Ministry for Primary Industries
Manatū Ahu Matua

Food Safety Law Reform Bill: policy proposals

Regulatory impact statement

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Growing and Protecting New Zealand

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Agency Disclosure Statement: final policy proposals for the Food Safety Law Reform Bill

This regulatory impact statement (RIS) has been prepared by the Ministry for Primary Industries. It provides an analysis of proposals to address some of the recommendations made by the independent Government Inquiry into the Whey Protein Concentrate Contamination Incident (WPC Inquiry) and make other improvements to the food safety system. The WPC Inquiry completed two reports and made 38 recommendations. Most of the recommendations have been, or are being, implemented through operational or non-statutory means.

The starting point of the analysis is that the Government has publicly committed to implementing all the WPC Inquiry recommendations, and agreed to an omnibus Bill as the vehicle for the recommendations that require statute change. The WPC Inquiry recommendations dealt with in this RIS are those that can only be implemented through statutory change, so there is no analysis of non-regulatory options in the RIS.

The RIS analyses options for implementing the recommendations about risk-based plans and programmes. For the other proposals, the analysis is of a single proposal compared to the status quo in each case. Multi-criteria analysis was used to determine the options and proposals that deliver the greatest net benefits.

The Ministry has used its internal knowledge and experience, information gathered as part of the WPC Inquiry, and information gained during the public consultation to inform our assumptions about the impacts of the proposals, and to estimate the potential impacts, costs, benefits and risks associated with the proposals. Where cost estimates are available they have been included.

The proposals with the greatest compliance costs are those relating to risk-based plans and programmes. We have assessed these impacts as far as possible at this stage, and the preferred options impose the least compliance costs while still implementing the intent of the WPC Inquiry recommendations. These risk-based plan proposals and some of the other proposals would create new, or extend existing, regulation-making powers in the three food safety Acts (the Animal Products Act 1999, the Wine Act 2003, and the Food Act 2014). The regulation-making process will be subject to further consultation and regulatory impact analysis. This process provides the opportunity for further analysis of specific costs, benefits and impacts once more detailed options are developed.

We will monitor the operation of the legislation and subsequent regulations once implemented. Over time this information will bring issues to light so that adjustments to the legislative framework can be made as necessary.

Karen Adair
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Executive summary

The 2013 Fonterra "botulism scare" made global headlines. Its impact led the Government to establish an independent Government Inquiry into the Whey Protein Concentrate (WPC) 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 Inquiry found that New Zealand's food regulatory system is fundamentally sound, but made some suggestions for improvements.

The Government accepted all of the WPC Inquiry's recommendations. Most of the recommendations have been, or are being, addressed through operational or non-statutory means. The proposals for the Bill signal to our trading partners the Government's continuing actions and intentions to address gaps identified by the WPC Inquiry and to make continuous improvements across the system.

The WPC recommendations and other improvements discussed in this RIS relate to enhancements of risk-based plans and programmes, better access to information in a food safety incident, and targeted alignment of the three food safety Acts.

The options and proposals in the RIS are assessed against the three criteria of improving certainty, enhancing effectiveness and being administratively efficient. Proposals that meet these criteria will enhance or contribute to one or more of the overarching complementary objectives of the food safety system, which are: food is safe and suitable; public health is protected; risks are identified and managed; New Zealand's good reputation increases access to overseas markets; and market access is facilitated.

The analysis against the criteria demonstrates that the following proposals deliver the greatest net benefits in addressing the problems and are therefore recommended.

- Enable regulations to be made to set the content, form and manner of a risk management programme or other risk-based plan, including requirements for differentiation of food safety matters from non-food safety material.
- Permit the Director-General to decline to register risk management plans or programmes where the regulatory requirements are not readily identifiable and easily understood, and to require operators to amend their risk management plans or programmes at any time on the same grounds.
- Enable regulations to be made to require food business operators to provide a full copy of their risk management plans or programmes to the regulator for registration (once the regulations are in place, with removal of ability to provide an outline of the plan), and to provide copies of all amendments to these plans or programmes to their verifying agency within a set timeframe.
- Give the Director-General a specific power under the Food Act to compel the disclosure of relevant information held by parties providing services to a food business and needed to identify or respond to a food safety incident.
- Provide a regulation-making power in the three food safety Acts to set requirements for operators to undertake mock traceability and recall exercises.
- Align the compliance and enforcement tools in the three food safety Acts by including in the Animal Products and Wine Acts an improvement notice, an infringement regime; a commercial gain penalty, and a compliance order.
- Enable the Director-General to make a privileged statement under the Animal Products Act to "inform" as well as to "protect" the public, similar to powers under the Food and Wine Acts.
- Explicitly provide for automated electronic systems in the Animal Products and Wine Acts, using the Food Act provisions as a model.

Background

The WPC Inquiry

1. In August 2013 Fonterra notified the Ministry for Primary Industries (the Ministry) 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 significant consequences for New Zealand's international reputation as a supplier of safe food.

2. Its impact led the Government to establish an independent Government Inquiry into the Whey Protein Concentrate (WPC) Contamination Incident. The WPC Inquiry investigated the causes of, and responses to, the incident and examined New Zealand's dairy food safety regulatory system, which is regulated under the Animal Products Act.

3. The Inquiry found that the New Zealand dairy food safety regulatory system is fundamentally sound and is consistent with international principles. However, as every system should be subject to continuous improvement it identified some areas where improvements could be made. The Inquiry considered that its recommendations should renew confidence, both internationally and domestically, in New Zealand's food safety regulatory system and encourage all participants to work together to ensure that our system continues to be among the best in the world.

Government's response to the Inquiry

4. The Government accepted all of the WPC Inquiry's recommendations and announced this to key trading partners. Most of the recommendations have been, or are being, addressed through operational or non-statutory means.

