In Confidence

Office of the Minister for Food Safety
Chair, Cabinet Economic Development Committee

**Proposed amendments to strengthen food recalls and improve risk management programmes**

## Proposal

1. This paper seeks Cabinet approval to strengthen the regulatory framework for food recalls and improve risk management programmes. The proposals address some of the final recommendations of the Whey Protein Concentrate Contamination (WPC) Inquiry.

## Executive Summary

2. The WPC Inquiry in 2013 identified improvements that could be made to food recalls and risk management programmes to strengthen New Zealand's food safety system.

3. Food production and food safety are regulated across three main food safety Acts[1]: the Animal Products Act 1999; the Food Act 2014; and the Wine Act 2003. The WPC Inquiry made a number of recommendations for legislative change that were implemented through the Food Safety Law Reform (FSLR) Act 2018. The FSLR Act included regulation making powers to strengthen food recalls and improve risk management programmes. In doing so, it took steps to harmonise the WPC Inquiry's recommendations across the three food safety Acts.

4. Food recalls are required to remove food from the supply chain that may be unsafe or unsuitable. Effective food recalls require systems to trace food and ingredients through food supply chains, so they can be quickly recalled if they are not safe or suitable. Current requirements are inconsistent between the three food safety Acts, are spread over numerous regulations and notices, and do not require recall systems to be tested to ensure businesses can effectively recall food when it does not meet safety or suitability requirements.

5. Risk-based plans and programmes are the key tool that a business uses to manage food safety and suitability risks under the three food safety Acts. The WPC Inquiry identified gaps in the information that needs to be supplied to the Ministry for Primary Industries (MPI) upon registration of a risk management programme under the Animal Products Act. This makes it difficult to identify important food safety information when needed.

1 The Food Act helps make sure that food sold throughout New Zealand is safe. The Animal Products Act manages risks to human or animal health arising from animal products and facilitates the export of these into overseas markets. The Wine Act provides for setting standards for safety of wine and export eligibility requirements.

6. In late 2018, MPI conducted public consultation on proposals to strengthen food recalls under the three food safety Acts and risk-based plans and programmes [DEV-18-MIN-0229 refers]. MPI received 34 in scope submissions. In general, there was support for the regulatory package. As a result of consultation some changes have been made to the proposals as the analysis showed the additional business compliance costs would not lead to any additional food safety benefits.

7. There are two suites of proposals: one addresses food recalls and the other risk management programmes under the Animal Products Act. The proposals in each seek to harmonise requirements across the three food safety Acts, assisting businesses working under them. The proposals make requirements more visible, explicit, and consolidated so all operators are aware of their responsibilities. The proposals ensure any costs imposed are minimised and proportionate, and consistent with the need for food to be safe and suitable.

8. The suite of proposals to promote effective and efficient food recall apply across all three food safety Acts and cover:
   - who must maintain food recall procedures;
   - what traceability procedures must achieve;
   - how quickly information is to be shared;
   - requirement to perform a mock recall; and
   - the format of traceability information supplied during a recall.

9. The proposals addressing the risk management programmes are specific to the Animal Products Act and cover:
   - supply of hazard identification and management information;
   - moving risk management programme requirements from notices to regulations; and
   - other minor and technical changes.

10. It is expected that the impacts of the food recall proposals will not be significant as many businesses are already adhering to private standards that go beyond the proposed requirements. Other businesses may experience a small increase in compliance costs. The proposals for risk management programmes only require operators to provide information to MPI they already hold and does not require new information to be created.

11. The FSLR Act legislated that the amended regulations for risk management programmes need to be in place within two years of the FSLR Act coming into force (by 1 March 2020).

## Background

*12. Food safety is important to New Zealand*

13. The excellent international reputation of New Zealand's food regulatory system underpins the high standing of New Zealand's food products in overseas markets. Our food system protects the health and wellbeing of consumers here and overseas by ensuring that the food we consume is safe and suitable to eat. It supports the food manufacturing, retail and service sectors that have exceeded $84 billion in turnover for the year to June 2018. Food exports over the same period exceeded $32 billion.

*The WPC incident and subsequent inquiry identified opportunities to strengthen New Zealand's food safety system*

14. In August 2013 Fonterra notified MPI that three batches of whey protein concentrate (WPC) were contaminated with *Clostridium botulinum.* Although this later turned out to be a false alarm, the "botulism scare" made global headlines and had significant consequences for New Zealand's international reputation as a supplier of safe food.

