "protecting" the public. Therefore, during an incident response when a statement related to an animal product under the Animal Products Act is required, it can only be for the public health purpose of "protecting".

It is appropriate to be able to use DG Statements to inform, as well as protect, the public.

Proposal

We propose to align the relevant provisions on DG Statements in food safety legislation so these statements can be published for the same purposes under each Act.

The Animal Products Act would be amended to enable privileged statements to be published for the purpose of "informing" the public (in addition to the current purpose of "protecting" the public) in line with the equivalent provisions in the Food Act 2014 and the Wine Act.

Why we are proposing this change

Providing the ability to make DG Statements under the Animal Products Act for the purposes of 'informing' the public allows the Director-General to, for example, correct unclear or inaccurate information already in the public domain.

It will help if there is a need to inform the public about, for example, misleading (rather than directly harmful) information in an advertisement relating to an animal product.

How it would work in practice

No change is proposed to the provisions governing the supply of additional information to affected parties at the time of publishing a DG Statement. DG Statements are, and need to remain, flexible instruments that the Ministry for Primary Industries can use to respond swiftly to fluid situations such as food safety incidents. It remains possible for the DG to both release information as appropriate under the "disclosure" sections of existing food safety legislation, and to release additional information when making a DG Statement.

Under this proposal it would therefore remain voluntary for the Ministry for Primary Industries to, on a case-by-case basis, provide additional information (for example scientific or test results) at the time of, or consequent to, making a DG Statement.

[22] *Report on New Zealand's Dairy Food Safety Regulatory System* Government Inquiry into the Whey Protein Concentrate Contamination Incident, December 2013, p.58

Advantages

- DG Statements continue to be available as a flexible tool for use in the interests of the public, particularly during food safety incidents.
- Aligns in the three Acts the purposes for which the Director-General can make statements, thereby avoiding potential conflict between statutes.

Disadvantages

- No disadvantages have been identified.

What do you think?

15. Do you agree with the proposal to permit Director-General Statements to be made to both inform and protect the public? If not, why not?

10.2 Compel disclosure of information needed to identify and respond to a food safety incident

Context

During the WPC contamination incident the Ministry for Primary Industries was unable to access the laboratory test results generated by the AgResearch laboratory, which initiated the incident. It took 48 hours for the Ministry to receive the full report of the test results, which affected its ability to assess the risks at the earliest time possible.

The response to the incident may have developed differently if the Ministry for Primary Industries had access to the complete laboratory test results, rather than just a high-level summary. When initiating a response to the botulism contamination the Ministry was not aware that the AgResearch laboratory had generated the information for "research purposes" only, and that the contamination was "likely" rather than "confirmed".

The WPC Inquiry recommended that the law be amended to give the Ministry for Primary Industries a specific power to compel the disclosure of relevant information needed to respond to a food safety incident, and that the power should include the ability for the Ministry to disclose the information to any affected party. The Food Act 2014 and the Animal Products Act both include provisions empowering the Ministry for Primary Industries to disclose information for a range of purposes. No legislative change is therefore required to implement that part of the WPC Inquiry recommendation.

Food Act 2014

The Food Act 2014 includes a power in section 292 that allows the Ministry for Primary Industries to obtain information from food business operators for the purpose of "determining the safety and suitability of food". Section 292 would partially cover the need identified by the WPC Inquiry for getting information from food businesses during a food safety incident. This power can be exercised by the chief executive (Director-General) or food safety officers on the basis of a reasonable suspicion.

A separate power exists under section 293 of the Food Act 2014 that can be applied to require a "person" to produce information if there is reasonable belief that a requirement of the Act has been breached.

Problem

It is important to move swiftly when identifying and responding to a food safety incident. The Ministry for Primary Industries did not have the statutory power to demand the information needed from the laboratory during the contamination incident, and was unable to promptly determine the level of risk. During a potential food safety incident, making a risk assessment of the situation at the earliest stage possible is essential for determining the scale of the response required.

Section 292 of the Food Act 2014 cannot be applied to parties providing services to, or contracted by, a food business (such as the laboratory involved during the WPC incident) that may hold information relevant to determining the safety and suitability of a food.

Proposal

It is proposed to:

- add a provision to section 292 of the Food Act 2014 so that the power to require information on a reasonable suspicion extends to businesses or individuals contracted by the operator of a food business who may generate or hold information relevant to identifying and responding to a food safety incident;
- ensure that the new power to gather information from these additional parties would be limited to use during the identification of and response to a food safety incident;
- as a further safeguard, specify that information obtained under the new provision will not be able to be used for any related compliance investigation purposes.

Why we are proposing these changes

The WPC Inquiry noted the importance of information sharing during a food safety incident response. In some cases this can happen smoothly if all parties co-operate. However the delay in getting crucial information during the WPC contamination incident demonstrated the need for the regulator to have a full toolkit of powers to require such information to be provided. The proposed additional power is intended to fit alongside other legislative tools for use during incidents.

The proposal would provide an extra tool for getting information relevant to a food safety incident, while giving reasonable protection to any persons supplying that information.

How it would work in practice

The proposal would mean that businesses or individuals contracted by food business operators and who hold relevant information would, on request from the Director-General, have an obligation to produce information for the Ministry for Primary Industries. However, information supplied under this new provision would not be able to be used for related compliance purposes.

Applies to animal products and wine

The proposed provision would also apply to animal products and wine (see also section 3.2 of this document), because there is no equivalent provision in the Animal Products Act or Wine Act. Section 292 of the Food Act 2014 is broad enough to apply to all food businesses.

Privileged information

Contractual obligations of confidentiality, one of the factors at issue in the first days of the WPC incident response, would not be a basis for refusing to produce information under the proposed new provision.

However, the privilege against self-incrimination and other privileges under the Evidence Act would still apply, as they do for the whole of section 292 of the Food Act 2014.

Advantages

- Ensures the regulator can get information or test results as needed during food safety incidents, to make informed assessments about the risks to human health.
- Appropriate safeguards are provided for people required to supply information.
- The presence of a power to compel disclosure of information would encourage affected parties to co-operate voluntarily, as businesses are also interested in protecting public health and safety.
- Does not impose additional costs on the Ministry for Primary Industries; the new statutory power to require information would be an additional tool available during response activities.

