Ministry for Primary Industries
Manatū Ahu Matua

# Proposals for regulations under the Food Act 2014

## Regulatory Impact Statement

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*Growing and Protecting New Zealand*

**Contents** **Page**

# Agency Disclosure Statement – Proposals for regulations under the Food Act 2014

This Regulatory Impact Statement (RIS) has been prepared by the Ministry for Primary Industries (MPI). It provides an analysis of options for regulations under the Food Act 2014 (the Food Act).

Our proposals for regulations draw on a number of factors. We have used our experience with the Food Act 1981 and the Food Hygiene Regulations 1974. We have built off the extensive analysis and consultation that went into the Domestic Food Review, which began in 2003 and led to the development of the Food Bill. Some food businesses are already operating risk-based measures under exemptions from the Food Hygiene Regulations and this has provided another body of experience to draw on. Some aspects of the new Food Act, such as verification, are similar to the systems we already operate under the Animal Products Act 1999. In early 2015 we consulted on our proposals for regulations and the feedback has added to our analysis. We have worked with two key advisory groups, the Territorial Authority Steering Group and the Food and Beverage Forum, and consulted with other stakeholder groups throughout the process.

We have used multi-criteria analysis to assess the options, namely the status quo (no regulations or guidance), guidance alone where this is a feasible option, and our proposals for regulations.

There are limitations on the analysis because the proposals have not been implemented, and the new regulatory regime will be very different from the existing scheme. The proposed regulations will all interact with each other, so that taking any one aspect away will impact across the system as a whole. It is not possible to analyse these future system-wide interactions. The options analysis has instead looked at each proposal as a distinct feature, but on the assumption that the rest of the system will operate as proposed. The options analysis is an 'ex-ante' best estimate of the impact of the proposals, based on our knowledge and experience and stakeholder feedback.

It is not possible to develop any average or common estimates of the likely costs of these proposed regulations for food businesses. The reasons for this are set out below.

- There is a very wide variety of food businesses and considerable differences in their size and scope. There is no average food business.
- Costs will vary depending on the extent to which a business is already performing well and the risk-based measure it will come under once it transitions to the new regime. A well performing business is unlikely to face extra costs, especially if it is already operating a risk-based measure under the Food Act 1981. If the business is in a lower risk sector, it may well face reduced ongoing costs. Performance-based verification frequencies will be a significant cost saving for well performing businesses.
- Registration and verification costs for many businesses will be subject to fees set by territorial authorities. These fees have not yet been set. Other businesses will be verified by third parties, with charges negotiated between the business and the verifier.

Despite these limitations we have provided some cost estimates in Appendix B. The sources for these estimates are the regulatory impact analysis done to support the Cabinet decisions on the Food Bill in 2009, and the analysis that supported the cost recovery regulations for the Food Act 2014. (See 'Regulatory impact statement 2009 — A reformed food regulatory regime', http://www.foodsafety.govt.nz/elibrary/industry/Regulatory_Impact-

Specifically_Covers.pdf, and 'Establishing cost recovery regulations to support the Food Act 2014' http://www.mpi.govt.nz/law-and-policy/legal-overviews/regulatory-impact-statements/).

We will monitor the operation of the Act and regulations once implemented. Over time this information will bring to light issues and their likely causes so that adjustments can be made as necessary.

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# Executive summary

This Regulatory Impact Statement (RIS) summarises MPI's analysis of options for regulations under the Food Act 2014 (the Food Act).

The objective of this work is to establish initial requirements for the implementation of the Food Act that effectively **support the safety and suitability of food for sale** and **maintain confidence in the food safety system** by:

- **being consistent and fair,** with differences **proportionate** and based as far as possible on **science–based risk assessments;**
- **providing certainty to food businesses** while still encouraging them to **take responsibility for the safety and suitability of their food;** and
- **promoting administrative efficiency by not imposing undue compliance costs** on either food businesses or regulators.

The areas where regulations are proposed are set out below. For each of these areas, the RIS briefly sets out the legislative framework under the Food Act 1981 and under the Food Act 2014. We discuss the issues and the proposals to address them. Where relevant, we outline the consultation responses.

**Registration: food control plans and national programmes.** The Food Act establishes basic requirements for registration of food businesses. The proposals concern the further detail that is required to provide for effective and consistent operation of registration. This includes the process for pre-registration evaluation of custom food control plans.

**Verification: food control plans and national programmes.** The Food Act requires food businesses to ensure their businesses are verified, that is, checked for their performance against the applicable risk-based measure. The proposals specify requirements in relation to frequency and process.

**Food safety and suitability: food control plans and national programmes.** The Food Act requires food businesses to achieve the safety and suitability of food. The proposals concern the further detail that is required to provide for effectiveness, consistency and certainty in relation to this requirement. They relate to issues such as facilities, equipment, supporting systems, and the competency and training of staff.

**Recognised agencies, persons, and classes of persons**. The Food Act provides for recognition of agencies, persons and classes of persons to undertake verification and to evaluate custom food control plans. The proposals set out specifications to help determine if an agency or person is 'fit and proper' for recognition, to monitor performance and to determine renewal of recognition. We propose that evaluators of custom food control plans must be 'recognised'.

**Approved documents, materials, facilities, persons and classes of persons.** The Food Act provides for the MPI chief executive to approve documents, facilities, persons and the like if the Food Act requires such an approval. We propose criteria for approvals as a means of adding rigour and transparency to the approvals process.

**Food standards.** The Food Act generally provides for food standards to be maintained in their current form. We have identified that further detail is required to manage the risks posed by residue levels from agricultural compounds that may have been involved in food

production. The proposals set out specifications for identifying and managing maximum residue levels (MRLs) in food.

**Imported food.** The Food Act requires food imported into New Zealand to be safe and suitable. As imported foods are produced overseas they have not necessarily been developed in a way that establishes they are safe and suitable by New Zealand's standards. Our proposals are designed to address these risks.

**Exemptions.** The Food Act enables regulations to be made to grant exemptions from certain provisions of the Act. We do not propose any such exemptions at this time. Should the need arise in the interim, the MPI chief executive has powers to grant exemptions by notice on a case-by-case basis.

**Infringement offences.** The Food Act enables regulations to specify which of the offences in the Act should become infringement offences. We propose some specific offences that should be designated as infringement offences.

**Transitional matters.** The Food Act provides for regulations to set the introductory period and requires regulations to set transition schedules for food sectors. Our proposals are designed to smooth the transition for businesses, while also spreading the workload for the registration authorities (MPI and territorial authorities).

The proposals in each of these areas are assessed against the following criteria:

**Effectiveness**: Promotes the **safety and suitability of food for sale** and maintains **confidence in the food safety system.**

**Administrative efficiency**: Does **not impose undue compliance costs** on either food businesses or regulators.

**Proportionality:** Differences are **risk–based**.

**Certainty:** Businesses are clear about how they will be impacted.

As well as assessing our regulatory proposals, we assess the status quo or 'do nothing' option. Where feasible, options for guidance alone and alternative regulatory proposals are assessed. In each case the 'do nothing' option does not meet the criteria. This reflects our prior analysis that led us to discount those areas where regulations are permitted but not required.

The proposals were consulted on from January to March 2015. The responses were generally positive, with many suggestions, including for additional matters to be included in regulations. As would be expected with such a broad range of proposals and given the vast and diverse nature of the food sector, there were varied responses to a number of the proposals. The proposals for safety and suitability regulations were a particular area where the submissions led us to refine requirements, delete some as unnecessary, or determine that some are more appropriate as guidance because it is not necessary for them to have regulatory force. Some matters are more suited to a tertiary notice because they are technical or administrative, and/or likely to be subject to frequent change.

Implementation will be supported by a programme of targeted and general information, with surveys of food businesses to help determine where effort is most necessary. We are continuing to work with food sector groups and industry leaders, and with territorial authorities as the co-regulators. Guidance and tertiary notices are being developed to support the Food Act.

We are preparing a programme for monitoring and review of the effectiveness of the Food Act and its implementation. This also will provide further information on the costs and other

impacts on food businesses. Key indicators are being developed, with the intention of establishing pre-implementation baselines which will be followed up with ongoing monitoring and reporting.

# Context

## The current situation

1. **There is a new Food Act coming into effect.** The Food Act 2014 (the Food Act) was passed in June 2014 and will gradually replace the Food Act 1981 over a three year introductory period from 1 March 2016. Groups of existing food businesses will transition to the Food Act over this introductory period. In general, higher risk businesses are proposed to transition before lower risk businesses. New businesses registering from 1 March 2016 will have to meet Food Act requirements immediately.

2. **The Food Act requires regulations, notices and guidance to fill in the details.** The Food Act provides the legal framework for the food safety system. The Act's overall approach is to establish general requirements and to empower the making of regulations and notices to set out in greater detail how 'things will work' on a more practical level. For instance, the Food Act establishes the requirement for verification, but leaves it to regulations and notices to detail what verification will involve. The other important implementation tool is providing information and guidance to food businesses.

3. **The Food Act takes a risk-based approach to food safety management.** This approach regulates types of food businesses at levels corresponding to the food safety risks presented by that type of business. This enables the system to be responsive to the diversity of businesses operating in the food industry.

4. **Food sectors are categorised according to risk and subject to different risk-based measures, or no measure for the lowest risk businesses.** High risk businesses will be required to have a **food control plan**, and medium to low risk businesses will operate by using a **national programme, level 3, 2 or 1**, with level 3 being the highest risk and level 1 the lowest. Schedules 1 and 2 of the Food Act set out which food sectors fit under which risk-based measure. Schedule 3 sets out the food sectors that are not required to operate under either a food control plan or a national programme. These are mainly businesses where food provision is not the primary activity (e.g. accommodation businesses that also provide snacks or breakfasts, or clubs that provide food to visiting sports teams). All food businesses should fit within one or more of the listed food sectors. Further information on the sectors and their classification is provided in Appendix A.

5. **Food control plans** must specify what the business risks are and how they will be managed. The quality of these plans is, therefore, critical to the effectiveness of the regulatory regime in maintaining food safety and suitability. Businesses may use either a template plan issued by the MPI chief executive, or develop their own custom food control plan. The businesses must operate according to their plan.

6. **National programme** businesses do not develop their own plan, but must instead operate according to the requirements set for the relevant national programme. These businesses are required to demonstrate how they comply with these requirements.

7. **This risk-based differentiation of food providers contrasts with the Food Act 1981, which has a one-size-fits-all approach to food safety.** The Food Act 1981 is supported by the Food Hygiene Regulations 1974, the Dietary Supplements Regulations 1985 and the Food (Safety) Regulations 2002. These regulations take a 'one size fits all' approach. This is most clearly illustrated by the existing requirement that, with

limited exceptions, all food for sale must be prepared in a commercial kitchen. This type of framework is no longer in line with international best practice and its lack of flexibility impacts on the ability to respond to emerging food risks and imposes unnecessary costs on businesses. The prescriptive nature of this regime has encouraged a compliance culture rather than one where the focus is on taking responsibility for the safety and suitability of food.

8. **The Food Act requires food operators to take responsibility for identifying and managing the food safety risks presented by their food business**. The regulations, notices and guidance developed to support the Act will flesh out the required outcomes, and either how these outcomes must be met (regulations and notices) or how these outcomes could be met (guidance).

9. **This difference means the existing regulations cannot be used to support the new Act.** These regulations will remain in place throughout the transition period. As each sector comes under the Food Act, the existing regulations will cease to apply to the sector. The very different approaches of the old and new Acts mean it is not an option to carry over these existing regulations. These regulations are, nevertheless, important sources of good practice and have informed our proposals for requirements and guidance under the new Food Act.