15. The impact of this incident led the Government to establish the independent WPC Inquiry. The WPC Inquiry investigated the causes of, and responses to, the incident. It 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 sound and consistent with international principles.

16. The WPC Inquiry made 38 recommendations, many of which have been implemented. Examples include strengthening traceability requirements for exporters of infant formula, implementing mandatory through-chain electronic traceability for dairy exports, and establishing a Food Safety Science and Research Centre.

17. The WPC Inquiry also recommended establishing a Dairy Traceability Working Group (the Working group). The Working Group concluded that strengthened traceability requirements were needed for the dairy sector, and recognised that traceability is essential to all food sectors. The recommendations were therefore applied to all food sectors.

*The Food Safety Law Reform Act 2018 enables new regulations*

18. Recommendations from the WPC Inquiry were implemented by the FSLR Act 2018. The FSLR Act amended the Animal Products Act 1999, the Food Act 2014 and the Wine Act 2003 (food safety Acts) to harmonise the provisions across the whole food sector.

19. The FSLR Act enables regulations to be made to strengthen food recalls and improve risk management programmes. To provide certainty for businesses, the FSLR Act legislated that the regulations for risk management programmes need to be in place within two years of the FSLR Act coming into force (by 1 March 2020).

*Risk based plans and programmes*

20. Each of the three food safety Acts requires a food business to have a risk-based plan or programme, unless exempt. These risk-based plans and programmes are the key tool a business uses to manage its food safety and suitability risks and are legally binding.[2]

**Opportunities for strengthening food safety regulations**

*Requirements can be strengthened to improve food recalls*

21. Generally, businesses that operate under a risk-based plan or programme are already required to be able to trace food from their suppliers and to their customers (the 'one up, one down' model).

22. However, the Working Group identified that the current requirements do not provide the necessary framework as they:
    - differ between food safety Acts;
    - are spread out over numerous regulations and notices;
    - do not include all businesses in the food supply chain (exporters who do not handle or store the food are generally not currently covered); and
    - result in the effectiveness of recall systems not being fully tested until a food safety incident occurs.

23. Addressing these concerns will reduce the risk of health, economic, and reputational impacts from a food safety incident.

*Risk management programmes requirements can be improved*

24. The WPC Inquiry found that businesses could provide an outline of their risk management programme to MPI (rather than the whole document) when seeking registration. This provided MPI limited oversight of the details of the specific processes operators have agreed to follow to address identified risks. MPI also lacks information to identify an operator's food safety risk management strategies and practices quickly and accurately.

25. Another concern was that the key requirements for risk management programmes are found in a number of notices and policy statements. This makes it difficult for businesses to be clear about what their legal obligations are and where in the regulations they are located.

2 They are Risk Management Programme under the Animal Products Act, National Programmes and Food Control Plans under the Food Act and Wine Standards Management plan under the Wine Act.

## Objectives of new regulations

26. Regulatory proposals were guided by the objectives to:
    a. harmonise requirements across the three food safety Acts to assist businesses who work under the three Acts as much as possible;
    b. make the requirements more visible, explicit, and consolidated so that all operators throughout the food system are aware of their responsibilities;
    c. ensure the requirements promote effective and efficient food recalls; and
    d. ensure any costs imposed are minimised and proportionate, and consistent with the need for food to be safe and suitable.

## Food recall proposals

27. The proposals seek to strengthen food regulations by amending regulations, notices and specifications under the three food safety Acts by imposing the following requirements:
    - all food businesses that have a risk-based plan or programme, or import or export food, to maintain food recall procedures;
    - traceability systems to be accurate, allow for effective tracing and recall of food, and for businesses to be able to identify and locate ingredients and food within their operations;
    - traceability information to be shared with MPI within the time specified by an MPI warranted officer (food safety officer, animal products officer, or wine officer), or within 24 hours, whichever is shorter;
    - recall procedures to be tested annually; and
    - information to be supplied in a readily usable format.

28. Some of these proposals will embed common, good practice into regulation. Many food businesses are already compliant with all or some of these requirements, and will face little to no additional compliance costs.

*Proposal A - Who must maintain food recall procedures*

29. It is proposed that all businesses with risk-based plans or programmes, and importers or exporters of food, must maintain food recall procedures. This extends recall requirements to include exporters who do not have a risk-based plan or programme. These exporters may not physically handle the exported food, however if something goes wrong they will be the only link between the importing country and the food supply chain in New Zealand.