Disadvantages

- The source of the power (in the Food Act) to compel production of information during a food safety response may not be immediately apparent to operators normally regulated under the Animal Products Act or Wine Act.
- Some contractors to food businesses may not normally be regulated under the food safety regime, and may see the proposal as extending the scope of businesses covered by the Food Act 2014.

What do you think?

16. Do you support the proposed extension to the power in the Food Act 2014 to require disclosure of information during a food safety response by persons or businesses that contract with food business operators?

17. Are the proposed safeguards appropriate? If not, why not?

10.3 Statutory oversight for food safety contingency planning

The WPC Inquiry recommended that the Ministry for Primary Industries should be given statutory responsibility for food safety contingency planning, and should work with industry in the simulation of tracing and recall plans.

"Contingency planning" refers to planning for the response to a food safety incident.

Context

Preparing overarching food safety response plans is part of ongoing work within the Ministry for Primary Industries to develop a Single Scalable Response Model that can be applied to any food safety incident. This model implements the national framework for response management (the Coordinated Incident Management System known as CIMS).

The food safety regulatory system relies on industry developing and testing its own plans. Several industry bodies are actively developing response plans to use in the event of a food safety incident, either in partnership with or separate from the Ministry for Primary Industries. The Ministry can help industry, but should not be responsible for all contingency planning.

Food Act 2014

The WPC contamination incident occurred before the Food Act was passed in May 2014. Section 18 of the Act sets out a number of roles for the Ministry for Primary Industries in the food safety regime, in a way not previously seen in food safety legislation. The "food safety regime" is defined broadly to include the legislation that regulates trading in food.

Problem

The role of "co-ordinating" emergency responses is included as one of the chief executive's responsibilities under section 18 of the Food Act 2014. However, this provision does not explicitly state that the role of the Ministry for Primary Industries includes "planning" for food safety responses. Given the definition of "food safety regime" in the Act, the co-ordination of responses to food safety emergencies under section 18 of the Food Act covers all food, animal, and wine products.

Although in practice the Ministry for Primary Industries assumes authority for overarching contingency planning for food safety incidents, the importance of this planning makes it desirable that the legislation is clear on the responsibilities of this role.

Proposal

It is proposed that the role of contingency planning for food safety emergencies is added to section 18 of the Food Act 2014. This change would confirm that the Ministry for Primary Industries' role in the food safety regime includes oversight of, and leadership responsibilities for, response planning for food safety emergencies, in addition to its existing role of coordinating the response at the time of an incident.

How it would work in practice

The drafting would make clear that contingency planning is a role of the Ministry for Primary Industries, but it would not specify how that role should be performed. No implementation additional responsibility or actions for the Ministry are proposed. Food safety response planning and simulations with industry are established and ongoing initiatives.

Advantages

- Makes clear that the Ministry for Primary Industries has oversight of, and leadership responsibilities for, food safety response planning.
- Supports the framework of food safety response coordination under the Food Act 2014.

Disadvantages

- No disadvantages have been identified.

What do you think?

18. Do you support a change to make it explicit that the Ministry for Primary Industries has a statutory role in contingency planning for food safety incident responses? If not, why not?

11 Proposals on verification

The WPC Inquiry made several recommendations about verification by recognised agencies and persons. It concluded that New Zealand's verification model is sound and fundamental change is not required, but it also suggested improvements.

Most of the verification recommendations are being addressed through non-regulatory means, but those that require amendments to the primary legislation to implement are discussed below.

This chapter discusses:

- clarifying that verifiers owe their duties primarily to the regulator;
- making sure the Ministry for Primary Industries has copies of verifiers' accreditation reports.

11.1 Clarify that verifiers owe their duties primarily to the regulator

Context

Verification is part of the RMP process under the Animal Products Act. It is carried out by recognised agencies or persons ("verifiers") who audit a business's RMP against the requirements set in legislation.

Verification services are also provided under the Food Act 2014 for verification of food control plans, and under the Wine Act for wine standards management plans.

At present, under the Wine Act and Animal Products Act agencies and persons recognised as being able to carry out verification have an obligation to avoid compromising their impartiality and independence when working with businesses, and to manage any conflicts of interest.[23]

The Ministry for Primary Industries carries out regular audits of the verification system and receives regular high-level reports from verifiers on operator performance. Recognised agencies work directly with operators to manage failures to meet particular requirements, which are managed according to the level of risk they pose to the food safety system. Territorial authorities may also assist operators.

Problem

The main verification issue discussed by the WPC Inquiry that would require legislative change is a potential conflict of interest for verifiers where, under the third party provider model, recognised agencies and persons (verifiers and evaluators) may be vulnerable to commercial pressures from the businesses they hold their contracts with. There is a risk that businesses have an incentive to reduce their verification costs, which could be detrimental to the quality of the verification service able to be provided.

The WPC Inquiry therefore recommended that the system should be strengthened to "provide greater clarity of the verifier's role as agent of the ministry to make clear the true client is the regulator, not the industry".[24]

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[23] For example, MPI's policy is that a RMP verifier cannot verify a particular RMP if they have been involved in the evaluation of that RMP or any other RMP at the same site (ie physical location) within the past 2 years.

[24] *Report on New Zealand's Dairy Food Safety Regulatory System* Government Inquiry into the Whey Protein Concentrate Contamination Incident, December 2013, p.43

The potential for conflicts of interests to arise in the third-party verifier system has been observed by some overseas regulatory authorities. Although this perception may not indicate real conflicts of interest exist, some level of reputational risk remains.

Proposal

It is proposed that the food safety Acts affirm that when conducting verification, audits, evaluations, tests, and other checks, recognised agencies and persons are confirming business compliance against regulatory requirements primarily on behalf of the regulator (not the industry).

Why we are proposing this change

The WPC Inquiry considered there is a need to define the regulator's expectations by clarifying and specifying the role of verifiers and who their true client is.

The aim of this change is to, for the avoidance of doubt, confirm that verifiers owe their duties primarily to the regulator. This approach will support verifiers in complying with their independence obligations, and signal to businesses the nature of the verifier role.

How it would work in practice

The current verification model would not change. Although the proposed amendment would give clarity in the statute about who the verifier's true client is (that is, they undertake verification services on behalf of the regulator), verifiers would need to continue to manage any potential or actual conflicts of interest that arise. The change would apply to all relevant recognised agencies and persons.