10. **Some businesses are already operating risk-based measures.** Following a 1997 amendment, the Food Act 1981 does allow for some risk-based measures. There are currently 4 390 restaurants, cafes and caterers operating with a template food safety programme under the voluntary implementation programme. A further 2 463 businesses such as supermarkets, fast food retailers and bakeries are operating a custom food safety programme. Transition for these businesses is expected to be relatively smooth given their experience with these measures, which are similar to the risk-based measures of the Food Act.

11. **In the absence of new regulations, notices and/or guidance the food safety system will be costly, inconsistent and ineffective.** There would be nothing in place to amplify the general framework established by the Food Act. This would not provide an effective food safety system because there would be insufficient clarity for:

    a. food businesses on what they must achieve, and in the case of higher risk businesses, how they must achieve it;

    b. other key operators in the system, especially verifiers, as the Act does not specify details such as what they must look for and the processes they must follow to protect against risks; and

    c. for those responsible for compliance and enforcement action.

12. This would be likely to lead to a continuation of the current situation under which territorial authorities have made by-laws to fill gaps left by the Food Act 1981 and the Food Hygiene Regulations 1974. These by-laws are costly and time consuming for the territorial authorities, and tend to be regionally focused and not nationally consistent.

**How significant is this issue?**

13. The issue is significant because:

    a. **The Food Act covers the whole food sector,** that is, all businesses, activities, or undertakings involving trade in food, including food that is imported. The Act does not distinguish between food intended for domestic consumption or for

export. Food businesses come in a very wide range of types and sizes; from the corner dairy to nationwide supermarket chains.

b. **The food sector contains a large number of businesses, and makes a substantial contribution to New Zealand's economy.** There are approximately 45,000 food providers (operating from about 85,000 premises). Overall the food retail sector turns over an estimated $28 billion annually, and food manufacturing about $47 billion.

c. **Foodborne illness can have a substantial impact on people's lives and the economy.** Consumers expect the food they eat to be safe and suitable for human consumption. Foodborne illness can cause significant harm to those who are directly affected and imposes costs on the health system and on businesses. In 2010, the cost to society of the six major foodborne illnesses in New Zealand was estimated at NZ$162 million.[1] An effective food safety system reduces the costs to society of foodborne illness.

d. **The domestic food safety regime contributes substantively to New Zealand's export performance.** The domestic food regulation requirements are used as the basis for negotiating equivalence agreements with our trading partners. This helps to minimise requirements from importing countries, thereby contributing to lower compliance costs for our exporters. The effectiveness of our domestic food safety system also makes a critical contribution to the value of New Zealand's reputation as a producer of safe and suitable food.

## Scope

14. This RIS analyses options for regulations and/or guidance in the following areas:

    a) **Registration: food control plans and national programmes.**

    b) **Verification: food control plans and national programmes.**

    c) **Food safety and suitability: food control plans and national programmes.**

    d) **Recognised agencies, persons, and classes of persons**.

    e) **Approved documents, materials, facilities, persons and classes of persons.**

    f) **Food standards.**

    g) **Imported food.**

    h) **Exemptions.**

    i) **Infringement offences.**

    j) **Transitional matters.**

    Regulations for cost recovery have already been made. These are the Food (Fees and Charges) Regulations 2015, which were gazetted on 14 May 2015.

15. The Act empowers the making of a very wide range of regulations in respect of most of these areas. We do not propose that regulations be made under all of these empowering provisions. We have limited the proposals for regulations to those areas where we have

[1] *The Economic Cost of Foodborne Disease in New Zealand*, Applied Economics Ltd, November 2010.

assessed that the Act alone does not provide sufficient detail to facilitate effective implementation and operation. Wherever we propose regulations, we have also considered whether guidance would be sufficient to supplement the Act. Where there is a feasible guidance option this is included in the analysis and compared with the regulatory proposals.

16. We consulted on the proposals through *Public Discussion Paper No: 2015/01 Proposals for regulations under the Food Act 2014*, which was released in January 2015. As part of this consultation we sought alternatives to our proposals. Where feasible alternatives have been suggested these are included in the analysis and compared with the original proposals.

17. Over time, we may develop further proposals as the new system is implemented and matures, and as it becomes clear what additional measures may be required to meet the purpose of the Food Act.

18. The following section sets out the issues and our proposals to address them. These proposals are analysed against the status quo in the later section 'Analysis of options'.

# Areas for analysis

## A: Registration: food control plans and national programmes

**Legislative provisions for registration**: **Food Act 1981 and Food Act 2014**

| **Food Act 1981 and the Food Hygiene Regulations 1974** | **Food Act 2014** | |
|---|---|---|
| | **Food control plan businesses** | **National programme businesses** |
| Annual registration. | Annual registration (section 61). | Duration of registration to be set by regulations (section 76). |
| Businesses operating under the Food Hygiene Regulations register with their local territorial authority.<br><br>Businesses operating with a food safety programme under an exemption from the Food Hygiene Regulations register with MPI. | Registration with MPI if a custom food control plan, registration with territorial authority if a template food control plan (section 52). | The appropriate registration authority is either MPI or the relevant territorial authority as provided for under regulations (section 82). |

| | | |
|---|---|---|
| | A custom food control plan must be independently evaluated as part of the registration process (section 53(3)(b)). | |
| | Regulations may prescribe matters including manner and form of registration, and conditions or restrictions (section 43(1)(d) and (e)). | Regulations may prescribe matters including processes and requirements, form and content, and conditions or restrictions, (section 76(1)(c) - (f)). |
| | Businesses listed in schedule 3 are exempt from the requirement to operate under a risk based measure and therefore exempt from the requirement to register. | |

## A Registration: issues and proposals

19. **Context**: The Food Act establishes a framework for registration but leaves the detail to be provided through regulations. We consider that further detail is required on the issues outlined below.

### A1: Evaluation of custom food control plans

Evaluation is a process conducted independently of the business operator. Its purpose is to confirm that a proposed food control plan will, if correctly followed by the operator, result in safe food. This is a critical step in the regulatory system as these plans are developed by the particular business to address its particular risks. The plans set out how these high risk businesses will operate to achieve the safety and suitability of their food, and each business's compliance with the plan is the basis for ongoing verification.[2] The Act does not provide any operational details for the evaluation process.

### Proposal

We propose a regulation to establish details to support a robust evaluation process. The regulation will require the following:

a. Evaluators to undertake an onsite assessment of the business, unless the MPI chief executive waives this requirement.
b. Food business operators to provide evidence to the evaluator that certain products or processes are safe, for example by validating a product or process.
c. Evaluators to include content in their evaluation reports about the products and activities to which the plan applies, the assessment of the validation process, and any technical experts used.
d. Evaluators to endorse both the evaluation report and the plan to certify that the plan has not been modified since the evaluation.

[2] Verification involves the application of methods, procedures, tests or other checks to confirm that the business is complying with its risk-based measure, that the risk-based measure is effective and continues to be applicable to the business, and that the operator is complying with the applicable requirements of the Food Act 2014.

The discussion paper set out proposals for regulations on these issues.

**Consultation response.** Most submissions agree with the proposals, but many suggested further detail that could be included. A number of submissions did not support the onsite visit waiver because they believe it is critical that the evaluator see the physical location and surroundings rather than rely on the papers alone to assess risks. Many other submissions supported the proposal, but wanted greater clarity on the particular circumstances in which waivers may apply. Similarly, submissions suggested a range of specific matters to be included in the evaluation reports.

**MPI response.** We have considered the suggestions for greater detail in the regulations, but concluded that is it best to retain the broadly expressed requirements and provide guidance to assist businesses and evaluators. We propose to retain the waiver option as it is a risk-based means to reduce unwarranted compliance costs.

**A2: Specifying the physical boundaries of a business subject to a food control plan**

Registration authorities require information about the size and layout of the premises in which a food business operates to help them understand how activities undertaken there might affect food safety and hence the adequacy of the plan. Verifiers require this information so they can be sure of the physical boundaries within which their verification should take place.

**Proposal**

The discussion paper set out proposals for regulations to require all businesses wishing to register food control plans to provide information about the physical boundaries of their premises, and the activities undertaken within these boundaries.

**Consultation response**. Most submissions supported this proposal, although several said it was unnecessary and onerous. Some submissions called for clarification and asked for guidance on what should be included, especially for mobile food businesses.

**A3: Setting the registration duration for national programme businesses**

Registration information needs to be reasonably up to date and reliable as it enables regulators to be aware of legitimate food businesses, to have effective monitoring programmes, and to manage compliance activity. It is especially important in relation to incident responses such as food recalls. Registration information is recorded in a public register of all businesses that operate under a food control plan or national programme. The MPI chief executive is required to maintain this register (Food Act, Schedule 5). The Act does not set the registration duration for national programme businesses.

**Proposal**

The discussion paper proposed annual registration. This is the same as under the Food Act 1981 and the same as for food control plan businesses.

**Consultation response**. Submissions varied, with some considering this is an unnecessary revenue raising exercise. Others suggested registration be tied to verification frequencies, and some suggested less frequent registration for lower risk businesses. Territorial authorities indicated strong broad based support for the proposal.

**MPI response**. Linking registration to verification outcomes would conflate two separate aspects of the regime. Whereas verification checks that requirements are met, registration is

an administrative task. It is designed to keep details up to date and is not linked to risk.

In response to the consultation responses, we have considered the option of registration renewal every 2 years as well as the original proposal for annual re-registration.

**A4: The appropriate registration authority for national programme businesses**

The Act specifies that the registration authority is either MPI or the territorial authority as set by regulation.

**Proposal**

The discussion paper proposed a regulation to require that all national programme businesses register with the territorial authority responsible for the district where the business is located. Three exceptions to this general rule are proposed, as outlined below:

a. Mobile or vehicle-based food businesses will register with the territorial authority of their home base even if they operate across territorial authority boundaries.
b. Multi-site food businesses that operate at sites in more than one territorial authority district may either register each site individually with the relevant territorial authority, or register all sites with MPI.
c. Food businesses that have their own industry programmes could work with MPI to determine whether these businesses can register under their industry programme instead of the national programme relevant to their sector. MPI would accept applications for registration from the representative body on behalf of the businesses registered with that industry, so businesses need register only once to cover both Food Act registration and their industry programme registration.

**Consultation response.** There was support for the proposals on the registration authority. A suggested alternative to registration with the territorial authority was to allow more complex businesses to register with MPI. This suggestion does not, however, take account of the administrative nature of registration. It does not really matter how large or complex the business is, the requirements are the same.

**MPI response**. The submissions on industry programme registration have raised questions about how it would fit with existing industry structures and how it would be implemented. We will, therefore, give further thought to this option, and will work with industry groups to better understand their needs and intentions and how these can best be accommodated within the requirements of the Food Act. It is likely that this option can be dealt with by way of an exemption issued through a notice under section 33.

**A5: Annualising of registrations for national programmes**

The discussion paper did not propose 'annualising' registrations of national programmes so they align with the financial year end. The Food Act allows for this with food control plans. Territorial authorities have indicated that such a regulation would be helpful to streamline their workflows.

**Proposal**

In response to submissions from territorial authorities, a regulation should allow the

registration authority the option to annualise the registration of national programme businesses to align with the financial year end.

## B: Verification: food control plans and national programmes

**Legislative provisions for verification**: **Food Act 1981 and Food Act 2014**

| **Food Act 1981 and the Food Hygiene Regulations 1974** | **Food Act 2014** | |
|---|---|---|
| | **Food control plan businesses** | **National programme businesses** |
| Businesses operating under the Food Hygiene regulations are inspected annually by territorial authorities.<br><br>Businesses that have developed their own food safety programme are audited by third party auditing agencies approved by MPI.<br><br>Businesses that operate under a template food safety programme issued by MPI are audited by their local territorial authority. | The operator must ensure that the business is verified by an appropriate recognised agency or person (section 50(1)(f)). | The operator must ensure that the business is verified by an appropriate recognised agency or person (section 80(e)). |
| | Regulations may be made prescribing verification requirements, including provisions that deal with the frequency, intensity and cost of verification (section 43(1)(c))). | Regulations may be made prescribing verification requirements, including provisions that deal with the frequency, intensity and cost of verification (section 76(1)(b)). |

**Verification: issues to be addressed**

20. **Context**: Verification is intended to test and confirm whether a business is complying with the applicable requirements of the Food Act, whether it is complying with a risk-based measure, the applicability of the risk-based measure for the particular business, and the effectiveness of the risk-based measure. The Act does not prescribe a system for verification.