30. As some exporters will be new to food regulation, a new requirement will be needed for these businesses to notify MPI as soon as possible, and no later than 24 hours of having knowledge of an event, where food they hold or have exported becomes no longer safe nor suitable. This will allow MPI to assist and monitor (if necessary) their decision to recall food.

31. In the event of a recall, this proposal would make sure all relevant businesses in the food supply chain have adequate traceability records and are able to recall food effectively.

*Proposal B - What traceability information should achieve*

32. It is proposed to make it an explicit requirement for traceability systems to be accurate and allow for the effective tracing and recall of food. At a minimum, businesses should be able to trace food coming in, and food going out of their operations, and identify and locate food that is within their operations. If a business is currently required to maintain more detailed internal tracing procedures, these are to be maintained.

33. This proposal embeds what is currently expected of food recall systems and the outcome focus allows businesses to design their own systems and process in way that matches their business needs while meeting food safety needs.

*Proposal C - How quickly information should be shared*

34. It is proposed that traceability information held by a food business be provided to MPI within the time specified by an MPI warranted officer (food safety officer, animal products officer, or wine officer), or within 24 hours, whichever is shorter. Many businesses believe they may have much longer to provide information to MPI and may not be prepared to supply information quickly when needed. However, food safety officers already have the power to request information within a reasonable time, and this is used when the risk presented by a food safety incident requires a more rapid response.

35. This proposal would create a consistent traceability information sharing provision under the food safety Acts by aligning regulations to what currently happens under the Food Act. It makes it clear to businesses that MPI may require traceability information faster than apparent minimum baseline requirements (like the two-day requirement in specifications under the Animal Products Act) and lead to the improvement of traceability systems.

*Proposal D - Requirement to perform a mock recall*

36. It is proposed to require mock recalls to be performed every 12 months. A mock recall includes developing a recall scenario, identifying and tracing the potentially affected food (this step is already performed by businesses when they are verified), determining who has received affected product, and demonstrating ability to draft appropriate communications and checking the contact details of appropriate parties (customers, supplier, and potentially MPI).

37. If a genuine recall (where a real food safety or suitability risk has been identified and food has been recalled from the food supply chain) has occurred in the previous 12 months, a mock recall would not be required to be performed. The genuine recall would need to be successfully managed, which MPI would assess giving consideration to factors such as the number of corrective actions identified, the proportion of product successfully returned, and the time taken.

38. Annual mock recalls would see recall systems tested prior to being needed for a genuine recall. Testing will identify faults and inaccuracies and allow kinks in systems to be ironed out before being needed. This would improve the efficiency and effectiveness of recalls. Verification of the mock recalls would align to current verification frequencies[3]. The records of mock recalls are to be checked upon a business's next verification.

*Proposal E - Format of traceability information supplied during a recall*

39. It is proposed to require the information supplied by a business in the event of a recall to be in a readily accessible format (that is, information a business provides needs to be presented in a consistent format on each page, and allow for key information to be extracted easily from either digital or hard copy documents). When format is consistent, MPI can more easily and quickly process the data it receives during a recall.

40. This provides flexibility for businesses. The alternative of specifying the format would create additional administrative, financial, and time burdens for businesses. This would result in either change required to most existing traceability systems, or to time being wasted putting information into the prescribed format when a recall is required. Flexibility allows business to avoid additional administrative, financial, and time burdens, while still meeting food safety objectives.

**Risk management programmes (RMPs)**

41. I propose to improve RMPs under the Animal Products Act by:
    a. requiring the hazard identification and management information to also be supplied if registering an outline of a RMP; and
    b. moving the requirements for what needs to be in an RMP from notice into regulations.

*Proposal F - Requiring hazard identification and management information*

42. The hazard identification and management information is used to identify and manage significant food safety hazards. It is an internationally recognised system and ensures food safety for businesses.

43. Operators have the option of sending in their full RMP or an outline for registration. Currently, the outline does not require the hazard identification and management information to be included.

3 Verification is the independent audit of a food business to determine whether they are following regulatory requirements. The frequency of verification can be determined by factors including the inherent risk presented by a food sector and the businesses historical food safety performance.