Advantages

- Reinforces the recognised agency/recognised person duties under the legislation.
- Would give a stronger base from which the Ministry for Primary Industries can communicate to customers and overseas regulators that recognised agencies and persons work on behalf of the regulator when they are auditing businesses for compliance against regulatory requirements.
- Strengthens the basis for ongoing independence of verifiers within the verification system, and underlines the importance for verifiers to avoid conflicts of interest.
- Clarity for operators about the verifier's role.
- Does not require change to the existing third party contestable verification model.

Disadvantages

- No disadvantages have been identified.

What do you think?

19. Do you support the proposal to, for the avoidance of doubt, clarify in the legislation that recognised agencies and persons owe their duties primarily to the regulator? If not, why not?

11.2 Make sure MPI has a copy of the verifiers' accreditation reports

The WPC Inquiry identified that the Ministry for Primary Industries is not receiving accreditation reports in a consistent manner for applicants seeking recognition as a verifier (or evaluator). The Inquiry noted that the current practice of the two main accreditation bodies in providing these reports to the Ministry for Primary Industries varies.

Context

When a person or agency seeks accreditation in order to apply for formal recognition as a verifier or evaluator, an accreditation body uses international standards to assess the applicant's competence in technical skills, inspection tasks, and management of systems including record keeping. Assessment reports of the accreditation body are part of the evidence used by the Ministry for Primary Industries when it recognises agencies or persons as being suitable to undertake verification and evaluation (that is, checking that businesses are complying with their regulatory requirements).

The Ministry for Primary Industries receives most but not all of these accreditation reports from verifiers or accreditation bodies at the time when the person or agency first seeks formal recognition and when renewing their recognition. The onus is currently on the verifier to supply the Ministry with accreditation reports. However, ongoing accreditation reports are generated in between the formal recognition cycle, and the Ministry does not always receive these.

Note that not every recognised person is required to be individually accredited against international standards. For example, an agency as a whole may be accredited without every individual employee undergoing the accreditation process.[25]

Issue

The WPC Inquiry noted that "MPI's access to information from a variety of sources, including systems audit data, puts it in a unique position to identify areas of particular concern, emerging issues or risks, compliance trends and ways of assisting the verifiers (as well as industry generally) to improve".[26]

In addition to requirements for recognition, any inconsistency in the provision of accreditation reports to the regulator may restrict the ability of the Ministry for Primary Industries to identify and analyse emerging trends or risks for verification services.

Proposal

It is proposed to amend the primary legislation to require that organisations responsible for accrediting agencies or persons under international standards supply their accreditation reports directly to the Ministry for Primary Industries. It is also proposed that this should happen both when the initial application to be recognised is made, and when additional reports are prepared as part of ongoing accreditation requirements.

[25] This is called the Team Leader Model.
[26] *Report on New Zealand's Dairy Food Safety Regulatory System* Government Inquiry into the Whey Protein Concentrate Contamination Incident, December 2013, p.42

Why we are proposing this change

The WPC Inquiry noted that all parties agree consistency of practice is essential, including full and transparent reporting to the Ministry for Primary Industries.[27]

Ensuring that the Ministry for Primary Industries receives all reports from the bodies accrediting verifiers against international standards would improve oversight for the regulator of the skills, experience and competence of verifiers. Requiring accreditation bodies to supply these reports directly to the Ministry will ensure the regulator has the most up-to-date information on hand and no delay occurs in receiving these reports during the formal recognition process.

The Director-General provides recognition to the agency or person following examination of their application, including consideration of whether they have met their accreditation requirements. It therefore follows that the Ministry should see the accreditation reports, both before initially recognising the applicant, and on an ongoing basis.

This change would enable the Ministry to identify any issues with particular recognised agencies earlier than at present. It would provide more information from which trends in the system can be assessed when the Ministry undertakes audits or examines non-compliance issues.

How it would work in practice

Bodies assessing applicants for accreditation would provide their reports directly to the Ministry for Primary Industries at the same time as they supply them to the verifier. The Ministry would then have this information should it be needed.

Note that this proposal does not place any additional requirements on persons who are currently able to be recognised as verifiers or evaluators without needing an accreditation assessment.

Advantages

- Provides increased transparency of information to the regulator about the competencies and qualifications of applicants for recognition.
- Is a more efficient way of ensuring the information is available to the regulator.
- Enables the regulator to assess the need for improvements in the verification system.

Disadvantages

- Some cost for the accreditation bodies to supply the report copies directly to the Ministry for Primary Industries may result, as these agencies have not previously been *required* to do so.

What do you think?

20. Do you agree that the legislation should require accreditation bodies to provide their accreditation assessment reports directly to the Ministry for Primary Industries? If not, why not?

[27] ibid

12 Enhance electronic transactions

In December 2014 Cabinet agreed that the Food Safety Law Reform Bill should include enhancements to food safety legislation that can be developed and consulted on within the timeframe for the Bill. One enhancement is to permit more activities to occur via electronic means.

Context

Unlike the Food Act 2014, the Animal Products Act and Wine Act do not specify that an automated electronic system can be used for some functions and activities, in particular statutory decision-making.

In certain circumstances the Director-General can require information to be provided electronically.

Automated electronic systems

An automated electronic system is where a computer programme can step a user through the various requirements to achieve a decision, without needing a person at the other end. Many government regulators use automated electronic systems (for example, New Zealand Customs Service; Immigration New Zealand; the Ministry for Primary Industries) as do many businesses.

Problem

First, the lack of a specific ability to use automated electronic systems for all functions leads to:

- longer than ideal timeframes for processing documents and making decisions;
- unnecessary costs of manual systems, for both the Ministry for Primary Industries and business;
- continued use of outdated paper-based decision-making methods and associated costs of document dissemination and storage;
- sub-optimal use of government's investment in technology.

Second, it is not clear whether the regulator can always require businesses to engage via electronic means, where appropriate; for example, electronic registrations and the provision of test results.

12.1 Permit use of automated electronic systems for statutory functions, including decisions

Proposal

It is proposed to make an enabling legislative amendment to both the Animal Products Act and Wine Act, so that the Ministry for Primary Industries has the ability to exercise a power, carry out a function or duty, and undertake decision-making via automated electronic means. (Each Act would have different persons specified as being appropriately empowered).