5. Cabinet agreed to develop an omnibus bill (the Bill) to address the recommendations that require primary legislation change. Cabinet also agreed that the Bill would contain other statutory enhancements to food safety legislation that could be developed within the timeframe for the Bill. This RIS covers all of the proposals that are subject to regulatory impact analysis.

The regulatory model

6. Three main Acts regulate food safety – the Animal Products Act 1999, the Wine Act 2003 and the Food Act 2014 (which comes fully into effect from 1 March 2016). Territorial authorities are co-regulators for the Food Act.

7. 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, including giving official assurances to foreign governments. The Wine Act applies to wine produced for the purposes of trade or export, and also has a trade facilitation role. The Food Act focuses on ensuring that food for sale (both in the domestic market and for export) is safe and suitable, but does not include provisions for official assurances.

8. There is some overlap between the food types regulated by the three food safety Acts, as "food" includes wine and animal products that are for human consumption. This overlap is managed under the respective Acts.

9. The three Acts 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 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).

Problem definition

10. New Zealand's food regulatory system generally has a good international and domestic reputation for providing food that is safe and suitable. The food safety scene is constantly evolving and New Zealand must be able to continuously adapt the system to meet new challenges and opportunities, both here and overseas. Every year brings food technology advances, new products and processes, new diagnostic techniques, and new scientific knowledge about food safety and risk. There is also continuous change in consumer expectations about food, its quality, and its source.

11. Much of the above evolution can be managed and addressed under the current food safety regulatory framework. However, the WPC incident demonstrated a need for improvements in some areas, and the Ministry has identified some further areas where enhancements would be beneficial. Without these improvements and enhancements, if the Ministry were to face similar issues in future its ability to respond effectively would continue to be hampered by factors such as an inability to get timely access to information.

12. There is also an opportunity that the improvements and enhancements may help prevent a subsequent incident (such as through greater clarity of requirements or by increasing the likelihood of compliance) and will help to future-proof and strengthen the system.

13. The WPC incident also impacted the perceptions and reactions of our trading partners. New Zealand is a global player in food markets. There is a risk if the Government is not seen to address all the issues identified that confidence in the food safety system may be affected despite the system being world class.

14. Issues with the food regulatory system can have far reaching consequences because the food sector accounts for more than 10 percent of New Zealand's Gross Domestic Product and employs one in every five employees. The following figures provide an indication of the scope of this system:
    - approximately 40,000 regulated businesses;
    - approximately 85,000 food premises;
    - food retail and service turnover of $27.6 billion for the year to June 2014;
    - food manufacturing of $47.2 billion for the year to June 2014;
    - food imports of $3.9 billion for the year to June 2014;
    - food exports of $29.3 billion out of total exports of $51.2 billion for the year to June 2014.

15. Incidents such as the WPC incident have demonstrated the potential for significant economic harm and reputational damage, even when they are a false alarm. The impact of these incidents is correlated to the length of time taken to resolve them.

Objectives

16. There are five complementary overarching objectives of the food safety regulatory system: food is safe and suitable; public health is protected; risks are identified and managed; New Zealand's good reputation increases access to overseas markets; and market access is facilitated. A food safety regulatory regime that meets these objectives will be a world class one.

17. Any changes to the current food safety regulatory system must enhance and/or contribute to one or more of the identified objectives. A proposal will do so if it:

    - provides more **certainty** (for example the food safety requirements are clearer and more accessible to all parties involved in the food system, businesses know what is expected of them, and public health is thereby protected);
    - enhances **effectiveness** (for example the likelihood of business compliance is increased; it contributes to the responsiveness of the system to meet future challenges and opportunities; food is fit for purpose – all of which will protect New Zealand's good reputation);
    - is **administratively efficient** (for example compliance costs are kept as low as possible for businesses and regulators while staying consistent with the need for food to be safe and suitable).

18. Certainty, effectiveness, and administrative efficiency are the criteria we have used to assess the options to address the WPC Inquiry recommendations and other improvements. While administrative efficiency is useful for differentiating between particular options or for assessing proposals, the certainty and effectiveness criteria carry more weight as they more directly contribute to the five objectives of the food safety system.

Scope

19. The WPC recommendations and other enhancements discussed in this regulatory impact statement (RIS) can be grouped as follows.

    A: Enhancement of risk-based plans and programmes:
    - better identifying the food safety content of risk-based plans and programmes;
    - requirements to provide full risk-based plans and programmes to the regulator and verifiers.

    B: Better access to information in a food safety incident:
    - compelling information disclosure;
    - strengthening traceability and recall systems through mock recalls.

    C: Targeted alignment of the three food safety Acts:
    - compliance and enforcement tools;
    - informing the public;
    - automated electronic systems.

20. The Cabinet paper seeking policy approval for the Food Safety Law Reform Bill contains a number of other proposals covering traceability and recall, legislative design, minor adjustments to verification provisions, and technical amendments. These proposals are not required to be included in this RIS as they either have only minor or no impacts on businesses or individuals and/or are technical revisions to improve legislative clarity.

A. Enhancement of risk-based plans and programmes

21. Options to improve risk-based plans and programmes were considered and consulted on. The two proposed areas for change relate to:
    i. better identifying the food safety content of risk-based plans and programmes
    ii. requirements to provide full risk-based plans and programmes to the regulator and verifiers.

Background

22. A central principle of the food safety regulatory model is that businesses are required to operate under a risk-based plan or programme (a risk-based plan). These risk-based plans aim to ensure businesses take responsibility for managing their food safety product and process risks.

23. Under the Animal Products Act there are risk management programmes (RMPs) and regulated control schemes. The Food Act provides for food control plans (FCPs) and national programmes. The Wine Act has wine standards management plans (WSMPs).

24. RMPs, FCPs and WSMPs may either be developed in a "custom" format, or in line with a template that is provided or approved by the Ministry. The Ministry provides templates for RMPs in several animal products sectors, but not all. Operators of WSMPs are currently all using templates. The templates for FCPs are currently being developed by the Ministry. FCPs are not yet in place as the Food Act comes fully into effect from March 2016.