**B1: Verification frequency**

The Act does not specify when initial verification should take place nor specify the ongoing verification frequencies. These timeframes need to be formalised. Initial verification is critical to checking the risks and risk management processes for new businesses and for existing businesses transitioning to the Food Act. Ongoing verifications test whether systems

and processes remain fit for purpose and whether a business is maintaining the required performance. Setting verification frequencies is a means of introducing performance-based verification. Well performing businesses would be verified less often and face lower costs.

**Proposal**

In accordance with the risk-based focus of the Act, the proposed timeframes for initial and ongoing verification frequency differ according to the risk-based measure under which the business is operating. The discussion paper set out proposals for regulations as outlined below.

| **Food sectors subject to:** | **Initial verification of existing businesses** | **Initial verification of a new business** | **Verification variation** | |
|---|---|---|---|---|
| | | | **Maximum frequency** | **Minimum frequency** |
| **Custom food control plans** | Within 6 months of registration | Within 3 months of registration | 3 months | 18 months |
| **Template food control plans** | Within 1 year of registration | Within 1 month of registration | 3 months | 18 months |
| **National programme Level 3** | Within 6 months of registration | Within 1 month of registration | 3 months | 2 years |
| **National programme Level 2** | Within 1 year of registration | Within 1 month of registration | 3 months | 3 years |
| **National programme Level 1** | Within 1 year of registration | Within 1 month of registration | Nil unless a situation arises | |

These proposals are based on the following:

a. The proposed timeframes for new businesses will allow operators time to implement the requirements and to start generating records to provide evidence to verifiers. The slightly longer timeframe for businesses subject to custom food control plans reflects the greater complexity of these plans and the time it will take such businesses to implement the new requirements. In addition, they will have already been subject to an evaluation of their plan, usually including an onsite visit.
b. The timeframes recognise most businesses will have a track record of producing safe and suitable food, while also allowing time for them to be able to demonstrate how they are meeting the new requirements.
c. Beyond the initial verification, frequency will vary according to performance, as discussed below.
d. Beyond the initial verification, level 1 businesses would only be verified if information indicates this is necessary. This information could arise as a result of things such as recalls, increased sporadic illness, MPI's monitoring of the food safety system through routine systems audits or benchmarking surveys, or any other indicator which points to potential food safety issues.

We propose a series of interim steps between the maximum and minimum frequencies, with businesses to progress along these steps depending on their verification results. This supports performance-based verification and encourages operator responsibility.

The outcome of a verification is determined by the verifier, and will be subject to specific requirements as proposed in B2 below. For businesses subject to food control plans, an acceptable initial verification will result in the verification frequency being set at 12 months. If the business receives two consecutive acceptable verification outcomes, it will transition to an 18 month frequency.

Upon an initial acceptable verification, businesses subject to national programme level 3 will start at 2 years, level 2 will start at 3 years, and level 1 will start at no routine verification. These businesses will move to more frequent verification if the verifier recommends this to the registration authority on the basis of unacceptable verification reports.

**Criteria to determine verification frequency.** We propose criteria to be used by the verifier in determining ongoing frequencies. These criteria are:

a. confidence in management;
b. food safety behaviour;
c. the effectiveness of process controls;
d. the effectiveness of environmental controls; and
e. compliance history.

**Consultation response**. A number of submitters felt that the timeframe for initial verifications of new businesses was too short. We note, however, that the initial verification timing has to strike a balance between how long a business can be allowed to operate without checking (verifying) that they are producing safe and suitable food, and what is practical for the business in terms of starting to compile records. We have practical experience of this system, as under the Animal Products Act 1999 we undertake initial verification of high risk businesses within one month.

A substantial number of submissions expressed concerns at the proposal that national programme level 1 businesses not be subject to routine verification beyond the initial verification. We note that most of these businesses will not be receiving any visits at the moment, and the initial verification will provide the opportunity to identify any areas needing corrective action. If the initial verification identifies such issues, the verifier would recommend to the registration authority that the business be subject to more frequent verification until further verifications show it is performing well enough to move to no routine verification.

**B2: Specifying the verification process**

The Act does not provide details on the verification process, but it is important that there is certainty and consistency in how it is undertaken given that:

- poor verification will not provide proper warnings of safety and suitability problems, including alerting registration authorities when compliance action may be necessary;
- over-zealous verification will impose undue costs on businesses; and
- verification will be done by a wide range of recognised agencies and persons, including territorial authorities.

**Proposal**

To provide greater certainty and consistently to the verification process, the discussion paper proposed regulations to set out the following:

a. **Verification scope**. Verifier to identify the scope of the verification before beginning the process. Submissions questioned the need to require that the verifier define the scope. This is part of standard verifier practice, and we agree that this is best addressed in guidance to verifiers. No regulation proposed.

b. **Verifiers' duties to inform the operator** within a reasonable time of any deficiencies found, the likely outcome, and timing for the next verification visit.

c. **Verifier to negotiate and confirm corrective actions** with the operator if the verifier detects non-compliance. Some submissions questioned this process. We see this as an important aspect of businesses taking responsibility for the safety and suitability of their food, and it enables each business to consider how best to address the issues within their own context. The verifier has the final decision as to whether the proposals, including the timeline, are acceptable, and must confirm that the planned actions have been completed.

d. **Verifier to assign an outcome**. To designate the outcome as acceptable, the verifier must be satisfied that:
    i. the operator is complying with all applicable regulatory requirements; or
    ii. if there have been any departures from regulatory requirements that the operator's corrective actions have been, or are being, applied appropriately and are effective.

    The verifier will be required to designate the outcome as 'unacceptable' if he/she has determined that the operator is not complying with all applicable regulatory requirements relevant to their operation and corrective action is not being taken or is ineffective. Submissions suggested there should be more than two possible verification outcomes, acceptable or not acceptable. This reflected a concern that the verification outcome would be 'unacceptable' if the operator did not meet just one of many possible requirements. This will not be the case as the verifier will exercise an overall judgement when making his or her decision. The regulations will set out an indicative list of relevant factors which the verifier will use to guide this judgement.

e. **Verifier to provide a written report to the operator**. This must include the outcome, any agreed corrective actions, any aspects of an unacceptable outcome that triggered an increase in verification frequency, and when the next verification will be undertaken.

f. **Business operator to have the right to request a reconsideration of a verification decision**. A number of submissions did not support this. We consider it important for reasons of natural justice that the right of review be available in relation to all verification decisions.

g. **Verification of multi-site businesses**. Each premises or site must receive an initial verification assessment. Following this initial verification, each premises or site may be treated as part of the wider food business, and the verification frequency and scope may

vary between each premises or site.

h. **Verifiers to report to MPI**. Verifiers must make verification reports available to MPI as reasonably necessary. The verifier must inform the MPI chief executive of any 'critical non-compliance' as soon as possible, and include any recommendations about the actions that the MPI chief executive should undertake. We note that such reports will happen in most, if not, all cases where there is an unacceptable verification result.

i. **Operator verification**. The discussion paper proposed that operators of all food businesses in food control plan or national programme sectors must ensure that internal practices, procedures and activities comply with the applicable requirements of the Food Act by performing regular checks of places, facilities, equipment, people, processes, practices and the like. The one submission on this was in support. We have reconsidered this, and now propose that this be required only of operators working under a custom food control plan. This fits with the higher degree of specialisation and individual responsibility associated with such businesses. In all other cases, it is sufficient that this be dealt with through best practice guidance.

## C: Safety and suitability: food control plans and national programmes

**Legislative provisions for safety and suitability**: **Food Act 1981 and Food Act 2014**

<table>
<tr><td>Food Act 1981 and the Food Hygiene Regulations 1974</td><td colspan="2">Food Act 2014<br>The meaning of safety and suitability is defined as follows:<br>• Safety means a condition in which food, in terms of its intended use, is unlikely to cause or lead to illness or injury to human life or public health.<br>• Suitability means a condition in which the composition, labelling, identification, and condition of the food are appropriate to food in terms of its intended use</td></tr>
<tr><td rowspan="3">The Food Hygiene Regulations establish a defined set of prescriptive requirements for all food businesses subject to these regulations.<br><br>Food businesses that are exempt from the Food Hygiene Regulations because they operate under a food safety programme are already taking a risk-based approach.</td><td>Food control plan businesses</td><td>National programme businesses</td></tr>
<tr><td>Business operator must 'implement and resource all operations …to achieve the safety and suitability of food' and ensure that all operations are commensurate with the capability and capacity … to achieve the safety and suitability of food' (section 50(1)(d)(e)).</td><td>Business operator must 'implement and resource all operations …to achieve the safety and suitability of food' (section 80(d)).</td></tr>
<tr><td colspan="2">Regulations may be made relating to food control plans (43(1)) and national programmes (section 76(1)), including regulations on the following matters:<br>• requirements relating to the safety and suitability of food and good operating practice;</td></tr>
</table>

| | |
|---|---|
| | • controls, restrictions, requirements, and prohibitions, including provisions about how a food sector must manage or deal with risks that arise from trading in food;<br>• requirements for persons to demonstrate competency, to undergo appropriate training, and the provision of training by operators for staff;<br>• requirements for samples and tests to be carried out; and<br>• requirements for management of risks to public health. |

**Safety and suitability: issues to be addressed**

21. The Act requires operators to achieve the 'safety and suitability' of their food, but does not include detail as to what this requires. This detail is to be provided in regulations, and there is also provision for notices on these issues (sections 405 and 406).

22. Further detail on safety and suitability is required to:

    a. protect the consumer;
    b. give certainty and clarity for food businesses and for evaluators and verifiers;
    c. give certainty and clarity for regulators and provide a basis and ability on which to take action;
    d. achieve consistency with other food legislation administered by MPI;
    e. achieve consistency with the application of Codex[3] principles and alignment with international legislation and best practice; and
    f. incorporate the latest knowledge to achieve safe and suitable food.

    The following proposals aim to achieve these purposes.

23. The Food Act aims to move the food safety system from a prescriptive rules-based regime to a performance or outcomes based regime. Consequently, regulations setting out requirements to ensure the safety and suitability of food will generally allow food businesses to determine for themselves how best to achieve a prescribed outcome. The proposed regulations differentiate between food control plans and national programmes in the level of prescription that is provided. Food control plan operators will generally have more discretion to demonstrate how they meet requirements than national programme operators. This is because food control plan operators will operate under their own plans, whereas national programme operators will operate under a programme specified in the regulations.

**C1: Places where food is produced, processed and handled**

Places need to be designed, constructed and located so that they are appropriate for the type of food activities taking place, to help protect food from the risk of contamination, to enable hazards to be effectively controlled or minimised, and to facilitate the effective implementation of supporting systems.

[3] International food safety standards are co-ordinated through the Codex Alimentarius Commission (*codex alimentarius* is Latin for 'food code'). New Zealand is an active participant.

**Proposal**

The discussion paper proposed regulations to require business operators to ensure that places used for food are designed and located in ways that ensure they are suitable with regard to their proximity to incompatible sites and land uses, run-off, flood water, irrigation water, or other environmental contaminants that could introduce hazards, and any prior uses that could result in contamination or unacceptable residues in the food.

Construction and finishes must not be a source of food contamination, and must allow for effective maintenance, cleaning, sanitising, and pest control. They must facilitate the capability and capacity that is needed for food safety, including protecting against cross contamination, providing accessible hand washing and drying, and providing appropriate storage for chemicals, cleaning materials and the like.