The Food Act 2014 contains appropriate relevant provisions to use as a model.[28]

The legislative provisions will have built-in safeguards for users' privacy considerations (relating to personal information collection and use).The provisions will require that a process must be available under which a person affected by an action done by the system can have the action reviewed by a suitable official without undue delay. In addition, if the system operates in such a way that the action done or partly done by the system is clearly wrong, the provisions will ensure corrective action can be taken by an appropriate person.

Why we are proposing these changes

The Ministry for Primary Industries wants to be able to use automated electronic systems for, among other things, issuing wine export eligibility certificates and official assurances for wine. In the future it is possible that the Ministry may want to manage other decisions using an automated system.

Although not all of the Ministry for Primary Industries' systems are yet capable of delivering a fully automated service from start to finish, this proposal is future focused so that more automated electronic methods can be used as various information technology (IT) systems are upgraded.

Future-proofing now will allow the Ministry to accommodate technological advances without further legislative change being required in a piecemeal way. Consistency on this matter across the three food safety Acts is desirable.

How it would work in practice

Where an automated electronic system is to be used for particular statutory decisions, the first step will be for the Director-General to issue a statement setting out the criteria that will be used for the decision-making process. This will ensure transparency for all parties using the system. The system will then be programmed to follow the criteria.

Advantages

- Ensures legislation is explicit that the regulator can undertake its statutory functions via automated electronic means.
- Is future focused, and responds to the need for modern business interactions.
- Makes the most of government investment in existing data systems.
- Services to business can be provided faster and at less cost.
- Aligns the Animal Products Act and Wine Act with the provisions already in the Food Act 2014.

Disadvantage

- Industry may have concerns around the automated process.

[28] See Food Act 2014, sections 374 and 375

12.2 Requiring information via electronic means

Proposal

It is proposed that, where necessary and appropriate, the regulator could require that certain information must be supplied in a particular electronic format. Although this ability currently exists under particular provisions in the food safety Acts, there are no powers that would apply generally.

For some transactions, it is recognised that some smaller food businesses may not routinely use computers. It is therefore proposed that where the regulator normally requires a business to use electronic means for information exchange or other services, the use of a paper-based system will continue to be made available on a case-by-case basis (with an appropriate charge for manual processing), at least during a suitable transitional period.

Why we are proposing this change

Electronic systems allow the regulator to: be flexible in the way it can interact with customers; keep up with the technological advances of its clients; reduce costs; and decrease processing time. As well, the Ministry needs to ensure it has a dynamic and agile system that is future-proofed as New Zealand's trading partners move towards more online interactions. It needs to be able to undertake approvals, process applications, and receive required information, for example, returns.

How it would work in practice

Not all of the Ministry for Primary Industries' systems are yet capable of delivering a fully computerised service. This power would be enabling, so that more electronic methods can be used as various IT systems are upgraded.

Advantages

- It is more efficient and cheaper for parties to transact electronically.
- Allows more use of electronic means to process applications, registrations, and listings.
- Ensures New Zealand is able to provide services in the way its trading partners expect.

Disadvantages

- Some smaller businesses may not yet use computers routinely, so it could involve potential costs for them (but also potential cost savings for business).
- Some areas of the country where farms or small businesses are located, or off-shore islands, may not have adequate internet access.

What do you think?

21. Do you support making it explicit in the Animal Products Act and Wine Act that automated electronic systems can be used (as appropriate) for all statutory food safety functions, as the Food Act 2014 currently permits?

22. Do you agree that where appropriate the Ministry for Primary Industries should be able to require persons to use electronic means and specific formats to provide information or for transactions? If not, why not?

13 Technical amendment proposals

The opportunity presented by the FSLR Bill enables us to make some technical amendments and enhancements to the food safety Acts. These proposals aim to:

- harmonise and align similar requirements;
- clarify legislative inconsistencies;
- make minor enhancements.

13.1 Proposals to harmonise and align similar requirements

Certain provisions in the food safety legislative regime should be more consistent with each other. Often the differences have come about because practice has changed over time and some statutes have been updated but others have not.

13.1.1 Align the limitation periods for bringing criminal proceedings

Context

Time limits for bringing enforcement actions for breaches of legislation involve two strong public interests: the prompt enforcement of legislation, and ensuring that someone who has committed an unlawful act does not escape punishment because their actions remained undetected for a long time. Limitation periods balance an individual's right to a fair hearing, the need for legal certainty in business, and the public interest in seeing unlawful or otherwise wrongful conduct addressed.[29]

The Criminal Procedure Act 2011 generally provides for standardised limitation periods for filing charging documents based on the category of offences and the maximum penalties provided (6 months, 12 months, or 5 years depending on the offence). However, these provisions can be overridden by other enactments that provide a different limitation period.

Problem

In the food sector, limitation periods need to provide a sufficient amount of time for problems to come to light and for potentially long and complex investigations to be carried out. There is currently inconsistency between the limitation periods for bringing criminal proceedings under the Food Act 2014, the Animal Products Act, and the Wine Act.

The Food Act provides a limitation period of **four years** for any offence, or any longer time that may be allowed by the Criminal Procedure Act. However, the Animal Products Act and Wine Act provide for a limitation period of **two years** for specified offences, with other offences subject to the Criminal Procedure Act.

Proposal

It is proposed to harmonise the limitation periods in the three Acts by bringing the Animal Products Act and Wine Act into alignment with the Food Act 2014. All three Acts would then have limitation periods of four years.

The non-compliance that may occur under the three Acts may be very similar in nature. It is therefore appropriate that the same limitation period for bringing charges applies to all three Acts. This change would bring consistency across the food sector and address unlawful

[29] Legislation Advisory Committee Guidelines 2014

conduct, which is in the public interest. It also recognises the complex investigations that may need to be undertaken in the food sector.

What do you think?

23. Do you agree with the proposal to align the limitations period to 4 years across the three food safety Acts? If not, why not?