25. Where the discussion below refers to RMPs (because of the WPC Inquiry's focus) the analysis also applies to all risk-based plans and programmes because, where appropriate, any amendments will be made across the food sectors.

26. The guidance manual provided by the Ministry suggests material other than food safety matters and related regulatory requirements can be included in custom RMPs as long as the food safety elements are clearly identifiable. Operators are not required to follow the guidance and it is not enforceable.

27. When registering a RMP under the Animal Products Act either an outline of the RMP (with the content required in the outline set by notice) or the full RMP may be provided to the Ministry. This is provided along with an independent evaluator's report stating that the RMP is acceptable. Registration costs are recoverable from the business.

28. Any "significant amendments" (as defined under the Animal Products Act and Animal Products (Risk Management Programme Specifications) Notice 2008) to RMPs must also be registered by the relevant registration authority. Operators must also periodically notify the Ministry of changes that are not significant. These amendments do not need to be registered. A business must provide its RMP to the Ministry within two working days of any request.

29. After registration, all RMPs are independently verified at intervals based on the assessed food safety risk of the business. Verifiers who assess an operator's compliance with a RMP do not always hold a copy of the RMP.

i. Better identifying the food safety content of risk-based plans and programmes

Problem

30. The WPC Inquiry considered that some RMPs have become too complex and unwieldy. It noted that "some have grown to thousands of pages, made up of dozens of individual documents".[1] Some contain extensive material that is not related to food safety regulatory obligations, such as commercial specifications and matters related to staff safety. They may also be integrated into a general business risk and quality management system, impacting on the operator's awareness of which are the legal requirements of the RMP and which are not.

31. It is more difficult to evaluate and verify a RMP that is very complex and cross-references a large number of other documents. It is harder to determine whether and how the food safety legal requirements can be or have been met when the document is unclear and contains extraneous content. It also takes longer to take enforcement action against a breach of a RMP that has combined food safety obligations with other material.

32. The complexity issues more commonly arise with 'custom' RMPs, which have great variation of structure. (The same issues do not arise to the same degree under templates provided or approved for RMPs). There are currently 75 custom dairy RMPs and 471 custom non-dairy RMPs. Any options to address the complexity problem will also need to apply to food control plans (which as noted above are under development) and wine standards management plans as appropriate.

33. As an example of the problem, the Fonterra [Hautapu] RMP referred to manuals, process documents and other referenced documents, and comprised many thousands of pages in total. This made it difficult for the regulator and the WPC Inquiry to determine whether the company had complied with its obligations. Fonterra struggled to identify all the relevant documents, and it took them a number of weeks to finally provide them all to the Inquiry.

Options

34. The WPC Inquiry recommended that: "there should be a new requirement that risk management programmes be limited to food safety and related regulatory matters".

35. This recommendation seeks to ensure risk-based plans and programmes focus clearly on the core food safety requirements, and are easy to understand and use. The Ministry considered a number of options to address the problems identified by the WPC Inquiry, and consulted stakeholders on options 1, 2, 3 and 4 below.

36. The following assumptions were made when considering the options.

- Any changes will impact custom risk-based plans more than template risk-based plans, as the templates already limit the relevant plan to food safety matters and requirements.
- Proposals that affect the Food Act requirements will result in only a small additional cost (if any) to businesses currently developing FCPs because the policy will be known in sufficient time for any adjustments to be made before these plans are required to be registered.

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

- Some custom risk-based plans will already have the food safety obligations clearly highlighted or separated from non-food safety matters.

Option 1: Status quo

37. Under this option, the current situation (described earlier in this document) would continue.

38. Some action is required to address the issues raised by the WPC Inquiry, and to improve RMPs and other risk-based plans. Submitters who thought the status quo should be retained nevertheless indicated which of the other options below they preferred and those comments are captured under each option.

Option 2: Prohibit inclusion of non-food safety matters

39. The WPC Inquiry report considered that the key requirements for the content of a RMP are those in the Animal Products Act and related specifications notice,[2] plus any notification and reporting requirements. Under this option, the three food safety Acts would be amended to clarify that risk-based plans must not contain non-food safety matters.[3]

40. Operators whose risk-based plans or quality management systems currently have non-food safety material (such as commercial specifications or employee health and safety processes) would need to remove such content. If food safety matters are addressed in the context of a multi-purpose quality management system or plan they will be hard to extricate without disruption to the wider system or plan. This is likely to require major redesign (with attendant cost), and would likely trigger the 'significant amendment' test for a number of businesses. Significant amendments require independent re-evaluation (with attendant cost) and registration of the amendment. The Ministry's costs for registration are recovered from businesses.

41. A transition period would be required, given the degree of change required and the current capacity constraints in the food safety sectors (for example for redesign and re-evaluation). This means that the change could take some years to fully implement.

42. 37 submitters commented on this option, with 35 (including 28 from the seafood sector, 24 of which were a template response) being opposed.

Option 3: Clear identification of food safety and related requirements [preferred option]

43. There are different ways to make food safety regulatory requirements separate from other business processes within an existing document or quality system. For example, these requirements could be in a different colour from other material in the document, or there might be a road map for all risk-based plan regulatory requirements specifying where they are covered in the quality system of the business. Today's electronic technology enables greater manipulation of and access to relevant parts of a document or system.

44. The relevant food safety Acts would be amended to implement this option, with the actual requirements being set in regulations, including the acceptable manner of identifying the food safety requirements. Unlike option 2, wholesale change to documents/systems is not expected to be necessary, and the changes are less likely to be 'significant amendments' because systems and/or plans do not need to be taken apart and then reconstructed.

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[2] See Animal Products Act 1999, section 17 and the Animal Products (Risk Management Programme Specifications) Notice 2008; however, other relevant notices will also apply. These prescribe detailed requirements and augment the higher level requirements in the Acts.