We propose that regulations require food business operators to ensure that the places where food is produced, processed, handled and sold are:

a. designed, located and constructed to enable the safety and suitability of food to be achieved and maintained; and
b. maintained to facilitate cleaning and sanitising, and prevent contamination of food.

**C2: Supporting systems**

Effective systems are necessary to manage risks to food safety and suitability.

**Proposal**

The discussion paper proposed regulations to require all food businesses to have effective systems for: cleaning and sanitising; maintenance of places, facilities and equipment; control of pests; waste control; and storage, identification and use of chemicals and other maintenance compounds. Where necessary, to demonstrate compliance, the regulations would require documented procedures and records.

We propose that regulations require food business operators to:

a. Control pests, by conducting inspections and taking corrective action where they are found.
b. Manage waste and recyclable matter by disposing of these at sufficiently frequent intervals.
c. Use chemicals and maintenance compounds appropriate for the task to prevent them from contaminating food.
d. Ensure that water used with food and for cleaning is suitable for the purpose for which it is used.

**C3: Facilities, equipment and essential services**

These must be appropriate to protect food against cross-contamination. The environment must be one that maintains food safety (e.g. it controls temperature, removes moisture, prevents the build-up of moulds etc). They must be capable of being effectively maintained and cleaned to the appropriate standard. Water, sewage and wastewater systems must all be fit for purpose, as must storage, ventilation and lighting.

**Proposal**

The discussion paper proposed regulations to require facilities, equipment and essential services used for food to be appropriate to enable hazards to be effectively controlled, including the protection of food against cross contamination.

We propose that regulations require all food business operators to ensure that the facilities, equipment, and essential services for which they are responsible in relation to the production, 'processing and handling' of food are:

a. designed, constructed, and located to enable the safety and suitability of food to be maintained;
b. operated in a manner that does not exceed their capacity; and
c. are maintained to facilitate cleaning and sanitising procedures, function as intended, and prevent contamination of food.

We propose that regulations require all food business operators under national programmes to ensure that:

a. Adequate drainage and liquid waste disposal systems are provided, and designed and constructed to reduce the risk of contaminating food or water supply.
b. Adequate cleaning facilities are provided, with supply of clean cold and hot water.
c. Laundry activities are operated so as not to be a source of contamination of food.
d. Facilities and amenities are available to enable persons at places used for food to maintain an appropriate level of personal hygiene.
e. Equipment used to control the temperature of food is designed to achieve the required food temperature as rapidly as necessary in the interests of food safety and suitability, and to effectively maintain the temperatures.
f. Equipment is appropriate for the range and volume of food activities processed so that harmful or undesirable micro-organisms or their toxins are effectively controlled.
g. Air quality and ventilation is maintained, and adequate lighting is provided.
h. Adequate facilities are provided for the storage of food, packaging materials, cleaning equipment, and chemical and maintenance compounds.
i. Equipment used with food, and equipment for cleaning places, equipment and surfaces used for food is fit for intended use, and does not contaminate food.
j. Vending machines must only be able to dispense food that is safe and/or suitable at the time it is dispensed.

**C4:People**

The people involved in the production, processing and handling of food can pose risks to food safety and suitability. Relevant factors are personal cleanliness, illnesses or conditions, or inappropriate behaviour.

**Proposal**

The discussion paper proposed regulations to require all people involved in the production, processing and handling of food to follow good hygienic practices so they do not contaminate inputs or food-related accessories or other items.

We propose that regulations require food business operators to:

a. Ensure that all people at any place where food is produced or processed and handled follow an appropriate personal and hand hygiene routine that does not compromise the

safety and suitability of food.

b. Ensure that all people who are known to be, or suspected of being, infected by or a carrier of a disease or illness that is likely to be transmitted through food, are precluded from handling food.
c. Ensure that all people wear appropriate clothing and that the clothing itself does not become a source of contamination.

**C5: Ingredients and food related accessories**

Inputs including food, ingredients, additives and packaging can pose risks to food safety and suitability.

**Proposal**

The discussion paper proposed regulations to require food businesses to take responsibility for ensuring that inputs are sourced from a reputable supplier, and checked for safety and suitability on receipt or before they are used.

We propose that regulations require food business operators to ensure that:

a. Ingredients and food-related accessories that are used in the processing and handling of food are safe and suitable for their intended purpose, and are clearly identified if they are not fit for human consumption.
b. Packaging does not become a hazard to food.
c. They operate a traceability system that allows for the identification of food and enables the movement of food to be traced from the supplier, within the business and to the next person/business in the supply chain (other than the final consumer).
d. They have a procedure that enables recall of food or a food-related accessory where the safety and suitability of food is in doubt. Food businesses will also be required to report any food recall to the MPI chief executive.

**C6: Production, processing and handling**

All food businesses need to have adequate controls throughout their business for the consistent production of safe and suitable food.

**Proposal**

The discussion paper proposed regulations to set out minimum requirements for production, processing and handling.

We propose that regulations require food business operators to ensure that:

a. Food and food-related accessories are processed and handled in a manner that minimises the potential contamination or deterioration of the food.
b. Food does not contain biological, chemical, and physical hazards or extraneous objects, material, or substances. To ensure this, operators must identify hazards and methods to control those hazards, and keep records of critical controls and corrective actions taken if critical controls were not met.
c. When transporting food, operators must ensure that temperature, humidity, atmosphere or other characteristics to keep food safe are maintained, and that the food arrives in a condition that is safe and/or suitable for the intended use.

**C7: Documents, procedures and records**

To enable regulator confidence and due diligence in the event of incidents, documents, are

required to outline what the business will 'do' to ensure safe and suitable food, while records keep note of what the business has 'done'.

**Proposal**

The discussion paper proposed that regulations require documents to be kept four years, and to be readily accessible to any person with responsibilities under the risk-based measure. The documents must meet minimum standards, including legibility, dating, and authorisation.

We propose that regulations require food business operators to ensure that:

a. records are kept that enable the operator, the MPI chief executive, a food safety officer or a verifier to readily ascertain that the business is meeting its regulatory obligations; and
b. all records and documents required to be kept are legible, accurate and complete.

**C8: Corrective action**

Corrective actions will be necessary in the event of non-complying food, emergencies or recalls.

**Proposal**

The discussion paper proposed that regulations require food business operators to have, and effectively implement, a system to prepare for, mitigate, and effectively deal with non-complying food (e.g. food that contains undeclared allergens) and the impact of emergencies (e.g. earthquakes) on food safety and suitability.

We propose that regulations require food business operators to have a system for, and keep records of, corrective actions, including how control was restored, how any affected food was disposed of, and how the competencies of people involved with the loss of control were identified and dealt with.

**C9 Reporting**

Reporting is important when breaches occur or issues arise.

**Proposal**

The discussion paper proposed that regulations would require a food business operator to notify either the MPI chief executive or the territorial authority of any breaches of requirements (e.g. critical non-compliances), or emerging, new or exotic biological hazards or new chemical hazards that come to the operator's notice as soon as practical after their discovery. To assist operators in these reporting duties the regulation would define 'critical non-compliances'.

We propose that regulations require food business operators to report to their verifier any breach of a risk-based measure that has resulted in food that has the potential to cause or lead to illness or injury to human life or public health.

**C10: Competency and training**

People must have the required competencies for the foods and processes they are working with.

**Proposal**

The discussion paper proposed that regulations require food business operators to ensure that those working with food follow good operating practices and have the relevant competencies, or are supervised by a competent person. Requirements were also proposed for corrective action and documentation where necessary.

We propose that regulations require food business operators to ensure that:

a. Persons who can affect the safety or suitability of food, or who carry out activities where a particular competency or skill is required, have the necessary competencies or skills to carry out their tasks.

b. Food business operators must identify the competency or skill needed by the day to day manager and any other person who is responsible for specific tasks.

**Regulatory proposals not progressed**

The discussion paper proposed that the regulations include specific requirements in relation to sampling and testing, and finished products.

Taking account of the submissions and having given further consideration to these proposals we now consider that these aspects are best dealt with through guidance at this point. If this does not prove adequate we will consider regulatory proposals at a later date.

**Consultation response**

A substantial number of submissions were received on these proposals. Many considered that some aspects of the proposals were too prescriptive, while others considered that some proposals lacked adequate detail. In response to submissions some proposals have been:

a. refined to make it clear in which circumstances particular requirements would apply, to which risk-based measures they would apply and what documentary evidence would be required to show compliance;
b. deleted because, on reflection, they are already adequately covered; and
c. earmarked as being more suited to tertiary notices or guidance.

## D: Recognised agencies, persons, and classes of persons

**Legislative provisions for recognised agencies, persons and classes of persons**: **Food Act 1981 and Food Act 2014**

| **Food Act 1981 and Food Hygiene Regulations 1974** | **Food Act 2014** |
|---|---|
| Territorial authorities audit all food businesses operating under the Food Hygiene Regulations.<br><br>Auditors who meet certain criteria and are approved by the chief executive under | The permissible functions and activities of recognised agencies, persons and classes of persons include:<br>• verification functions and activities in relation to food control plans and national programmes;<br>• other verification functions and activities; and<br>• independent evaluations of the validity of custom food control plans.<br><br>Section 137 directly recognises territorial authorities as the |

| | |
|---|---|
| section 8ZV of the Food Act 1981 audit food businesses operating under a food safety programme. These auditors may be engaged by a third party auditing agency or a territorial authority. | sole verifiers of food businesses that operate under a template food control plan issued by the MPI chief executive, operate entirely within the district of the territorial authority, and primarily sell food directly to consumers. Duties that apply to territorial authorities are set out in section 174.<br><br>All other businesses operating under a risk-based measure are to be verified by an agency or person recognised by the MPI chief executive. If a territorial authority wishes to provide services to these businesses it must apply for recognition, and demonstrate that it meets the requirements of recognition in the same manner as any other recognised agency. The MPI website will host a public register of recognised verifiers and evaluators from which businesses will choose.<br><br>Duties that apply to recognised agencies and recognised persons are set out in sections 155 and 156.<br><br>Recognition may be granted to agencies and persons if the applicant is considered to be a 'fit and proper' person to carry out the functions for which recognition is sought. The term 'fit and proper' may include consideration of the applicant's competencies, qualifications and experience, and their character and reputation (sections 135 and 139).<br><br>Section 389(1) provides for regulations[4] to be made about recognised agencies, persons, and classes of persons. These regulations may prescribe:<br>• requirements and procedures for recognition and renewal of recognition;<br>• competencies, qualifications, experience, or other requirements that must be met;<br>• performance standards or other requirements that the recognised agency or person must meet when managing or carrying out their specified functions and activities; and<br>• any particulars that must be contained in the relevant public register. |

**Recognised agencies and persons: issues to be addressed**

24. Recognised agencies and persons have a critical role in helping to ensure the safety and suitability of food. Agencies will generally be incorporated companies, territorial authorities, or Crown entities. However, some sole traders may seek recognition as an agency.

25. Recognised agencies are responsible for managing and carrying out specified functions and activities which may include verification and/or evaluation. Recognised persons

[4] These regulations do not apply to territorial authorities operating under their statutory recognition at section 137. The statutory duties of territorial authorities at section 174 include expectations in relation to the competence of staff.

are responsible for carrying out specified functions and activities which may include verification and/or evaluation.

26. While the Act provides for recognition, it does not provide detail on many of the requirements of recognition. We have concluded that more detail is required to address the issues outlined below.

**D1: Determining whether a person or agency should be recognised**

Confirmation that agencies and individuals seeking recognition are 'fit and proper' would be aided by identification of core requirements and competencies. These must reflect the diverse range of food preparation and service activities and the associated levels of food safety risk of the businesses that will be verified by these recognised agencies and persons.

**Proposal**

The discussion paper proposed regulations to establish core requirements.

Given that agencies are responsible for managing and carrying out functions and activities the proposed core requirements for agencies are:

a. a documented Quality Management System;
b. management of technical competencies; and
c. management of potential conflicts of interest.