44. It is proposed to require the hazard identification and management information from operators if they choose to send in an outline of their RMP, as permitted by the regulations. This would address concerns by the regulator that the current outline provided by operators does not give MPI enough information about the detailed processes that operators intend to use to meet their food safety requirements.

45. Many businesses have already provided this information to MPI when requested. As operators already hold this information, operators would not be required to produce any new information, only to supply it to MPI if they choose to register an outline of their RMP.

*Proposal G - Replicating RMP requirements in one set of regulations instead of multiple notices*

46. It is proposed to replicate the requirements for what needs to be in a RMP from multiple notices into one set of regulations under the Animal Products Act. An operator's legal obligations will not change, regardless of whether requirements are set in a notice or a regulation (regulations are made under the delegated authority of an Act, while notices are a legal instrument issued by the Chief Executive). The following Animal Products requirements will be consolidated into regulations:
    - Animal Products (Risk Management Programme Specifications) Notice 2008;
    - Animal Products (Requirements for Risk Management Programme Outlines) Notice 2008; and
    - Animal Products Act 1999 Statement of Policy: Operator Responsibilities during Registration of a Risk Management Programme (Version 1).

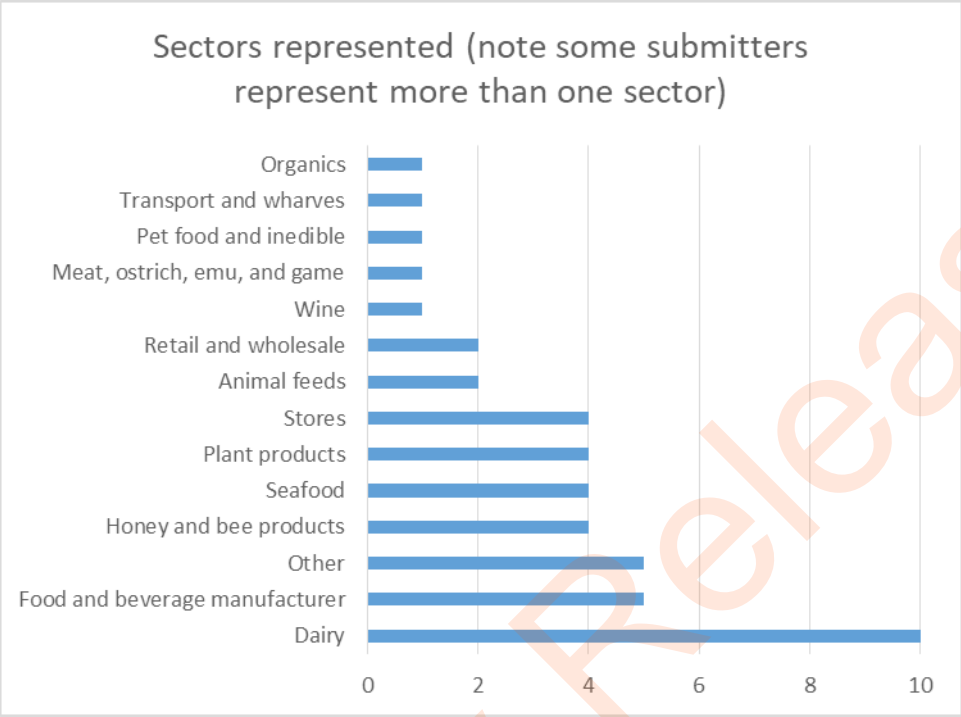
47. Having all the requirements for the contents of RMPs in fewer places will make it easier for operators to know their legal obligations. This will remove duplication and streamline requirements. Technical matters that are subject to frequent change will remain in a notice about RMP specifications. Minor and technical changes to the RMP requirements can be made at the same time notices are placed into regulations. The proposed minor and technical changes can be found in **Appendix One**.

**Public Consultation**

48. The three food safety Acts require that the Minister must be satisfied that appropriate consultation with affected stakeholders has taken place and the results of the consultation have been taken into account, before recommending the regulations be made.

49. Public consultation on the proposals opened in October 2018 and closed in December 2018. The public were invited to make submissions. The consultation was publicised through a media release, MPI's website, and emails to industry associations, businesses, and individuals.

50. MPI received 34 in scope submissions. A range of sectors submitted on the proposals. In general, there was support for the regulatory package. The graph below shows the range of sectors that submitted on the proposals:




51. Due to comments from several submissions, I recommend not proceeding with the proposal to extend the length of time records should be kept. This proposal would have created additional costs for some businesses for no significant improvement in food safety outcomes.