[3] Note this proposal also extends to Food Control Plans and Wine Standards Management Plans.

45. The regulation-making process would entail further stakeholder engagement and regulatory impact analysis. A transitional period for compliance would be used, which would not need to be as long as that required under option 2.

46. Of the 12 submissions that commented on the "clearly identify food safety requirements" option in the consultation document, 10 supported it and two thought no change was necessary although preferred this option over the others presented.

Option 4: Director-General, case-by-case, declines to register or requires amendments [additional preferred option]

47. This option would enable the Director-General to, on a case-by-case basis, decline to register new risk-based plans if the regulatory requirements are not readily identifiable and easily understood. It would also enable the Director-General to require amendments to existing risk-based plans at any time on the same grounds. This option is of a slightly different nature to the options discussed above because it would not provide a system-wide solution. It supports the preferred option of clearly identifying food safety requirements.

48. The first part of the proposal would provide a specific ground on which the Director-General of the Ministry could refuse to register a new risk-based plan. At present 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. A precedent for this kind of discretion is in the Biosecurity Act.[4]

49. The second part of the proposal addresses existing risk-based plans, and would apply at any future time that the Director-General becomes aware of a plan with problematic content. The most likely way the Director-General would become aware of problems with individual existing plans is by a verifier drawing the Ministry's attention to it.

50. Some redesign of the risk-based plans of individual operators would be needed, with resultant change costs (including any re-evaluation and registration costs) for those businesses. The Ministry would need to be clear in its guidance material about what 'can be readily understood' means.

51. There was a mixed response to this proposal by submitters to the consultation, ranging from total opposition by some who consider that the proposal would not deal with systemic problems or could be used in an inconsistent way, through to (particularly the seafood sector) preferring this proposal over all other options presented.

Impact analysis

52. Table 1 below sets out options 1 to 4 and assesses them against the criteria of certainty, effectiveness, and administrative efficiency.

[4] See Biosecurity Act 1993, sections 62(k), 71(j), 82(k), 91(j)

Table 1: Analysis of options for better identifying the food safety content of risk-based plans and programmes

KEY: **x** does not meet criterion; + somewhat meets criterion; ++ meets criterion. **RMP/plan** refers generically to risk-based plans and programmes

Criterion	Option 1: Status quo	Option 2: Prohibit non-food safety material in risk-based plan	Option 3: Clearly identify the food safety material in risk-based plan	Option 4: D-G case-by-case power to decline registration or require amendment
Certainty (a business's food safety requirements are clearly identified in the RMP and accessible to all parties involved in the food system)	+ - Food safety requirements not as clear as they could be in some plans because they are mixed in with other quality system material not required for food safety purposes.	++ - Businesses and their staff can easily see and access all food safety regulatory requirements, and the processes by which they will manage their risks, as they are in a dedicated document or system. - Builds on existing system (guidance material currently states – but does not mandate – that food safety requirements should be clearly identified).	++ - All food safety regulatory requirements, and processes by which the business will manage the risks are easily identified and accessed. - Builds on existing system (guidance material currently states – but does not mandate – that food safety requirements should be clearly identified).	+ - Accessibility and clarity would be improved for plans that are subject to this provision. - No guarantee that all risk-based plans with issues will come to the D-G's attention, with identification of issues likely to be *ad hoc*.
Effectiveness (practical, usable, likelihood of compliance is increased)	+ - RMPs are currently contributing to effective food safety system, but some RMPs have become complex and unwieldy and are difficult to verify and enforce.	+ - RMPs are able to be readily evaluated, verified, and enforced. - Achieves the intent of the WPC Inquiry recommendation because easy to distinguish food safety from non-food safety matters. But - Disrupts business processes; works against business having an intact, integrated operating system or document for everyday use (as RMP may become just one of a number of documents). - Will take some time to implement as there is a limited capacity to support redesign and re-evaluation etc, so would need relatively long transition period. - Maintaining more than one document risks staff confusion about food safety requirements, and increases staff training costs.	++ - Allows operator the flexibility to bundle food safety elements in business risk management systems/documentation. - Keeps food safety within operational systems so is likely to be part of integrated processes. - RMPs are able to be readily evaluated, verified, and enforced. - Achieves the intent of the WPC Inquiry recommendation because easy to distinguish food safety from non-food safety matters.	+ - Would signal to all operators the requirement for clarity and accessibility and consequences of this not being achieved. - Would focus effort and attention on the areas where it is most necessary. - Targets costs to those businesses with problem RMPs. - Builds on the existing statutory provision that permits conditions to be placed on registration. But - Does not address system-wide issues as improvements only made on a case-by-case basis as matters are brought to DG attention.

Criterion	Option 1: Status quo	Option 2: Prohibit non-food safety material in risk-based plan	Option 3: Clearly identify the food safety material in risk-based plan	Option 4: D-G case-by-case power to decline registration or require amendment
Administrative efficiency (minimising costs)	+ - No additional cost to businesses. - Difficulty in identifying food safety matters in plans may impose additional costs on regulators if investigating compliance or in event of food safety incident.	+ - No costs for RMP operators whose plans currently only contain food safety matters. But - Cost for operators will depend on the style and format of the individual business's existing plan and the degree of redesign required. - Because of the disruption caused by removing food safety matters, many operators are likely to face redesign and, re-evaluation costs, which are estimated in the range of $4.1-7.8 million overall.	++ - No costs for RMP operators whose plans currently clearly identify food safety matters. - Not all plans would need to be amended, most would not need to be re-evaluated. But - Cost for operators will depend on the style and format of the individual business's existing plan and the degree of redesign required, though likely to be less cost to businesses, and fewer associated risks to food safety focus compared with option 2.	+ - Targets costs to those with problem risk-based plans.
Conclusion	**Somewhat meets criteria**	**Somewhat meets criteria**	**Meets criteria (recommended)**	**Somewhat meets criteria (recommended)**

Conclusion

53. Option 3 (clear identification of food safety and related requirements) best meets the three criteria of certainty, effectiveness, and administrative efficiency and is recommended. It achieves the intent of the WPC Inquiry recommendation, but at a lesser cost to business than option 2.