13.1.2 Reliance on superior officer's reasonable belief

Proposal

Before compliance officers take some actions they need to have a "reasonable belief" that a certain situation exists (for example, section 87(2) of the Animal Products Act; section 302 Food Act).[30]

We propose to include in the Animal Products Act and the Wine Act provisions to the effect that compliance officers may rely on the reasonable belief and directions of superior officers or the Director-General when forming a reasonable belief. This aligns with section 320 of the Food Act.

What do you think?

24. Do you support the proposal that compliance officers may rely on the reasonable belief and directions of superior officers or the DG when forming a reasonable belief?

13.1.3 Completion of matters by other officers

Proposal

We propose to include in the Animal Products Act and the Wine Act provisions to the effect that matters started by one compliance officer may be completed by another compliance officer. This aligns with section 321 of the Food Act.

What do you think

25. Do you support the proposal that actions started by one compliance officer may be completed by another?

13.1.4 Align incorporation by reference provisions

Context

Incorporation by reference is a legislative drafting tool whereby separate written material can become part of the legal requirements of a legal instrument by referring to that written material in the legal instrument. It is often used to incorporate the content of international standards but may be used for operational technical material produced by the Ministry for Primary Industries.

[30] Animal Products Act, section 87(2), Power of entry; Food Act 2014, section 302, Power to issue improvement notice

Problem

The Wine Act, Animal Products Act, and Food Act 2014 all provide for different procedures for incorporating material by reference into legal instruments made under those Acts.

Since the provisions in these three Acts were drafted, the Legislation Act 2012 has been enacted. Although the Legislation Act is not designed to override incorporation by reference provisions of a particular Act, it must act as a guide to an appropriate incorporation by reference regime. At present none of the incorporation by reference provisions of the three Acts are consistent with the Legislation Act.

Proposal

It is proposed that the procedure for incorporation by reference provisions in the Animal Products Act (section 168), the Wine Act (section 121), and the Food Act (section 444 and Schedule 6) be aligned and, where suitable, follow the Legislation Act 2012.

The definition of material that can be incorporated by reference is fairly similar between the three Acts and the Legislation Act but there are some small differences.

The Legislation Act provides that an agency must consult on the material to be incorporated by reference, make it available on its internet website, and notify it in the *New Zealand Gazette*. Consultation on material incorporated will also occur when the notice itself is consulted on. This process would require greater scrutiny and thought to be given to the suitability of material for incorporation by reference into a notice.

The process for incorporating an *amendment* of material is different in each Act, but each has a process that requires some kind of action to incorporate updates.

One option is to have a statutory procedure whereby all updates of material must be specifically incorporated by a later instrument. This option is in line with the Legislation Act.

Another option may be to allow an instrument that incorporates material to specify that updates of certain material can be incorporated automatically.

What do you think?

26. Do you support the proposal to align the incorporation by reference provisions across the food safety Acts and generally follow the Legislation Act?

27. Do you have a preferred option for incorporating updates of material? Please give reasons.

13.2 Proposals to clarify intent

Some provisions in the food safety Acts are not as clear as they should be. This lack of clarity can lead to persons being captured by a piece of legislation when they should not be, or to confusion about how a particular provision applies.

13.2.1 Clarify no right of review of a decision to suspend an operation

Context

The Animal Products Act and Wine Act provide a power for the Director-General to deregister an exporter in certain circumstances. A process is set out in the Acts that requires the Director-General to give the exporter an opportunity to make submissions in relation to the proposed deregistration.

Another power enables the Director-General to *suspend* export operations in certain circumstances, pending a final determination on deregistration.[31]

Problem

There is a conflict in the legislation as to whether a decision to suspend an export operation is subject to a right of review, if that decision is made under delegation.

The specific provisions about deregistration of exporters[32] indicate that there is no right of review for the suspension. However, the provisions about rights of review[33] indicate that such a review is available.

The process set in the Acts for a suspension requires a final determination as to whether or not an exporter should be deregistered. It therefore makes no sense for there to be a review of the decision about the suspension when a decision on deregistration must occur (and the deregistration decision is reviewable).

Proposal

It is proposed to resolve this conflict by removing the reference to suspension of an exporter from the provisions about review of delegated decisions. These provisions will then align with the specific deregistration provisions.

What do you think?

28. Do you support the proposal to clarify that a right of review of a decision made under delegation only applies to the deregistration decision, rather than to the interim decision to suspend an exporter? If not, why not?

[31] Animal Products Act 1999, section 59 and 162; Wine Act 2003, sections 54 and 114
[32] Animal Products Act 1999, section 59; Wine Act 2003, section 54
[33] Animal Products Act 1999, section 162; Wine Act 2003, section 114

13.2.2 Clarify the process for, and finality of, decisions reviewing the exercise of delegated authority

Context

General rights of review of certain decisions made under delegated authority are provided for in the Animal Products Act and Wine Act. A person may seek a review of the delegated decision. This review may be undertaken by either the Director-General or a person designated by the Director-General.

Problem

Two drafting issues have been identified in the right of review provisions.

The first issue is that the provisions[34] could be read as if the person seeking the review may decide whether the Director-General or a designated person undertakes the review, rather than the Director-General determining who will undertake the review.

The second issue is that the provisions[35] could be read as if it is only a decision made by the Director-General that is final, and the decision made by a designated person is not final.

Proposal

It is proposed to make it clear that it is the Director-General who decides whether to designate a person to undertake a review of a decision. When a designated person makes a decision, that decision will be final unless determined otherwise by a court of law. These amendments will correct the drafting errors.

What do you think?

29. Do you support the proposal to clarify that the Director-General decides whether to designate a person to make a review decision?

30. Do you agree that just as the DG's review decision is final, so too should be the decision made by a person designated by the DG to undertake the review?

13.2.3 Clarify which provisions Overseas Market Access Requirements (OMARs) can be made under

Proposal

There are a number of provisions in the Animal Products Act and Wine Act relating to notifying overseas market access requirements (OMARs).[36] The way these provisions relate to each other in each Act is not as clear as it could be.

We propose to make it clear that OMAR notices can be made either under the specific provisions (Animal Products Act section 60; Wine Act section 41), **or** under the general empowering provisions for notices (Animal Products Act section 167; Wine Act section 120).