A recognised person will be required to demonstrate that they meet specified competencies in respect of skills, experience and knowledge, including in relation to the industry or sector for which recognition is sought.

**Consultation response**. There was strong support for establishing the core requirements for agencies and the core competencies for persons in regulations.

**D2: How agencies seeking recognition will demonstrate that they meet the core requirements**

Given the technical nature of the expected competencies, there needs to be a clearly defined process that can be consistently applied to determine whether or not an applicant for recognition meets these competencies.

**Proposal**

The discussion paper had a preferred option and two alternatives.

**Option 1 (preferred): Differentiation of demonstration method based on the risk and complexity of the food businesses be evaluated and/or verified**.

a. Agencies seeking (or renewing) recognition to manage and carry out the verification and/or evaluation of businesses operating under the highest risk-based measure (custom food control plans) would be required to demonstrate that they meet the requirements through holding accreditation to ISO 17020. This is the international standard for inspection bodies that certify products, processes and activities.

b. Agencies seeking (or renewing) recognition to manage and carry out all other verification functions and activities would demonstrate to the MPI chief executive that they meet the core requirements to the extent relevant to their recognition.

**Option 2: All agencies seeking recognition would be required to demonstrate that they meet the core requirements through holding accreditation to ISO 17020.**

**Option 3: All agencies seeking recognition would be required to be assessed against the core requirements by MPI.**

**Consultation response.** There was strong support for option 1.

**D3: Determining whether recognition should be renewed**

Renewal is an important safeguard as it provides the chief executive with the opportunity to determine whether the agency or person continues to be 'fit and proper' to provide assurances about the safety of food.

**Proposal**

The discussion paper proposed requirements for the renewal of recognition which related to:

a. confirmation that required accreditation remains current, or that the agency can continue to demonstrate the core management and other requirements relevant to its level of recognition;
b. confirmation that the person continues to meet requirements;
c. assessment of performance during the previous period of recognition;
d. consideration of any changes to the 'fit and proper' status of the recognised agency or person; and
e. payment of any prescribed fee.

**Consultation response**. All submissions supported these proposals.

**D4: Performance assessment of recognised agencies and persons**

Performance standards would enable MPI to clarify performance expectations and manage the ongoing performance of agencies and persons to ensure they are meeting their obligations under the Act and remain fit to provide the services for which they are recognised.

**Proposal**

The discussion paper proposed performance standards to be set in regulations.

These standards relate to how agencies manage and carry out their processes and procedures for verification, their corrective action procedures, reporting requirements, and requirements to retain and make available certain information.

The proposed performance requirements for recognised persons focus on ensuring they are meeting the core competencies and all obligations under the Food Act and remain fit to be recognised and provide their recognised functions.

**Consultation response**. Submissions generally supported the proposals. There were some suggestions for changes. One submission suggested that the standards should be in guidance rather than in regulations.

**D5: Requiring evaluators to be recognised**

Section A1 sets out proposals for evaluation of custom food control plans. The Act contemplates that evaluation is a 'permissible function' of a recognised agency or person, but does not require an evaluator to be recognised as such. We consider that the chief executive must have the ability to both nominate evaluators who are 'fit for purpose' and remove those

who do not perform. Requiring evaluators to be recognised will bring the Food Act requirements into line with those of the Animal Products Act 1999 and the Wine Act 2003.

**Proposal**

We propose that regulations require evaluators (agencies and persons) to be recognised.

**Consultation response**

This proposal was not explicitly included in the discussion paper, but the paper included evaluators in the proposals relating to how core requirements should be demonstrated, and in the discussion of core competencies for persons seeking recognition. (These are discussed at sections D1 and D2).

## E: Approved documents, materials, facilities or persons or classes of persons

**Legislative provisions for approved documents etc**: **Food Act 1981 and Food Act 2014**

| **Food Act 1981 and Food Hygiene Regulations 1974** | **Food Act 2014** |
|---|---|
| The approval provisions are similar to those in the Food Act 2014, but have broader scope as they include approving the auditors of food businesses. | MPI chief executive to approve certain documents, materials, facilities, persons or classes of persons, if such approval is a requirement of the Food Act or of regulations or notices made under the Food Act (section 291).<br><br>In making such approvals, the chief executive must first be satisfied that the item is appropriate, safe and suitable for the particular purpose, or if approval concerns a person or class of persons, that they have competencies, training, qualifications, and experience suitable for the particular purpose. The chief executive must take into account any criteria for approvals as set in regulations under section 386.<br><br>The chief executive issues approvals by notice. Further safeguards on approval are the maximum limit of three years for any approval, and the chief executive's power to set conditions on approval, and to suspend or withdraw approval. Section 405 sets out these provisions.[5] |

**Approvals: issues to be addressed**

27. Approvals help to ensure that facilities or people that have key roles in ensuring safety and suitability are suitable and competent for the task. Approvals also save time and money as a business does not have to research appropriate items, providers, processes, and the like, but instead has a list of approved options from which to choose. This helps to overcome the information asymmetry that often applies with technical and specialist

[5] The power of approval may relate to persons or classes of persons, but it cannot be used to 'approve' agencies and persons who will provide verification and related services. These agencies and persons must be recognised by the chief executive under the specific provisions of the Act as discussed above in section D.

skills, facilities and processes; that is, the food business will not necessarily have the information or capability to assess the competency or suitability of the people, facilities and the like. Assuming enough providers and items meet the approval standard, markets are maintained and businesses still have a choice of providers and items.

**E1: Ensuring robust, transparent and consistent approval decisions**

Given that 'approved' people and items are to be relied on, there needs to be rigour in the approvals process.

**Proposal**

Specifying criteria would provide greater transparency as to the factors the chief executive will take into account in approval decisions. The use of criteria should enhance consistency and contribute to better decision-making on approvals, promoting both the safety and suitability of food, and confidence in the food supply.

In 2005, criteria for approvals were consulted on as part of the Domestic Food Review. These criteria were generally supported in the submissions received at that time. The 2015 public discussion paper proposed that these same criteria for approvals be included in regulations.

Three criteria are proposed, as set out below:

a. ***Criterion 1: Improves credibility and confidence*** The approval provides or improves the credibility and confidence in the food supply because the approval reflects one or more of a range of specified factors. These include improved clarity on the competence of persons performing critical activities, industry standardisation that relates directly to food safety or suitability, and consistency with international standards.
b. ***Criterion 2: Improves efficiency*** The approval improves efficiency because the relevant approval will be applied widely and/or consistently, and/or standardisation will be increased.
c. ***Criterion 3: Improves clarity and transparency*** The approval is clear and delivers transparency because it ensures system accountability, and/or improves industry understanding.

**Consultation response.** The majority of submissions on approvals supported the criteria and the proposal that they be in regulations. Reasons cited related to consistency, providing a national benchmark, enhancing transparency and clarity of expectations, and ensuring the legal status of the criteria. A small number suggested the criteria should be in guidance or in a notice if flexibility is necessary.

**MPI response.** We do not support the suggestion that the criteria be in a notice to enable flexibility. Parliament has provided a specific regulation-making power for these criteria so it would not be appropriate to by-pass this and instead make the criteria under the general provision to make notices (section 405(3)). We have, however, considered whether the criteria need to be a legal requirement or whether they could equally serve their purpose to guide the Chief Executive's decision making if they were administrative criteria. This option is assessed in the **Analysis of Options** section of this RIS.

## F: Food standards

**Legislative provisions for food standards**: **Food Act 1981 and Food Act 2014**

| **Food Act 1981** | **Food Act 2014** |
|---|---|
| Arrangements are comparable to those under the Food Act 2014. | Generally provides for food standards to be maintained in their current form, including provision for adoption of joint food standards in compliance with obligations under the Australia New Zealand Food Standards Code (also known as the joint Food Standards Code, or the Food Standards Code). In certain limited and exceptional circumstances, food standards may be issued separately from those set out in the Food Standards Code (part 5, subpart 5). |
| The Minister for Food Safety may issue a standard setting the maximum amounts of contaminants or residues permitted in foods. | MPI chief executive to issue notices setting specifications on maximum amounts of contaminants or residues that may be present in food (section 406(1)(u)). |
| Determined in a standard issued by the Minister for Food Safety. | Regulations may be made to specify how residue levels are to be determined for specified foods, to prohibit the sale of any food containing residues of a substance that exceeds limits set by notice, and to provide for certain exemptions (section 383(4)). |

**Food standards: Issues to be addressed**

**F1: Setting maximum residue levels for agricultural compounds used in food production**

The safety and suitability of food can be affected by residue levels from agricultural compounds that may have been involved in its production. Maximum residue levels (MRLs) in food must be identified systematically and based on best available evidence.

**Proposal**

In the discussion paper we proposed regulations to establish:

a. Criteria to determine maximum residue levels. These include international best practice, consistency with the applicable Codex Standards[6], and methods to determine MRLs with respect to diluted or reconstituted food, or to calculate MRLs in a food consisting of one or more foods.

b. Information that must be included in notices issued by the MPI chief executive to set MRLs. This includes the compound's common name, the Chemical Abstracts Service registry number, and the components to be considered in determining the MRL. The notice must include the food(s) to which the MRL applies, the MRL for the compound

[6] See footnote 3 above.

in relevant foods, and any condition of approval such as a time limit for which the MRL will apply.

c. Conditions of sale for foods containing residues of agricultural compounds. This includes prohibiting sale of food containing residue of an agricultural compound that does not comply with regulatory limits, allowing the sale of food that does not exceed 0.1mg/kg residue of a particular compound unless specifically provided for in notice, and allowing sale of imported food containing residues if it complies with regulations or notices under the Food Act or applicable Codex standards.

d. Circumstances where a food containing a MRL may be exempt from the conditions of sale as specified in a notice under the Food Act, and where it pertains to an agricultural compound for the management of:
   i. plants, or parts of plants, from which food is derived; or
   ii. plants to be fed to animals from which food is derived; or
   iii. animals that are intended for food, or from which the food is to be derived.

**Consultation response**. Submissions were generally supportive of the proposals for regulations concerning maximum residue levels.

## G: Imported food

**Legislative provisions for imported food**: **Food Act 1981 and Food Act 2014**

| **Food Act 1981** | **Food Act 2014** |
|---|---|
| Food importers are required to list with MPI. (The requirement is set out in a notice issued by the MPI chief executive.) | Food imported into New Zealand for the purpose of sale is to be safe and suitable, and importers of food are required to be registered (section 106). |
| The Food (Prescribed Foods) Standard 2007 provides a mechanism for identifying high risk imported food. | Regulations may be made on a range of matters. These include general requirements or requirements specific to categories of food, requirements relating to clearance and in relation to food that is not cleared, when requirements must be met, who is responsible for ensuring they are met, sampling and testing, and record keeping (section 387).<br><br>Section 388 allows for regulations to prescribe verification requirements in relation to importers. |

**Imported food: Issues to be addressed**

28. As imported foods are produced overseas they have not necessarily been developed in a way that establishes they are safe and suitable by New Zealand's standards. Measures to address safety and suitability must take account of:
    a. the very diverse range of food that is imported, from basic ingredients for cooking and processing through to ready-to-eat retail products; and
    b. the range of food importers, from small, family-based operators to large companies and manufacturers.

**G1: Tracing the lifecycle of imported food**

Issues with the safety and suitability of imported food could occur at any point from sourcing of product in the exporting country, through storage and transport during the product's journey, and until the product is given clearance into the domestic market. This means that documentation that describes the lifecycle of imported food is critical if the importer is to demonstrate how they ensure the safety and suitability of the food.

**Proposal**

We propose regulations to set general and record keeping requirements. Importers will not be required to hold the information but must have access to it. The required information relates to: identification of the imported food; the quantity; information to enable verification; information on suppliers; documentation that enables traceability back to the supplier and forward to the next commercial purchaser; and documentation that identifies the location of the food at all times while it is under the importer's control.