54. Option 4 (D-G case-by-case power to decline to register) only partly meets the criteria because it is not a system-wide solution. However, this option is recommended as a useful further tool available to the Director-General, to better identify and amend risk-based plans with problematic content. It therefore supports option 3. This option would need to be accompanied by guidance to ensure the Director-General's use of the power is consistent and transparent.

55. Option 2 (prohibit non-food safety material in risk-based plan) partly meets the three criteria, but at high cost and with a significant risk that the plan may not be used as an everyday tool. This option attracted the most comment (37 submissions), with 35 industry submitters strongly negative. It is not recommended.

ii. Providing full plans and programmes to regulators and verifiers

Problem

56. The Animal Products Act allows businesses to provide only an outline RMP to the Ministry at registration. This has resulted in the Ministry having limited oversight of the details of the specific processes operators have agreed to follow to address identified risks. Although the current provisions require operators to notify the Ministry of updates this does not always happen, and so the operator of the risk-based plan and the regulator may refer to different versions of the plan. This situation creates confusion and can make compliance actions difficult.

57. The WPC contamination incident demonstrated the problem, with the Ministry being unable to source Fonterra's full RMP in a timely manner (discussed above in paragraph 38). During a food safety incident the regulator needs to know the specific processes an operator stated at registration they would use.

58. On an ongoing basis, the verifier must (on behalf of the regulator) judge whether the operator is complying with all their food safety legal obligations. During verification visits, a verifier does not necessarily look at the whole risk-based plan and may choose to focus on a specific part. It may not be clear to the verifier that parts of the risk-based plan have been amended, if they have not been kept up-to-date with changes made by the operator.

Options

59. The WPC Inquiry recommended that: "…the ministry should receive and maintain records of full and up-to-date [risk-based plans and] programmes".

Option 1: Status quo – outline or full risk-based plan provided

60. When seeking registration of a RMP under the Animal Products Act either an outline of the plan or the full plan may be provided to the Ministry (this is the same for a WSMP under the Wine Act, while with FCPs under the Food Act either specified information or the full plan may be provided).

61. The plan or outline is accompanied by an independent evaluator's report stating that the RMP is acceptable. Under the Animal Products Act very few (estimated 1%) custom RMPs are provided in full.

62. As noted above, any "significant amendment" must be registered by the registration authority, while minor amendments are periodically notified (but not registered). The RMP must be provided to the Ministry within two working days of any request. Verifiers who assess an operator's compliance with the risk-based plan do not usually hold a copy of it.

63. 34 of 45 submitters who commented on this proposal supported the status quo, including 28 from the seafood industry (24 of which were a template response), the NZ Winegrowers Association, the Meat Industry Association, and the Food and Grocery Council.

Option 2: Full risk-based plan provided to the Ministry [preferred option]

64. Under this option, the ability to provide an outline of a risk-based plan for registration would be removed. A regulation-making power would enable regulations to be made about how risk-based plans are to be provided to the Ministry, in what format, and in what timeframes.

65. The submissions that supported the status quo over this option generally considered that the problem lies only with the dairy industry, and that because operators can be required already to produce their full RMPs within two working days there is no benefit from the Ministry holding full programmes.

66. Supporters of the proposal included verifying agency AsureQuality, Fonterra, Foodstuffs NZ, Progressive Enterprises, and a regional public health service. Despite their support, there was some concern about the potential cost impact of providing more information. Because the detail of what must be supplied and how would be set in regulations, there will be an opportunity for further stakeholder consultation and regulatory impact analysis of options when regulations are being developed.

Option 3: Provide all significant and minor amendments to the verifier [additional preferred option]

67. Under this option, food business operators would be required to provide copies of all amendments to risk-based plans to their verifier within a timeframe set in regulations. The proposal consulted on was that these amendments would need to be provided either within 6 months of the change being made or before the next verification visit, whichever is the sooner. As well, verifying agencies would be required to hold up-to-date versions of the risk-based plans of the businesses they verify.

68. There was good support from the dairy sector and food and beverage submitters for this proposal. Some other submissions indicated qualified support. Verifier AsureQuality partially supported it but raised issues with the size and cost of potential IT investment, as well as impacts such as additional time needed for verification.

Impact analysis

69. Table 2 below sets out the above options and assesses them against the criteria of certainty, effectiveness, and administrative efficiency.

Table 2: Analysis of options for provision of risk-based plans and programmes to regulators and verifiers

KEY: **x** does not meet criterion; **o** to be determined; + somewhat meets criterion; ++ meets criterion. **RMP/plan** refers generically to risk-based plans and programmes

Criterion	Option 1: Status quo - choice of outline or full RMP	Option 2: Full RMP and significant amendments provided to the Ministry	Option 3: Full RMP and all amendments (significant or minor) provided to verifier
Certainty (clarity of requirements for all parties)	**x** - Regulator unlikely to have full copy so will not know detail of how operator intends to meet requirements - Not possible for regulator to gain oversight of common issues across sector. - Neither the regulator nor verifier has full up-to-date plan.	++ - Ensures the Ministry has a complete picture of the initial RMP, and updated information from any significant amendments that it registers.	++ - Ensures the verifier always has up-to-date versions of the risk-based plans of the businesses they verify, and therefore current information on business risks.
Effectiveness (practical; responsiveness of system; ability to meet future challenges and opportunities	+ - Difficult for regulator to identify where system improvements are needed. - Regulator's ability to investigate and respond to incidents is limited until regulator gets the full and up-to-date plan. - Verifier may not be aware of all changes made by operator so verifications may not be well targeted.	++ - Improves regulators' ability to investigate and respond to food safety incidents. - Enables the Ministry to develop risk profiles across the system and identify any systemic issues. - The Ministry can readily access relevant parts of the RMP for cross-sector audit purposes/identify sector verifier training needs.	++ - Will assist with the verification process and enable verifiers to identify in advance areas to focus on for next verification visit. - Verifier better placed to identify issues occurring across the specific industry and relay these to regulators. - Verifier can inform regulator about particularly problematic plans that are not easy to understand and may need to be amended.
Administrative efficiency (minimises or keeps costs as low as possible for businesses and regulators)	+ - Least cost option for businesses (because no change). But - Regulator may face additional costs when investigating compliance and trying to respond to potential incidents.	**o** - Will have cost implications for both businesses and regulators, depending on how implemented through regulations, eg, for electronic storage (though separate impact analysis and further consultation will be undertaken then).	**o** - More effective use of verifiers' time on site, so better value for business. But - Will have cost implications for both businesses and verifying agency, particularly for electronic storage, depending on how implemented through regulations.
Conclusion	**Somewhat meets criteria**	**Generally meets criteria (recommended)**	**Generally meets criteria (recommended)**