[34] Animal Products Act 1999, section 162(2) and Wine Act 2003, section 114(2)
[35] Animal Products Act 1999, section 162(8) and Wine Act 2003, section 114(8)
[36] See Animal Products Act 1999, sections 60, 60A, 164, and 167; and Wine Act 2003, sections 41, 116, and 120

What do you think

31. Do you support the proposal to make clear that OMARs can be made under either the specific provisions of the Animal Products Act and Wine Act, or under the general notice-making provisions?

13.2.4 Clarify the definition of "retail butcher" in the Animal Products Act

Problem

The current definition of "retail butcher" is potentially drafted widely enough for wholesalers or primary processing type businesses (such as a slaughter house) to be classified as retail butchers if they sell small amounts of meat directly to retailers. This lack of clarity means that, against the policy or legislative intent of the Animal Products Act, such businesses may potentially fall within the definition of a "dual operator butcher", because that definition means a retail butcher. If a business can be a dual operator butcher then it can also be a homekill service provider.

The Animal Products Act aims to minimise the likelihood of unregulated homekill meat entering the regulated system. Allowing wholesalers or processors to act as dual operator butchers increases the risk of that happening. The meat could also potentially enter the export system, which could have major consequences.

There was never any intention for such wholesalers or processing plants to be able to be listed as homekill service providers.

Proposal

It is proposed that the word "primarily" be inserted into the definition of "retail butcher", to clarify that dual operator butchers can only be retail butchers who primarily engage in retail trade.

What do you think?

32. Do you support the proposal to clarify that dual operator butchers can only be retail butchers who "primarily" engage in retail trade? If not, why not?

13.2.5 Clarify regulatory regime for dual operator butchers' premises

Problem

A dual operator butcher may carry out regulated animal product operations and homekill operations at the same premises, subject to a number of conditions. One of those conditions is that they must operate under a RMP under the Animal Products Act, rather than the Food Act. This condition is to manage the risk of non-regulated meat (homekill) being sold or traded, which is illegal.

A number of dual operator butchers also sell other food products from their premises. Section 71(1)(c) of the Animal Products Act has been interpreted to mean that no food items at that premises can be regulated under the Food Act, even if the Food Act regime is more appropriate.

Proposal

We propose to amend section 71 to clarify that all animal products at the premises must operate under the Animal Products Act but other food items also being sold at the premises may operate under the Food Act.

What do you think?

33. Do you agree with the proposal to clarify that all animal products at the premises must operate under the Animal Products Act, but other food items being sold at the same premises may operate under the Food Act?

13.2.6 Clarify the scope of "dairy processor" in the Animal Products Act

Proposal

The scope of the Animal Products Act extends to small retailers who are merely taking products such as milk powder, cheese or ghee from large portions and packing them into small amounts for retail sale direct to consumers in the store. This type of activity is not intended to be covered by the Animal Products Act and should more properly be subject to the Food Act.

We propose to amend the Animal Products Act to clarify this, as it is important that both the persons regulated and the regulator are clear on what obligations and which Acts apply to different activities.

What do you think?

34. Do you agree with the proposal to clarify the scope of a dairy processor? If not, why not?

13.2.7 Clarify the scope for section 60B of the Animal Products Act

Proposal

Section 60B of the Animal Products Act provides that the Director-General may exempt exporters from the requirements of "standards specified by notice under the Animal Products Act". However, in the Animal Products Act, standards are set as regulations, not notices.

It is proposed to clarify that the scope of section 60B covers all requirements, whether specified by regulation or notice.

What do you think?

35. Do you have any comment on the proposed clarification that section 60B of the Animal Products Act covers all requirements in regulations or notices?

13.3 Proposals for minor enhancements

The following proposals address two other minor issues in the food safety Acts.

13.3.1 Provide a notice-making power to notify levy formula components

Proposal

Under the three food safety Acts, regulations set the formula or bases on which an amount of fee, charge or levy is to be calculated. For fees and charges, the specific amount of a component of a formula may be specified by notice by the Director-General. However, there is not a comparable notice-making power to notify the specific amount of the component of the levy. We propose to provide such notice-making powers in the three Acts.

What do you think

36. Do you have any comment on the proposal to provide a notice-making power to notify people of the specific component of a levy formula?

13.3.2 Make references to "part-business" consistent in the Animal Products Act

Proposal

We propose to make references to "business" and "part-business" internally consistent by inserting the term "part-business" into section 28A of the Animal Products Act [to align with section 162(1)(b)] and into section 26 of the Wine Act [to align with section 114(1)(d)].

What do you think?

37. Do you support the proposal to insert "part business" into section 28A of the Animal Products Act and section 26 of the Wine Act to make the Acts internally consistent?

14 Implementation

An omnibus Bill will be required to implement the proposals in this paper. Amendments will need to be made to the Animal Products Act 1999, Food Act 2014, and Wine Act 2003.

The Government is planning for the FSLR Bill to be introduced to the House of Representatives in late 2015. The Ministry for Primary Industries intends to develop a comprehensive implementation and change programme to implement the proposed amendments, once the legislation is enacted.

As noted in the body of this paper, subsequent regulations or notices may be required to implement the high level changes made to the primary legislation, and these will have their own separate consultation processes.

The summary of submissions on these proposals will be made publicly available on the Ministry for Primary Industries' website.

The process of developing primary legislation includes consideration of the Bill by a Parliamentary select committee. The public has additional opportunities to make submissions on the legislative proposals as part of that process.

15 Monitoring, evaluation, and review

The Ministry for Primary Industries oversees the food safety system in partnership with the Ministry of Health and territorial authorities. The Ministry will monitor implementation of the legislative changes as part of its:

- ongoing food safety monitoring and evaluation programme;
- annual regulatory scanning and planning;
- stakeholder engagement forums;
- Food Act 2014 Monitoring and Evaluation Programme.

What do you think?

38. Are there any particular aspects we should consider when designing the approach to monitoring these amendments?

16 Appendix 1: List of consultation questions

Chapter 4: The problem/opportunity

1 Do you agree with the way the problem that the Food Safety Law Reform Bill is aiming to address has been described? If not, why not?

2 Are there any areas covered in the proposals in this document where you think the status quo (no change) should apply? Please provide evidence to support your views.

Chapter 5: The objectives

3 Have all the objectives of the FSLR Bill been identified? If not, what other objectives for the Bill should the Ministry for Primary Industries consider?