52. After considering stakeholder the feedback, I recommend not proceeding with the original WPC proposal to require operators of a risk-based plan or programme to differentiate their food safety material from their non-food safety material. The majority of submitters overwhelmingly objected to this proposal and felt that the food safety benefits would not outweigh the costs.

53. **Appendix Two** summarises feedback received on the proposals.

**Departmental Consultation**

54. The following government departments were consulted in the development of this paper: Ministry for Business, Innovation and Employment; and the Treasury. The Department of the Prime Minister and Cabinet and Te Puni Kōkiri were informed.

**Financial Implications**

55. There are no financial implications arising from these proposals.

## Legislative Implications

56. Implementation of the proposals will require new regulations to be created under the three food safety Acts.

## Impact Analysis

57. The impact of changes to traceability are minor, as many businesses adhere to private standards that go beyond the proposed requirements, and face little to no extra costs as a result of these proposals. Other businesses may experience a small increase in compliance costs from performing mock recalls and tightening their current traceability systems. The Impact Summary Assessment is attached as **Appendix Three.**

58. The impact of changes to RMPs are also minor as the changes simply replicate the legal requirements for risk management programmes in regulations will not change the legal obligations for operators.

59. A Quality Assurance Panel with representatives from MPI has reviewed the Regulatory Impact Assessment 'Food recalls and risk-based plans and programmes' produced by MPI and dated 8 August 2019. The Quality Assurance Panel considers that this meets the Quality Assurance criteria, noting the scope of options for analysis was constrained by the recommendations of the WPC inquiry, and the suite of proposals presented contributes to the complexity of the Impact Summary.

## Human Rights

60. This paper has no implications under the Human Rights Act 1993 or the New Zealand Bill of Rights Act 1999.

## Publicity

61. A summary of submissions has been prepared and will be published on MPI's website when the Cabinet paper is proactively released.

## Proactive Release

62. Following Cabinet consideration I intend to consider the release of this paper in full.

**Recommendations**

The Minister for Food Safety recommends that the Committee:

*Background*

1. **Note** the Whey Protein Concentrate Contamination (WPC) Inquiry and the Dairy Traceability working group identified that regulatory improvements were needed to strengthen food recalls and improve risk management programmes to protect New Zealand's reputation as a supplier of safe and suitable food;

2. **Note** the Food Safety Law Reform Act 2018 enables regulations to be put in place that strengthen food recalls and improve risk management programmes under the Food Act 2014, Animal Products Act 1999, and Wine Act 2003 as a result of the WPC Inquiry recommendations;

3. **Note** that public consultation for these proposals on food recalls and risk management programmes were undertaken from October to December 2018 and the proposals now take account of the feedback received;

4. **Note** that consultation showed overall general support for regulatory proposals;

*Food recall proposals*

5. **Agree** to require all businesses with risk-based plans or programmes, and importers or exporters of food, to maintain food recall procedures;

6. **Agree** to require traceability systems to be accurate and allow for the effective tracing and recall of food;

7. **Agree** to require businesses to be able to trace food coming in, and food going out of their operations, and identify and locate food that is within their operations. If a business is currently required to maintain more detailed internal tracing procedures, these are to be maintained;

8. **Agree** that Ministry for Primary Industries can request traceability information held by a food business be provided to it within a shortened timeframe;

9. **Agree** to require mock recalls to be performed around every 12 months, unless a successfully managed genuine recall has occurred in the previous 12 months;

10. **Agree** to require the information supplied by food businesses in the event of a recall to be in a format that is readily accessible;

*Risk management programme proposals*

11. **Agree** that, when providing an outline of the risk management programme as permitted by the regulations, the hazard and identification and management information be required to be supplied to Ministry for Primary Industries upon registration;

12. **Agree** to replicate similar requirements presently in Animal Product notices for what needs to be in a risk management programme into regulations instead;

*Legislative requirements*

13. **Authorise** the Minister for Food Safety to issue drafting instructions to the Parliamentary Council Office to implement the above policy decisions;

14. **Authorise** the Minister for Food Safety to make final decisions on minor and technical issues that are consistent with the policy intent described in this paper on any issues that arise during the drafting process.

Authorised for lodgement

Hon Damien O'Connor
Minister for Food Safety