Conclusion

70. Option 2 (full RMP and significant amendments provided to the Ministry) and option 3 (full RMP and all amendments (significant or minor) held by verifier) meet the criteria of certainty and effectiveness. The administrative efficiency of option 2 and option 3 will be more clearly determined during the development of options for implementation through regulations, with compliance costs to be minimised as far as possible. Option 2 and option 3 are both recommended.

71. Option 1 (status quo) only partly meets the three criteria as it does not enhance the certainty of requirements, and only somewhat contributes to the effectiveness of the system. It does have the least administrative cost as it requires no change. Although submissions indicated strong support for the status quo it is not recommended because it does not address the problems identified by the WPC Inquiry.

B. Better access to information in a food safety incident

Context

72. The food safety system involves a number of parties holding and sharing a wide variety of information. The WPC Inquiry noted that the Ministry's access to information from a variety of sources puts it in a unique position to identify areas of particular concern and emerging issues or risks. It can also see trends and assist the industry to improve.

73. There is an opportunity for the Ministry to have access to more comprehensive information to enhance its system oversight and emergency response roles. There is also an opportunity for businesses to ensure their food safety responses, such as traceability and recall, will work as expected during an incident.

Proposals and impact analysis

74. Two proposals for ensuring better access to information in a food safety incident were consulted on.
    1. Compelling disclosure of information.
    2. Strengthening traceability and recall systems through mock recalls.

Proposal 1: Compelling disclosure of information

Status quo and problem

75. During the early stage of the WPC incident the Ministry was unable to directly obtain the laboratory test results on which Fonterra's advice about the contamination was based. It took 48 hours for the Ministry to get the information, which affected its ability to assess the risks at the earliest time possible and to determine the scale of response required.

76. The WPC Inquiry recommended that the Ministry be given a specific statutory power to compel the disclosure of information needed to respond effectively to a food safety incident and that this power should over-ride any conflicting obligations (such as confidentiality).

77. The Food Act has a power that reaches across the food sectors (including those usually regulated under the Animal Products or Wine Acts), which allows the Chief-Executive (ie, the Director-General of the Ministry) to require a food business to produce information for the purposes of determining the safety and suitability of food.

78. However, this power does not extend to parties providing services to a food business, such as a laboratory or a cleaning company.

Proposal

79. The Food Act would be amended to ensure the Director-General can, when identifying or responding to a food safety incident, access information held by people or businesses not usually covered by this area of the Food Act, for example laboratories or cleaners. Having the power in the Food Act means it will apply to all food, which includes wine and animal products. It is also proposed that before using the power the Director-General must have a 'reasonable suspicion' the information is held by the party, and that the information is necessary for identifying and responding to a food safety incident.

Analysis of the status quo and the proposal against the criteria

80. **Certainty:** Compared with the status quo this will give certainty that the Ministry can access all relevant information.

81. **Effectiveness:** Speedy access to all relevant information will enable the Ministry to make a timely and informed assessment about any relevant risks to human health when determining whether a food safety incident has occurred.

82. **Administrative efficiency:** Will reduce costs for regulator as can better target responses on the basis of better information. May be some administrative costs for the business in providing the information.

83. There was support for the proposal by submitters, with caveats such as it should be limited to food safety response situations and have careful parameters (such as needing a reasonable suspicion that the information is held and necessary in the context of the response). Such protections are part of the proposal.

84. This proposal meets the criteria of certainty and effectiveness better than the status quo. Administrative efficiency is enhanced for the regulator, but there may be some new costs to the businesses providing the information as compared to the status quo. However, on balance, the proposal is recommended.

Proposal 2: Strengthening traceability and recall systems through mock recalls

Status quo and problem

85. Traceability and recalls are critical factors in the food safety system. Strong traceability facilitates the rapid identification of the quantity and location of food (including 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. Recalls help ensure that consumers are protected from unsafe food.

86. The WPC Inquiry recommended that regulations should require industry to simulate recalls, and that verifiers should to be able to audit such simulations.

87. In general, businesses operating under risk-based plans and programmes should have recall plans (which include traceability systems). However, currently there are no requirements for food businesses to regularly and actively test recall procedures. This exposes the food system to the risk that traceability systems are 'tested' during real product recalls. This situation increases the risk of harm to the health of consumers and, as a result, to New Zealand's reputation.

Proposal

88. This proposal would provide a regulation-making power in the three food safety Acts to set requirements for operators to undertake mock traceability and recall exercises to test their recall plans (such as simulating that a particular product is potentially unsafe or unsuitable and the business going through steps necessary to recall the product including a traceability exercise) which verifiers will check.

Analysis of the status quo and the proposal against the criteria

89. **Certainty:** The regulation-making power will enable detailed proposals for what would be required in a mock traceability and recall exercise to be determined during the regulation-making process, providing greater certainty for businesses about expectations.