Chapter 6: Legislative design proposals

4 Do you support the proposal to provide more guidance and direction for the delegated notice and regulation-making powers under the food safety Acts?

Chapter 7: Improving risk management programmes (RMPs)

5 Which of the options for limiting the content of RMPs (and potentially FCPs and WSMPs) to food safety and related regulatory matters, as recommended by the WPC Inquiry, do you support? Please give reasons.

6 What would the impact be on your business from each of these options? What costs might your business incur? Please give details.

7 Do you agree that the proposal will adequately address the WPC Inquiry recommendation to ensure better access to full and up to date RMPs? If not, why not?

8 What impacts might there be from implementing this proposal?

Chapter 8: Traceability and recall

9 Do you agree that the Food Act 2014, Animal Products Act, and the Wine Act should be clearer about traceability requirements? If not, why not?

10 Are the amendments proposed sufficient to enable traceability systems for ingredients and other inputs? If not, please identify what else is needed, and explain why.

11 Do you agree with the proposal to widen the regulation- and notice-making powers for traceability and recalls in the three food safety Acts? If not, why not?

Chapter 9: Alignment of compliance and enforcement tools

12 Do you agree that the enforcement and compliance tools should be aligned between the Food Act 2014, the Animal Products Act, and the Wine Act? If not, why not?

13 Do you agree that the Animal Products Act should include:
   a improvement notices
   b an infringement regime
   c a penalty based on commercial gain?
   If not, why not?

14 Do you agree that the Wine Act should include:
   a improvement notices
   b an infringement regime
   c compliance orders
   d a penalty based on commercial gain?
   If not, why not?

Chapter 10: Proposals to improve responses to food safety incidents

15 Do you agree with the proposal to permit Director-General Statements to be made to both inform and protect the public? If not, why not?

16 Do you support the proposed extension to the power in the Food Act 2014 to require disclosure of information during a food safety response by persons or businesses that contract with food business operators?

17 Are the proposed safeguards appropriate? If not, why not?

18 Do you support a change to make it explicit that the Ministry for Primary Industries has a statutory role in contingency planning for food safety incident responses? If not, why not?

Chapter 11: Proposals on verification

19 Do you support the proposal to, for the avoidance of doubt, clarify in the legislation that recognised agencies and persons owe their duties primarily to the regulator? If not, why not?

20 Do you agree that the legislation should require accreditation bodies to provide their accreditation assessment reports directly to the Ministry for Primary Industries? If not, why not?

Chapter 12: Enhance electronic transactions

21 Do you support making it explicit in the Animal Products Act and Wine Act that automated electronic systems can be used (as appropriate) for all statutory food safety functions, as the Food Act 2014 currently permits?

22 Do you agree that where appropriate the Ministry for Primary Industries should be able to require persons to use electronic means and specific formats to provide information or for transactions? If not, why not?

Chapter 13: Technical amendment proposals

23 Do you agree with the proposal to align the limitations period to 4 years across the three food safety Acts? If not, why not?

24 Do you support the proposal that compliance officers may rely on the reasonable belief and directions of superior officers or the DG when forming a reasonable belief?

25 Do you support the proposal that actions started by one compliance officer may be completed by another?

26 Do you support the proposal to align the incorporation by reference provisions across the food safety Acts and generally follow the Legislation Act?

27 Do you have a preferred option for incorporating updates of material? Please give reasons.

28 Do you support the proposal to clarify that a right of review of a decision made under delegation only applies to the deregistration decision, rather than to the interim decision to suspend an exporter? If not, why not?

29 Do you support the proposal to clarify that the Director-General decides whether to designate a person to make a review decision?

30 Do you agree that just as the DG's review decision is final, so too should be the decision made by a person designated by the DG to undertake the review?

31 Do you support the proposal to make clear that OMARs can be made under either the specific provisions of the Animal Products Act and Wine Act, or under the general notice-making provisions?

32 Do you support the proposal to clarify that dual operator butchers can only be retail butchers who "primarily" engage in retail trade? If not, why not?

33 Do you agree with the proposal to clarify that all animal products at the premises must operate under the Animal Products Act, but other food items being sold at the same premises may operate under the Food Act?

34 Do you agree with the proposal to clarify the scope of a dairy processor? If not, why not?

35 Do you have any comment on the proposed clarification that section 60B of the Animal Products Act covers all requirements in regulations or notices?

36 Do you have any comment on the proposal to provide a notice-making power to notify people of the specific component of a levy formula?

37 Do you support the proposal to insert "part business" into section 28A of the Animal Products Act and section 26 of the Wine Act to make the Acts internally consistent?

Chapter 15: Monitoring, evaluation and review

38 Are there any particular aspects we should consider when designing the approach to monitoring these amendments?

17 Appendix 2: WPC Inquiry recommendations

Note that the highlighted recommendations are the ones being dealt with in this consultation process.

Report on New Zealand's Dairy Food Safety Regulatory System - Consolidated Recommendations

The recommendations of the Inquiry are:

The wider view

- The ministry, in consultation with the industry and other relevant government agencies, should focus on emerging risks and prepare a high-level risk register identifying such risks to dairy food safety and supply.
- The ministry should convene a working group to develop a strategic plan to build up sector-wide dairy processing and regulatory capability.
- A centre of food safety science and research, which could be a virtual centre, should be established to ensure New Zealand remains a leader in the food safety field.
- In collaboration with other government agencies, the ministry should step up its role and resources, both here and abroad, to allow more effective interaction with New Zealand's most important, and emerging, export markets, particularly China.
- All organisations in the sector should endeavour to increase collaboration, whether among regulators, the ministry and the industry, or within the wider dairy industry.

Regulatory design

- The ministry should accelerate the standards integration programme, using specialist drafters, technical industry experts and recognised agencies from the start of the process. In particular:
    - Risk management programme requirements should be elevated to regulations, along with the requirements for the notification and reporting of food safety events.
    - There should be a new requirement that risk management programmes be limited to food safety and related regulatory matters.
    - The ministry, verifiers, laboratories and industry should jointly work on drafting and publishing escalation guidelines for food safety incidents.
- Following the rewrite of the requirements for risk management programmes, the ministry should receive and maintain records of full and up-to-date programmes.
- It is important that risk management programmes be periodically re-evaluated.