We propose that registered importers must have access to this information for four years. This aligns with current practice and with other requirements in the Food Act. Documentation must be in English, or else an English translation may be required. This aligns with current practice and with the Customs and Excise Act 1996.

**G2: Storage and transport**

The manner in which imported food is stored, transported, and handled, both before arrival at the border and at the border, has implications for the safety and suitability of the particular food and of other foods that it may contaminate.

**Proposal**

Regulations will set out storage, transport and handling requirements for imported food (both before arrival at the border and at the border).

**G3: Management of imported food that is not cleared or until it is cleared**

Product that has not been cleared must be properly stored and managed to make sure it does not contaminate other products and does not get into the food system.

**Proposal**

Regulations will establish requirements for registered importers in relation to food that is not cleared to ensure it is clearly identified and withheld from distribution until clearance or direction from a food safety officer. This includes evidence requirements.

**G4: Managing imported food according to risk**

As noted, there a wide variety of foods and importers. Effective and efficient management of the risks posed by the food means that a 'one size fits all' approach cannot be taken to this food. It needs to be categorised according to likely risk and management measures applied as appropriate.

**Proposal**

Regulations will establish risk-based categories of imported food and requirements in relation to food in each category. The categories of imported food are:

a. Food of 'high regulatory interest'. This is high-risk food, or food that is otherwise defined as low risk, but where the food safety controls in the country of origin do not deliver the same or equivalent level of protection from known safety risks as is provided by New Zealand standards. This is comparable to existing provisions for prescribed foods.
b. Food of 'increased regulatory interest' because of uncertainties or concerns about the food's known risk to safety.
c. Food that is not categorised as either high or increased regulatory interest will be considered as low regulatory interest. There will be no requirements specific to this food in regulation.

Regulations will require the MPI chief executive to have regard to specific matters when categorising imported foods. The chief executive must prepare a categorisation report for food that requires clearance. The report will identify the risk level attributed to the food.

High regulatory interest food will require clearance for entry into New Zealand. Regulations will set criteria for clearance.

There are likely to be emerging issues and insufficient information for 'increased regulatory interest' food. Regulations will set requirements to respond to the emerging issue, apply additional measures necessary to ensure the food that is unacceptable is not imported and/or sold in New Zealand, to gather information such as test results and assurances, and to manage issues until resolved. Food in this category may require clearance.

Sampling and testing may be required for high or increased regulatory food and this should be done at a laboratory that has been approved as suitable for the purpose. (See section E Approvals). Food safety officers need a discretion to decide the frequency of testing for consignments of a specific food from a specific importer.

**Consultation response**

Submissions suggested a range of details that should or should not be included in these regulations, but overall did not oppose the proposals. Guidance will be developed to supplement the regulations, for instance in relation to the powers of food safety officers, and to show importers ways to demonstrate compliance.

**G5: Verification of importers**

As noted above in section B, verification is an important tool in ensuring safety and suitability by testing whether a business is complying with the applicable requirements.

**Proposal**

The discussion paper proposed no routine verification of food importers. This proposal was based on the overall risks posed by imported food and the proposed management of risks through categorisation. Importers would, however, be subject to verification if information from other sources indicated this was necessary. This information could come, for instance, from routine systems audits, adverse outcomes through food system monitoring, or compliance action against the importer. Such verification would take place according to a schedule determined by MPI as the registration authority. The schedule would apply until verification outcomes confirm no further verification is required.

**Consultation response**

A number of submissions thought that importers should be subject to routine verification in the same way as businesses operating under food control plans and national programmes. These submissions did not, however, take account of the risk-based categorisation of imported food and the procedures to manage foods of 'high regulatory interest' and 'increased regulatory interest.'

## H: Exemptions

**Legislative provisions for exemptions**: **Food Act 1981 and Food Act 2014**

| **Food Act 1981** | **Food Act 2014** |
|---|---|
| Part 1A provides for a range of exemptions from the Food Hygiene Regulations 1974 for the purpose of facilitating adoption of a food safety programme. (This was introduced in 1997 to provide for a move away from the prescriptive nature of the regulations to a risk-based approach). | Regulations for exemptions may be made under the following provisions:<br>• Section 32 provides for the general exemptions in section 31 not to apply. (These relate to fund-raising activities).<br>• Section 208 provides for exemptions from fees, charges or levies.<br>• Section 343 provides for exemption from the Food Act generally.<br>• Section 345 provides for exemptions of food that is to be exported. |

29. The objective of exemptions is to acknowledge that in some cases better results can be achieved through flexible application of the Food Act's requirements, and that the Act's purposes can still be met despite a particular exemption.

30. The discussion paper proposed only to make a regulation under section 208 to provide for exemptions from fees, charges or levies. This proposal has already been enacted as part of the Food (Fees and Charges) Regulations 2015. There are no further issues in respect of exemptions at this time. After a period of operation, it will become clear whether specific exemption regulations might need to be considered. In the interim, the MPI chief

executive has powers to grant exemptions by notice in particular circumstances, such as for exports. These are adequate to deal with areas for exemption on a case-by-case basis.

## I: Infringements

**Legislative provisions for infringements**: **Food Act 1981 and Food Act 2014**

| **Food Act 1981** | **Food Act 2014** |
|---|---|
| There is no provision for infringement offences. All offences are subject to prosecution. | Sections 222 to 244 specify 22 offences.<br><br>Section 391 empowers the making of regulations about offences. This includes the power to state which of the above offences are to be infringement offences (s391(1)(a)).<br><br>Section 391 further specifies that the offences of breaching or failing to comply with a food standard (as defined in section 243), and breaching or failing to comply with any requirement of the Act or its regulations or notices (section 244) may be prescribed as infringement offences.<br><br>Section 391(1)(d) provides for a fee of up to $1000 to be set for each infringement offence, with provision for different fees for first offence, second offence and subsequent offences. |

**Infringements: Issues to be addressed**

31. An infringement regime enables a compliance officer to quickly and effectively deal with minor offences that warrant more than a warning but less than the full sanction of criminal law. The objective of an infringement scheme is to change behaviours to reduce the harm caused by relatively minor offending.

32. Infringement offences are dealt with by way of a fixed financial penalty, which is served through an infringement notice. A person who commits an infringement offence must pay the fee but does not receive a criminal conviction. The person does not face the expense of going to court to defend a charge. They do, however, have the right to challenge the infringement notice in court. Infringement offences save regulators the costs of prosecutions for relatively minor offences. The requirement to pay the infringement fee provides, however, for effective enforcement and acts to encourage compliance with the law, to hold people accountable for their actions, and to promote a sense of responsibility and educate people about unacceptable conduct.

**I1: Determining which offences should be designated as infringement offences**

To get the maximum benefits from an infringement scheme it is important that the offences are well chosen. Suitable offences are those that are relatively minor and are strict liability (that is there is no need to prove intent or any other state of mind). Suitable offences are those that cover a relatively narrow range of seriousness of conduct, so that a fixed penalty is appropriate. Offences that could involve conduct of a relatively wide range of seriousness are more suited to prosecution and the discretion of a sentencing judge if there is a conviction.

**Proposal**

Our discussion paper proposed that certain offences be designated in regulations as infringement offences. Our process for determining these offences involved analysis of the

offences in the Food Act and requirements in the Australia New Zealand Food Standards code to determine which may be suitable. This analysis was done in accordance with the Ministry of Justice and Legislation Advisory Committee guidelines on infringement offences, and the Ministry of Justice was consulted throughout the process. Submissions were sought from territorial authorities as the co-regulators and proposals were further developed following feedback. To determine the proposed fees we looked at the fees in other infringement schemes and also considered factors relevant to the particular offence, for instance, the costs of registration for the offence of failing to register.

The discussion paper proposed the following infringement offences and fees.

| **Infringement offence** | **Infringement fee** |
|---|---|
| Section 234(1)(c): Failure to register as an importer if required to do so under the Food Act. | $450 |
| Section 240(2): Failure to register a food control plan or to register under a national programme if required to do so under the Food Act. | $450 |
| Section 243(1)(a) Breach of certain requirements in the Australia New Zealand Food Standards code. | $300 (for breach of requirements that relate to general information).<br><br>$450 (for breach of requirements that relate to food safety/public health and a breach of which could contribute to an adverse food safety and public health outcome).<br><br>$650 (for breach of requirements that relate to food safety and a breach of which *would* have a high probability of causing an adverse food safety outcome). |

The discussion paper noted that infringement offences relating to food safety and suitability requirements may be appropriate, but since these requirements were being developed as part of the same round of regulations, infringement proposals could not be developed at that point.

**Consultation response**. There was general support for the proposed offences. A number of submitters felt that the proposed fees were too low. Some proposed making use of the provision for different fees for first offence, second offence and subsequent offences.

We do not propose at this point to use the power to create higher fees for second or subsequent offences. This is a matter we will keep under review once the scheme has been implemented.

Once the Food Act regulations are in force and the authorised transition period for each food sector has ended, we will consider whether any further infringement offences are required. This will provide enough time for businesses to understand the requirements of the new

system. It will also allow time to bed in the range of new tools such as improvement notices. We can then consider whether these tools provide the necessary graduated approach before any expansion of the infringement scheme.

## J: Transitional matters

**Legislative provisions for transitional matters: Food Act 2014**

The introductory period begins on an appointed date and ends three years after that date, unless extended by regulation to a date up to two years later.

During the introductory period each food sector will have an authorised transition period to be set by regulations. This is intended to provide businesses with a staggered and orderly transition to the new requirements (section 413(4)). Up until the end of their particular transition period, businesses will either operate with a deemed food control plan or remain subject to the Food Hygiene Regulations 1974.

Any business that starts on or after 1 March 2016 is immediately subject to the Food Act 2014.

Section 418 provides for transition schedules for the various food sectors to be set in regulations. At the end of the authorised transition period, each food business must operate under the applicable risk-based measure for its food sector, unless the food business is in a sector not subject to a risk-based measure (as set out in Schedule 3).

**Transitional matters: Issues to be addressed**

**J1:Specifying the introductory period**

The introductory period may be extended up to two years beyond the date three years from the appointed start date.

**Proposal**

The discussion paper proposed that regulations extend the introductory period to 30 June 2019 to align more closely with common financial and planning cycles. The first authorised transition period would be 16 months long (1 March 2016 – 30 June 2017), while the second and third would be 30 June to 1 July periods, ending on 1 July 2019.

**Consultation response.** Most of the submissions on this proposal came from territorial authorities, and most of these submissions supported this proposal. Those who did not support it expressed concern that the introductory period would be too long and that the proposal does not address inconsistencies between territorial authorities. Some submitters suggested that the tax or calendar year may be more appropriate.

**MPI response.** After further consideration we propose not to extend the introductory period at this time. Instead we will remain with the three year period as intended by the Act, and retain the ability to extend the introductory period at a later date if it is necessary to do so. The introductory period will therefore end on 28 February 2019. The authorised transition periods will be 1 March 2016 to 30 June 2017, 1 July 2017 to 30 June 2018, and 1 July 2018 to 28 February 2019.

**J2: Specifying the transition timeframes and schedules**

Regulations are required to specify the authorised transition period for each food sector. Setting transition periods helps to smooth the transition for businesses and gives them time to understand and prepare for the new requirements. It helps to spread the introductory workload for the regulators and means both they and the verifiers can better manage their start up roles alongside their new business-as-usual roles.

Transitional matters were consulted on in 2006, 2007 and 2009. Based on these exercises, we identified the main considerations for a transition schedule are spreading the workload for regulators and verifiers across the introductory period, and managing industry expectations. The latter includes minimising surprises, allowing time for businesses subject to national programmes to understand the new requirements, and allowing businesses to register under the new system at the time they are next due to register to avoid additional registration costs.