90. **Effectiveness:** Undertaking mock traceability and recall exercises will help ensure that the traceability and recall plans businesses already have in place are effective and will work in a food safety or suitability incident, assisting with preparedness for such a situation.

91. **Administrative efficiency:** Costs will be minimised for a business if the traceability and recall system works as it should during an incident. Compliance costs will be identified and considered when making specific regulations. The development of regulations will include further consultation and regulatory impact analysis.

92. Submissions were generally supportive of widening the regulation-making powers for traceability and recall.

93. Compared to the status quo where traceability and recall systems may only be tested in an actual response, the proposal to provide for mock traceability and recall exercises in regulations better meets the three criteria of certainty, effectiveness, and administrative efficiency. It is therefore recommended.

C. Targeted alignment of the three food safety Acts

Context

The Food Act has some provisions and tools that the Animal Products and Wine Acts do not. There is an opportunity for some targeted alignment between the three Acts to improve certainty, effectiveness and administrative efficiency.

Three proposals for alignment were consulted on.

1. Compliance and enforcement tools.
2. Purposes for which the Director-General can make privileged statements.
3. Ability to use automated electronic systems.

Proposals and impact analysis

Proposal 1: Alignment of the compliance and enforcement tools

Status quo and opportunity

94. The Food Act has a wider range of compliance and enforcement tools than the Animal Products and Wine Acts, including an improvement notice, infringement regime, compliance order and a penalty based on commercial gain for specified offences.

95. The WPC Inquiry recommended that the compliance and enforcement tools in the Animal Products Act should be aligned with those in the Food Act to ensure there is a broad suite of tools available across the food safety regime.

Proposal

96. An improvement notice, infringement regime, and a penalty based on commercial gain for specified offences (based on the identified Food Act offences) will be added to the Animal Products Act. These tools and also a compliance order will be added to the Wine Act. Additionally, it is proposed that the relevant two year statute of limitation periods for laying criminal charges under the Animal Products and Wine Acts are aligned with the four year period in the Food Act.

97. Infringement offences and specific infringement fees (up to a maximum of $1,000) will be set in regulations, with further public consultation and regulatory impact analysis to be undertaken at that time. The maximum penalties for breaching an improvement notice under the Animal Products and Wine Acts will be $100,000 for a body corporate and $20,000 for an individual, and for breaching a compliance order under the Wine Act $250,000 for a body corporate and $50,000 for an individual. These proposed maximum penalties are consistent with the maximum penalties for similar types of offending under the respective Acts, rather than the higher penalties provided under the Food Act. This approach maintains internal consistency within the Acts.

Analysis of the status quo and the proposal against the criteria

98. **Certainty:** Under the status quo, responses by the regulator for similar offending under the different Acts may differ, due to different tools being available. Certainty for businesses and the regulator is provided when responses to non-compliance or offending is consistent, graduated and proportionate. Alignment of the tools across the three Acts provides for this.

99. **Effectiveness:** Having an appropriate range of tools to address various levels of non-compliance and offending is critical to the effectiveness of a compliance regime achieving the desired deterrence, behavioural change and compliance. The proposal therefore enhances the effectiveness of the Acts as compared to the status quo, by broadening the suite of responses.

100. **Administrative efficiency:** Administrative efficiency is improved when similar offending by businesses under the different food safety Acts can be responded to in a similar and consistent manner, including the time that may be required to identify and investigate offending. Where matters are more appropriately dealt with by infringement notice, both businesses and the regulator may save the cost and time of prosecutions.

101. Most submissions supported the alignment of the compliance and enforcement tools in the Acts. However, some submitters considered the current regimes for animal products and wine provide sufficient responses to non-compliant behaviour.

102. The Ministry has considered the submissions, and for the reasons given above recommends that the specified compliance and enforcement tools be aligned.

Proposal 2: Alignment of the purposes for which the Director-General can make privileged statements

Status quo and problem

103. The three food safety Acts allow the Director-General of the Ministry to make privileged statements for the purposes of "protecting" the public. However, currently only the Food Act and Wine Act allow the Director-General to also make a statement to "inform" the public. It is not always clear where the line between “informing” and “protecting” lies. Because the Animal Products Act only has one of these purposes, it creates uncertainty in the areas where it is not clear if the public needs their health protected or to be generally informed.

Proposal

104. This proposal would enable the Director-General to make a privileged statement under the Animal Products Act to “inform” the public as well as to “protect”. This is similar to Director-General's powers under the Food Act and Wine Act.

Analysis of the status quo and the proposal against the criteria

105. **Certainty:** Compared with the status quo, this proposal will provide more clarity around the circumstances under which the Director-General may make privileged statements. Different considerations may be taken into account when determining if a statement is for the purposes of “protecting” or “informing” the public, and enabling the Director-General to do both under the Animal Products Act removes any uncertainty as to the threshold for such a statement.

106. **Effectiveness:** Being able to provide information to the public under the Animal Products Act for the purposes of informing them will contribute to the effectiveness of the food safety regime. The Director-General may provide information to correct unclear or inaccurate information already in the public domain, or be able to inform the public about, for example, misleading (rather than directly harmful) information in an advertisement relating to an animal product. Having this power will act as a deterrent and thereby increase the likelihood of compliance by businesses.

107. **Administrative efficiency:** This proposal minimises the risks of rumour or incorrect information being in the public domain and attendant information search costs.

108. Ten of the 12 submitters who commented on this proposal supported it. Two submitters were concerned that greater expectations may be placed on the Director-General to provide wider information than should be permitted under privilege. The Ministry does not consider this will be an issue as the power is a discretionary one.

109. Taking into account the submissions and the analysis above, the proposal to align the purposes for which the Director-General may make privileged statements across the three Acts is recommended.

Proposal 3: Alignment of ability to use automated electronic systems

Status quo and opportunity

110. Unlike the Animal Products and Wine Acts, the Food Act explicitly provides for an automated electronic system to do various actions such as exercising a power, carrying out a function or making a decision. An automated electronic system allows a computer programme to step a user through the various requirements to achieve a decision, without necessarily needing a person to be directly involved.