Role of the regulator

- A Food Safety and Assurance Advisory Council should be established to provide the ministry with high-level independent strategic advice and risk analysis and report annually to the Director-General on the performance of the system.
- The ministry should consider the following aspects of its operations:
    - Structure: ensure a more integrated focus on the dairy sector and food safety generally.
    - Roles: ensure greater clarification of multiple, and sometimes conflicting, roles.
    - Capacity and capability: ensure additional skilled staff in food safety generally and specifically in the dairy sector.
    - Visibility: ensure greater prominence of the ministry's food safety role.
    - Risk communication: ensure greater resourcing of, and priority for, this role.
    - Engagement: hold regular workshops and participate fully in overseas forums.

- Additional funding should be allocated to Vote Food Safety, targeted at food safety and dairy-related capability; China and new markets capability; the redrafting of regulations; and the Food Safety and Assurance Advisory Council.

Role of verifiers

- The independent verification system should be strengthened in the following ways:
  - Provide greater clarity of the verifier's role as agent of the ministry to make clear the true client is the regulator, not the industry.
  - Subject dairy processing operators using template risk management programmes to more rigorous scrutiny.
  - Encourage verifiers and the industry (with ministry approval) to consider how the regular auditing process can provide more evaluation without straying into consultancy.
  - Involve verifiers in product dispositions featuring novel or improvised reworking.
  - Provide verifiers' accreditation reports directly to the ministry to ensure full and transparent reporting.
- The ministry should carry out more analysis of audit information to identify areas of particular concern, emerging issues or risks and compliance trends.
- Accreditors and verifiers should endeavour to consult and collaborate as appropriate to ensure continued improvements to the accreditation and verification systems.

Testing: quality and integrity

- SRC testing should not be mandatory for all dairy products.
- The ministry should compile and maintain a list of accredited laboratories for non-standard or novel tests.
- The ministry should give priority and resources to better analysis of existing data to identify trends, including extending its surveillance programmes where appropriate.

Implementation of food safety standards

- The ministry, recognised agencies and industry should work to foster a positive food safety culture, and identify mechanisms to evaluate the food safety culture within companies.
- The ministry should promptly inform industry of new overseas market access requirements and where practicable consult industry about such requirements.
- The compliance and enforcement tools in the Animal Products Act 1999 should be aligned with those in the Food Bill, which is currently before Parliament, and should include a full range of tools.
- The ministry should prioritise analysis of food safety compliance data.

Traceability, recall and contingency planning

- The ministry should convene a working group to consider first, the most appropriate regulatory provisions for traceability of dairy products, and secondly, a code of practice or similar to guide industry in implementing such provisions.
- Recall provisions should be revised, in particular:
  - Mandatory recall provisions in food legislation should be aligned.
  - Voluntary recall obligations should be set out in regulations rather than in risk management programmes.
  - Regulations should require industry to simulate recalls, audited by verifiers.
  - Circumstances in which privileged statements can be made should be clarified.

- The ministry should be given statutory responsibility for food safety contingency planning. Industry and regulators should simulate tracing, recall and general food safety incidents from time to time as part of such contingency planning.

Infant formula

- The ministry should prioritise its infant formula work programme, and complete the revision of food safety-related regulatory requirements for the manufacture of infant formula (and, if appropriate, ingredients for infant formula) within six months.
- The ministry, with input from the relevant working groups, should resolve whether infant formula and other high-risk products should routinely undergo SRC testing, based on scientific, risk-based and cost-benefit analysis.
- The ministry should strengthen requirements for exporters of infant formula to ensure traceability.
- Regulatory requirements under both the Animal Products Act 1999 and the Food Act 1981 should be aligned.
- The ministry, in consultation with the industry, should develop options to provide foreign markets with the assurance of authenticity of New Zealand-manufactured infant formula products.

Recommendations – the WPC80: Causes and Responses

The Inquiry recommends:

- The ministry, in consultation with the dairy industry and verifiers, should:
  - Revise the rules for non-routine reworking that requires a product disposal request
  - Ensure the industry's strict compliance with reporting times for product disposal requests, critical exception reports and export non-conformances
  - Continue to strengthen its monitoring and auditing activities to ensure early detection of potential food safety problems.
- The ministry should continue its work to ensure readiness for a food safety response, including:
  - Finalising its food incident protocol (as part of its single scalable response model), ensuring it is consistent with CIMS and benchmarked against international models. A draft should be provided to the food industry and other key stakeholders for comment before final publication
  - Undertaking regular exercises/simulations of its food incident protocol ranging from smaller desktop exercises through to large-scale, multi-agency rehearsals
  - Ensuring staff are fully trained to respond to food incidents.
- In any food incident, the ministry should:
  - Start, and document, a risk assessment identifying both scientific and strategic risks as soon as practicable and update the assessment as the incident develops
  - Document the use of statutory powers, particularly Director-General statements, including written advice from officials about available options and the underlying scientific and risk assessment information on which recommendations are based
  - Co-ordinate with all relevant parties to ensure a single integrated response.
- The ministry should re-establish a group of scientific experts along the lines of the previous NZFSA Academy.
- The law should be amended to give the ministry a specific statutory power to compel disclosure of relevant information (including test results) needed to respond effectively to a food safety incident. The power should include the ability to disclose such information to any affected party.

- The ministry should receive targeted funding to ensure it:
    - Has the resources – over and above those needed for day-to-day operations – to conduct a regular programme of simulations
    - Completes the much-needed reform of dairy regulations.
- The law should be amended to make clear what tests must be conducted in accredited laboratories.
- Industry participants should be required to seek approval from the ministry when no accredited laboratory or validated method is available for diagnostic testing, or a significant variation to a validated method is unavoidable.
- The ministry, the New Zealand Food Safety Science and Research Centre (in the process of being established) and laboratories should collaborate to establish, test and maintain:
    - Mechanisms for sourcing controls (such as reference cultures and antitoxins), if required for non-standard testing in New Zealand
    - A global register of accredited laboratories and scientific experts able to undertake, or advise on, microbiological testing, especially for pathogenic and uncommon organisms
    - Arrangements (including customs and biosecurity clearances) that ensure minimal effects on cultures during transport to overseas laboratories for tests that cannot be conducted in New Zealand.