**Proposal**

The discussion paper proposed a transition schedule that generally takes a risk-based approach to the transition, with higher risk (food control plan) businesses in the first two transition periods and lower risk businesses (national programmes) in periods two and three. National programme level 1 businesses (the lowest risk) would all transition in period three. Based on the proposed schedule, we estimate the number of businesses transitioning in each period to be: period one: 9365; period two 17,220; period three 19,285.

**Businesses already operating under a risk-based measures.** The discussion paper also sought views on the transition options for businesses currently operating risk-based measures. These businesses are either in the voluntary implementation programme (4 390 restaurants, cafes and caterers) or are operating under an approved food safety programme (2 463 supermarkets, fast food retailers and bakeries). The question is whether they should transition with their sectors in the first or second period, or whether they should be free to transition at any time until the conclusion of the third period.

**Consultation response.** The majority of submissions supported the proposed schedule. Submitters supported the broad intent of moving the highest risk first, and saw the schedule as allowing for effective management of workload.

Submissions generally supported extending the transition period for operators under the voluntary risk-based measures. Supporters noted the lower risk posed by these early adopters and the greater flexibility this would allow for businesses. Other submissions did not support the later transition. These submissions noted that it should not be difficult for these businesses to transition and they should continue to be industry leaders by transitioning early.

**J3 Timeframe for registration applications**

The discussion document proposed that registration applications must be received three months before the relevant transition period ends. This is designed to avoid a potential logjam of businesses choosing to register right at the end of their transition period.

**Consultation response.** Submitters did not express views on this proposal. The proposal will be retained.

# Objectives and assessment criteria

33. The Food Act, section 4 states that the purpose of the Act is to:
    a. Restate and reform the law relating to how persons trade in food; and
    b. Achieve the safety and suitability of food for sale; and
    c. Maintain confidence in New Zealand's food safety regime; and
    d. Provide for risk-based measures that-
        i. Minimise and manage risks to public health; and
        ii. Protect and promote public health; and
    e. Provide for certainty for business in relation to how the requirements of this Act will affect their activities; and
    f. Require persons who trade in food to take responsibility for the safety and suitability of that food.

34. Any regulations to implement the Food Act should be designed so as to further the purpose of the Act in ways that are as consistent as possible with good regulatory practice. This includes being effective and administratively efficient by not imposing undue burdens or compliance costs on the regulated community. Regulations should be practical and feasible to understand and apply, both for the food businesses and for the regulators, especially in relation to compliance and enforcement. Requirements must be consistent and fair across sectors and groups, with differences based as far as possible on science–based risk assessments.

35. Talking account of the purpose of the Food Act and the characteristics of good regulatory practice as noted above, the overall objective for this work to:

    establish initial requirements for the implementation of the Food Act that effectively **support the safety and suitability of food for sale** and **maintain confidence in the food safety system** by:

    - **being consistent and fair,** with differences **proportionate** and based as far as possible on **science–based risk assessments**;
    - **providing certainty to food businesses** while still encouraging them to **take responsibility for the safety and suitability of their food**; and
    - **promoting administrative efficiency by not imposing undue compliance costs** on either food businesses or regulators.

## Criteria for assessment

36. We have used this objective to develop criteria for analysis. Where there are trade-offs to be made between criteria, effectiveness in promoting the safety and suitability of food for sale is the most important, as this is the overall purpose of a food safety regulatory system.

37. The criteria are:
    a) **Effectiveness**: Promotes the **safety and suitability of food for sale** and maintains **confidence in the food safety system.**
    b) **Administrative efficiency**: Does **not impose undue compliance costs** for either food providers or the regulators.
    c) **Proportionality:** Differences are **risk–based**.
    d) **Certainty:** Businesses are clear about how they will be impacted.

38. In the following section we use these criteria to analyse the status quo 'do nothing' option, and to analyse our proposals for regulations, as well as proposals for guidance

alone where this is a feasible alternative. This analysis uses the criteria to assess the likely impacts of each option and identify which options provide the greatest net benefit to New Zealanders.

39. The symbols × and ✓ indicate the assessment, ie whether the option on balance meets or does not meet the criteria. Where the symbols are doubled (× × and ✓ ✓) the option very clearly meets or does not meet the criteria. In some cases the assessment is neutral (—).

# Analysis of options

## A: Registration

### A1: Assessment of options for formalising the evaluation of custom food control plans

| | Effectiveness (promotes food safety and suitability) | Administrative efficiency (does not impose undue compliance costs) | Proportionality (in relation to risk) | Certainty (on how businesses will be impacted) | Summary |
|---|---|---|---|---|---|
| **Status quo No regulations or guidance on the evaluation process** | × × Each evaluator would develop their own process, which may or may not provide information sufficient to enable MPI to make a robust registration decision. | × × If reports need to be redone because there is insufficient information this will result in costs and delays for businesses, evaluators and MPI. | × × It would be contrary to a risk-based approach to provide no framework for the evaluation of these plans, which represent the highest risk within the food control plan category. | × × There would be no certainty. | Does not meet the criteria. |
| **Guidance on the evaluation process** | × Reports that do not follow the guidance may not provide the necessary assurance to the registration authority (MPI) on whether the plan is adequate to address the risks of the business. | × Depending on the extent to which evaluators follow the guidance, there may be a wide variation in the coverage and quality of evaluation reports. This may require extra work for MPI in assessing the report, possibly requiring extra work from the evaluator and in turn imposing extra costs on the business. | × As noted above, these are the highest risk businesses, so a robust evaluation process is critical and this cannot be assured by the use of guidance alone. | — Guidance would stop short of providing certainty to the business, though it would provide a reasonable expectation. | Does not meet the criteria. |

| | Effectiveness (promotes food safety and suitability) | Administrative efficiency (does not impose undue compliance costs) | Proportionality (in relation to risk) | Certainty (on how businesses will be impacted) | Summary |
|---|---|---|---|---|---|
| **Regulations to set minimum requirements for the evaluation process** | ✓ Setting legal requirements increases the likelihood that the evaluation process will fulfill its purpose as a major safeguard against registration of an unfit plan or business. | ✓ ✓ Setting legal requirements helps to contain evaluation costs as evaluators will know what to do, and there will be less chance MPI will require further evaluation because of unsatisfactory reports. Standardised reports can be quickly assessed. The waiver power for on-site visits means costs can be avoided where they are not justified. | ✓ ✓ Given the high risks associated with businesses operating under a custom food control plan and the importance of the evaluation report in managing these risks, it is appropriate to specify the legal requirements. Proportionality is enhanced by the risk-based waiver power for on-site visits. | ✓ ✓ Businesses will know what to expect from the evaluation process. | Meets all criteria. The regulations were broadly supported by submissions, with comments mainly on the details. Guidance will supplement the regulations in respect of areas where submitters sought more detail. |

## A2: Assessment of options for specifying the physical boundaries of a business subject to a food control plan

| | **Effectiveness (promotes food safety and suitability)** | **Administrative efficiency (does not impose undue compliance costs)** | **Proportionality (in relation to risk)** | **Certainty (on how businesses will be impacted)** | **Summary** |
|---|---|---|---|---|---|
| **Status quo No regulations or guidance on specifying the boundaries** | × × Registration authorities and verifiers would need to seek this information in any case, and would need to specify each time what they need. | × × There would be cost and time delays while this information is sought and especially if further requests need to be made. | × × These are higher risks businesses so it is important that the registration authorities and verifiers have information to help them perform their roles. | × × There would be no certainty as requests for information would vary according to the registration authority or the verifier. | Does not meet the criteria. |
| **Guidance on specifying the boundaries** | × While guidance may be followed it does not need to be. Registration authorities and verifiers may need to seek further information. | × If the guidance is not followed there will be cost and time delays while information is sought and especially if further requests need to be made. | × These are higher risks businesses so it is important that the registration authorities and verifiers have information to help them perform their roles. This cannot be assured by the use of guidance alone. | — Guidance would stop short of providing certainty to the business, though it would provide a reasonable expectation. | Does not meet the criteria. |

| | Effectiveness (promotes food safety and suitability) | Administrative efficiency (does not impose undue compliance costs) | Proportionality (in relation to risk) | Certainty (on how businesses will be impacted) | Summary |
|---|---|---|---|---|---|
| **Regulations to require information about the physical boundaries to which the food control plans apply** | ✓ Provides information to assist decisions on registration and to facilitate subsequent verification. | ✓ Information required is not onerous. Larger businesses are likely to have such information as part of building approvals processes. Smaller businesses can provide a simple sketch. | ✓ Businesses provide the degree of detail that is appropriate to their circumstances as long as they meet the information requirements. | ✓ Businesses know this is a part of the registration process. | Meets all of the criteria. Most submissions supported the proposal. Guidance will supplement the regulations and assist businesses with examples of how they might meet this requirement. |

## A3: Assessment of options for the duration of registration for businesses operating under national programmes

| | Effectiveness (promotes food safety and suitability) | Administrative efficiency (does not impose undue compliance costs) | Proportionality (in relation to risk) | Certainty (on how businesses will be impacted) | Summary |
|---|---|---|---|---|---|
| **Status quo No regulation to set registration duration** | × × Registration authorities could administratively set durations, but these would vary and re-registration would be voluntary, so registration information would become out of date. | × Businesses would not face re-registration costs but registration authorities may request business information in any case, resulting in costs for both them and the businesses. | × The absence of reliable information about food businesses will make ongoing risk assessment through monitoring and compliance very difficult. | × × There would be no certainty as businesses may be subject to administrative requests for information in any event, and registration authorities would have no certainty they would receive the information. | Does not meet the criteria. |

| | Effectiveness (promotes food safety and suitability) | Administrative efficiency (does not impose undue compliance costs) | Proportionality (in relation to risk) | Certainty (on how businesses will be impacted) | Summary |
|---|---|---|---|---|---|
| **Regulations to set the duration of national programme registration at 12 months** | ✓ Annual turnover of food businesses is about 25%, so annual registration should enable registration authorities to have reasonably up-to-date information on the food businesses for which they are responsible. | — Annual registration imposes a cost on businesses. This is not a new cost for most businesses as they are already subject to annual renewal. Most of these businesses will register with territorial authorities (TAs), so the cost will depend on the fees the TAs set. The TAs are, however, required to have regard to the Act's cost recovery principles, to not recover more than reasonable costs, and to undertake public consultation on their fees. In calculating their reasonable costs TAs will need to take account of any contribution they need to make to MPI for the cost of building and operating the national register, as well as their own business system and labour costs. | — These are medium to low risk businesses, so it may not be proportionate to have them on the same registration renewal timeframe as the higher risk businesses subject to food control plans. However, having reasonably up to date information on the public register assists with identifying and managing risk through monitoring and compliance actions. | ✓ ✓ Business know what is required. | Meets the effectiveness, and certainty criteria. Although submissions varied in their responses, there was strong support from territorial authorities. |

| | Effectiveness (promotes food safety and suitability) | Administrative efficiency (does not impose undue compliance costs) | Proportionality (in relation to risk) | Certainty (on how businesses will be impacted) | Summary |
|---|---|---|---|---|---|
| **Regulations to set the duration of national programme registration at 24 months** | × Given the turnover of food businesses, this would result in a less reliable public register of food businesses than would be the case with annual renewal. A reliable register is important for monitoring by regulators and during incident responses such as targeted recalls. | ✓ May result in a small reduction in registration fees relative to annual renewal. This would be due to lower variable costs for TAs. (They would service this function once every 2 years only). Some of these businesses will register with MPI, which would also face slightly lower variable costs. However, MPI would still need to cover the fixed costs of building and operating the national register and TAs would still need to contribute to these costs. These fixed costs will be the same whether registration is annual or biennial, so the overall fee reduction to businesses may not be significant. | — Could be regarded as proportionate to have these businesses on a longer registration renewal timeframe than the higher risk businesses subject to food control plans. On the other hand, risk identification and management will be inhibited by the reduced reliability of the register. | ✓ ✓ Business know what is required. | This option does not meet the effectiveness criterion as the register is likely to become quite out of date over the 2 year period. It meets the efficiency criterion through a likely small reduction in the fees businesses would pay, but this reduction is not expected to be material. |