111. Other regulators use automated electronic systems, such as New Zealand Customs Service (border clearance) and Immigration New Zealand (SmartGate border entry systems). There is an opportunity to align the three food safety Acts to enable the use of automated electronic systems.

Proposal

112. The Food Act provisions to enable automated electronic actions would be used as a model to more explicitly provide for automated electronic systems in the Animal Products and Wine Acts.

Analysis of the status quo and the proposal against the criteria

113. **Certainty:** Consistency on this matter across the three food safety Acts is desirable, and explicitly enabling automated electronic systems provides certainty around their use for the regulator and business.

114. **Effectiveness:** Although not all of the Ministry's systems are yet capable of delivering a fully automated service from start to finish, explicitly enabling automated electronic systems in the Animal Products and Wine Acts is future focused and will allow more automated electronic actions to occur as technology advances.

115. **Administrative efficiency:** Future services to businesses may be able to be provided faster and at less cost.

116. Submissions were supportive of this proposal and it is recommended.

Consultation

117. 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.

118. From mid-March to early May 2015 the Ministry sought public input on proposals for inclusion in the Food Safety Law Reform Bill. The consultation document was posted on the Ministry's website. A media statement was issued by the Minister for Food Safety to accompany the paper's release. Individual letters were sent to key stakeholders advising them of the consultation, and more than 3,400 notifications of the consultation were sent to all those who have signed up to receive such notifications.

119. Most industry sectors were represented in the 50 submissions. There were 28 submissions from the seafood sector, 24 of which were template responses based on Seafood New Zealand's submission.

120. Overall, the submissions were generally supportive of the proposals. Where substantive issues were raised about a proposal they have been discussed and taken into account in the relevant section of the RIS. No proposals were changed as a result of the submissions; however, where options were provided related to the enhancement of risk-based plans and programmes, submissions informed the decision on which options to recommend.

121. The Ministry also consulted with other government agencies including the Ministries of Business, Innovation and Employment; Foreign Affairs and Trade; Health; Justice; the Department of Internal Affairs; New Zealand Customs Service; State Services Commission; Te Puni Kōkiri; and the Treasury. The Parliamentary Counsel Office and the Department of the Prime Minister and Cabinet were informed of the proposals. No substantive issues were raised.

Conclusions and recommendations

122. The recommended options and proposals will result in improvements to the food safety regulatory system that meet the criteria of improving certainty, enhancing effectiveness, and being administratively efficient. This in turn will help enhance and contribute to the five complementary objectives of the food safety system of: food being safe and suitable; public health being protected; risks are identified and managed; New Zealand's good reputation increasing access to overseas markets; and market access being facilitated.

123. The analysis against the criteria demonstrates that the following proposals deliver the greatest net benefits in addressing the problems and are therefore recommended.

- Enable regulations to be made to set the content, form and manner of a risk management programme or other risk-based plan, including requirements for differentiation of food safety matters from non-food safety material.
- Permit the Director-General to decline to register risk management plans or programmes where the regulatory requirements are not readily identifiable and easily understood, and to require operators to amend their risk management plans or programmes at any time on the same grounds.
- Enable regulations to be made to require food business operators to provide a full copy of their risk management plans or programmes to the regulator for registration (once the regulations are in place, with removal of ability to provide an outline of the plan), and to provide copies of all amendments to these plans or programmes to their verifying agency within a set timeframe.
- Give the Director-General a specific power under the Food Act to compel the disclosure of relevant information held by parties providing services to a food business and needed to identify or respond to a food safety incident.
- Provide a regulation-making power in the three food safety Acts to set requirements for operators to undertake mock traceability and recall exercises.
- Align the compliance and enforcement tools in the three food safety Acts by including in the Animal Products and Wine Acts an improvement notice, an infringement regime; a commercial gain penalty, and a compliance order.
- Enable the Director-General to make a privileged statement under the Animal Products Act to "inform" as well as to "protect" the public, similar to powers under the Food and Wine Acts.

- Explicitly provide for automated electronic systems in the Animal Products and Wine Acts, using the Food Act provisions as a model.

Implementation plan

124. The Cabinet paper that this RIS accompanies, *Food Safety Law Reform Bill: final policy approvals*, proposes that Cabinet agree to the recommended options in this RIS and a number of other proposals not subject to the RIS requirements.

125. It is proposed that the changes be progressed in an omnibus Bill, the Food Safety Law Reform Bill, to be introduced at the end of 2015. This Bill will amend the Animal Products Act 1999, the Wine Act 2003 and the Food Act 2014.

126. Some of the proposals, such as the ability to compel the provision of information in a food safety incident, will come into effect immediately the Bill is passed. Other proposals (such as those related to risk-based plans and mock traceability exercises) enable regulations to be made to set the particular detail on how the proposals will be implemented. Further consultation with stakeholders and regulatory impact analysis will be undertaken to identify the impacts of different options to implement the proposals during the regulation-making process, with a view to minimise compliance costs while remaining consistent with the need for food to be safe and suitable. The Ministry will agree a regulation-making timetable with the Minister for Food Safety.

127. The Ministry will engage with sectors both before and during implementation of the risk-based plans and programmes proposals, to help ensure businesses are developing their plans in accordance with requirements. Information technology solutions will be investigated by the Ministry to help implement the proposals in a future-focused and cost-effective manner (such as the requirement for risk-based plans to be provided to the Ministry).

128. Public announcements will be made when relevant proposals come into effect (for example, on the passing of the Bill, when any transitional periods end, when regulations are promulgated). The Ministry will also make information releases to its food safety stakeholder distribution lists and forums at relevant times, and provide information on its public websites.

Monitoring, evaluation and review

The Ministry 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;
- stakeholder engagement forums;
- Food Act 2014 Monitoring and Evaluation Programme.