## A4: Assessment of options for the appropriate registration authority for businesses operating under national programmes

| | Effectiveness (promotes food safety and suitability) | Administrative efficiency (does not impose undue compliance costs) | Proportionality (in relation to risk) | Certainty (on how businesses will be impacted) | Summary |
|---|---|---|---|---|---|
| **Status quo No regulation to set the registration authority** | This is not an option. Section 82 requires that the appropriate registration authority (MPI or the relevant territorial authority) is provided for by regulations under section 76. | | | | |
| **Regulations to establish MPI as the registration authority** | × Given that the registration authority is also responsible for compliance, this option would detract from effectiveness as a national organisation is not well placed to be aware of local issues and context. | ✓ The fee for registration with MPI has been set already under the Food (Fees and Charges) Regulations 2015. | × The Act makes MPI the registration authority only for higher risk businesses, (custom food control plans). It would be inconsistent, to have MPI as registration authority for these medium and low risk businesses. | ✓ All businesses would know who to register with. | Does not meet the effectiveness and proportionality criteria. |

| | Effectiveness (promotes food safety and suitability) | Administrative efficiency (does not impose undue compliance costs) | Proportionality (in relation to risk) | Certainty (on how businesses will be impacted) | Summary |
|---|---|---|---|---|---|
| **Regulations to establish the territorial authority (TA) as the registration authority, with choice of TA for mobile businesses operating across TA boundaries, and choice of MPI or registration with each TA for multi-site businesses** | ✓ Continues status quo. Preserves existing relationships and ongoing relationships between TAs and local businesses. | — This will depend on registration fees set by TAs but they are required to have regard to the Act's cost recovery principles, to not recover more than reasonable costs, and to undertake public consultation on their fees. | ✓ Registration with TAs in most cases is consistent with the risk-based approach. | ✓ Businesses will have certainty and some would have a choice. | This is a better option than registration with MPI in terms of effectiveness and proportionality. Submissions provided overall support for the proposals. |

## B: Verification

## B1: Assessment of options for specifying verification frequencies and enabling performance based verification frequency

| | Effectiveness (promotes food safety and suitability) | Administrative efficiency (does not impose undue compliance costs) | Proportionality (in relation to risk) | Certainty (on how businesses will be impacted) | Summary |
|---|---|---|---|---|---|
| **Status quo No regulation to set verification frequencies** | × × It would not be effective to leave it to the business to determine frequency. Poor performing businesses would have no incentive to be verified. To leave the registration authority to establish frequencies administratively would be ineffective. | × × Businesses that do not choose to be verified would not face any costs but registration authorities would face the costs of seeking compliance information in other ways. | × × Given the importance of verification to managing risk this is not proportionate. | — It would be up to businesses how often they are verified. There would be no certainty for registration authorities. | Does not meet the criteria. |
| **Regulations to set verification frequencies** | ✓ The proposed initial frequencies will provide relevant information within a reasonable time of establishment. Ongoing frequencies will provide information at a frequency that matches performance. | ✓ ✓ Ongoing performance-based verification frequency reduces compliance costs for well performing businesses. | ✓ ✓ The initial schedule is set according to the risk-based measure. Ongoing performance-based verification frequency responds to identified risks. | ✓ All businesses would know what to expect. | Meets all criteria. Guidance will be developed to assist verifiers to make recommendations on movements between verification frequency steps |

## B2: Assessment of options for specifying verification processes

| | Effectiveness (promotes food safety and suitability) | Administrative efficiency (does not impose undue compliance costs) | Proportionality (in relation to risk) | Certainty (on how businesses will be impacted) | Summary |
|---|---|---|---|---|---|
| **Status quo No regulations to set verification processes** | × × Verifiers will operate according to their own practices which may or may not produce relevant information. | × × Verifiers will operate according to their own practices so there will be less certainty that the processes will not impose undue compliance costs. | × × Given the significance of verification to the overall system it does not make sense to not formalise the process to some extent. | × × Processes will vary according to verifiers so businesses will not have certainty. | Does not meet the criteria. |
| **Regulations to set verification processes** | ✓ The proposed requirements are designed to provide the relevant information and encourage businesses to take responsibility for safety and suitability. | ✓ The requirements should standardise the process and help to reduce costs. | — The requirements are the same for all businesses that operate under a risk-based measure. | ✓ ✓ All businesses will know what to expect. | Meets the effectiveness, efficiency and certainty criteria. |

## C: Assessment of options to address safety and suitability

| | Effectiveness (promotes food safety and suitability) | Administrative efficiency (does not impose undue compliance costs) | Proportionality (in relation to risk) | Certainty (on how businesses will be impacted) | Summary |
|---|---|---|---|---|---|
| **Status quo: No regulations to establish requirements for safety and suitability** | × × The lack of safety and suitability specifications would make it very difficult for businesses, verifiers and regulators to determine what is required. Preventative compliance action may be difficult and this is likely to lead to an increase in food safety incidents. | × × The lack of safety and suitability specifications may impose extra costs as businesses do not know what is required and may take unnecessary measures. | × × This would not be proportionate to the risks posed by the identified areas. | × × Businesses would not know what is required in order to ensure their food is safe and suitable. | Does not meet criteria. |
| **Guidance to establish requirements for safety and suitability** | × While guidance may be followed, it does not need to be. Guidance does not provide a standard that regulators can enforce, so preventative compliance action may be difficult. There may be an increase in food safety incidents. | — Guidance does not impose compliance costs as businesses can determine whether or not to follow it. If businesses do not follow the guidance, and this results in food safety incidents, the businesses will face prosecution costs. | × This would not be proportionate to the risks posed by the identified areas. | — Guidance would stop short of providing certainty to the business, though it would provide a reasonable expectation. | Using guidance alone to address safety and suitability risks is out of step with a risk-based approach of the Act. |

| | Effectiveness (promotes food safety and suitability) | Administrative efficiency (does not impose undue compliance costs) | Proportionality (in relation to risk) | Certainty (on how businesses will be impacted) | Summary |
|---|---|---|---|---|---|
| **Regulations to set requirements for safety and suitability** | ✓ ✓ Prescribing outcomes for specific matters provides standards that verifiers can use to assess businesses and identify where corrective actions are required. This enables proactive management of risks before they escalate into food safety incidents. | ✓ ✓ Requirements are mostly set at outcome levels. Businesses can determine for themselves how best to meet the prescribed outcomes. | ✓ ✓ Setting requirements in regulation takes account of the risks posed by the identified areas. The outcomes focus means requirements can be met in ways that are commensurate with risk. | ✓ ✓ Businesses know the outcomes that are required. | Meets the criteria. Regulations to establish outcomes in the identified areas set clear expectations, but move away from the prescriptive 'one size fits all' approach of the Food Act 1981. |

## D: Assessment of options for regulations to specify requirements for the recognition process

| | Effectiveness (promotes food safety and suitability) | Administrative efficiency (does not impose undue compliance costs) | Proportionality (in relation to risk) | Certainty (on how businesses will be impacted) | Summary |
|---|---|---|---|---|---|
| **Status quo: No regulations to establish requirements for the recognition process** | — Given that MPI decides on recognition, MPI would still have to measure that agencies and persons meet requirements. Effectiveness will depend on how this is done. | × Leaving these matters unspecified may lead to costs and delays as MPI works out the procedures and seeks information from agencies and persons. | × × Leaving these matters unspecified is not proportionate to the key roles of recognised agencies and persons in assuring food safety. | × × Agencies and persons will not be clear on what is required to meet the 'fit and proper' person requirements. Operational requirements can be changed without any consultation with stakeholders. | Does not meet criteria. |
| **D1,3,4: Regulations to set core requirements and competencies for recognition, to set requirements for renewal, and to define performance standards** | ✓ Specifying these matters will help ensure that all relevant matters are taken into account, and there is a consistent approach. | ✓ The requirements are set at a high level so that agencies and persons can demonstrate them to the degree appropriate to their level of recognition. | ✓ ✓ Given the key roles of recognised agencies and persons it is proportionate to set requirements in relation to recognition and ongoing performance. | ✓ ✓ Agencies and persons will know what is required. Requirements can only be changed after a formal consultation process. | Meets criteria. |

## D2: Assessment of options for demonstrating core requirements as part of recognition

| | Effectiveness (promotes food safety and suitability) | Administrative efficiency (does not impose undue compliance costs) | Proportionality (in relation to risk) | Certainty (on how businesses will be impacted) | Summary |
|---|---|---|---|---|---|
| **Option 1: Regulations to set different demonstration method for core requirements, based on the food safety risks of the businesses being evaluated or verified (preferred)** | ✓ Accreditation to ISO 17020 provides a robust, independent assessment of those seeking to undertake evaluations and verifications of the highest risk tools (custom food control plans). The MPI assessment should be sufficient for other applicants who will verify lower risk businesses. | ✓ Most third party auditing companies already have accreditation to ISO 17020 or perform to that standard.<br><br>The costs of accreditation by a certified accreditation agency may be higher than the costs of assessment by MPI. This could be a disincentive for sole operators and small businesses looking to enter the market, and could reduce choice and increase costs for some food businesses. On the other hand, the MPI assessment process would be expected to result in reasonable costs for most applicants, and in turn for food businesses. | ✓ ✓ This proposal matches the demonstration method to the food safety risks of the businesses being evaluated or verified. | ✓ Those applying for recognition will know what is required, although with less certainty regarding the MPI process until it becomes more established. | Meets the criteria. This option was strongly supported in consultation. |

| | Effectiveness (promotes food safety and suitability) | Administrative efficiency (does not impose undue compliance costs) | Proportionality (in relation to risk) | Certainty (on how businesses will be impacted) | Summary |
|---|---|---|---|---|---|
| **Option 2 Regulations to require all agencies seeking recognition to demonstrate core competencies through accreditation to ISO 17020** | ✓ This would promote a high level of consistency in the national approach to recognition. It is consistent with current requirements under the Animal Products Act. | × The requirements of accreditation could be disproportionate for small agencies with small client bases among whom to spread costs, thus impacting on compliance costs. | × This sets a standard that is not necessarily required for all verification activity, particularly for businesses operating under template food control plans. | ✓ Those applying for recognition will be clear on what is required | Requiring all recognised agencies to hold accreditation to an international standard would impose compliance costs that are not commensurate with the risk level of the businesses that most agencies will verify. |
| **Option 3: Regulations to require all agencies seeking recognition to be assessed against the core requirements by MPI** | × Although MPI holds ISO 17020 accreditation it is not a certified accreditation body, and is unlikely to provide assessment to the same level as an ISO accreditation. This would detract from effectiveness in relation to the higher risk recognitions. | ✓ The cost of MPI assessment may be less than the cost of ISO accreditation. | × Using the same demonstration method regardless of the nature of the food operation being verified or evaluated does not take a risk-based approach. | — Those applying for recognition would know what is required, although there may be less certainty than under ISO accreditation as the MPI process is yet to be developed. | Does not meet any criteria other than efficiency. |

## E: Assessment of options to specify criteria for approvals

| | Effectiveness (promotes food safety and suitability) | Administrative efficiency (does not impose undue compliance costs) | Proportionality (in relation to risk) | Certainty (on how businesses will be impacted) | Summary |
|---|---|---|---|---|---|
| **Status quo No regulations or guidance for approvals** | × × Approvals will be based on the provisions in the Act but without the benefit of extra specification as to what constitutes appropriateness, safety and suitability and the like in this context. | × × Costs and delays may arise as those applying for approval will not be clear as to what they need to demonstrate. | × × Given the significance of approvals in managing risks, it is not proportionate to have no formal criteria to guide decision-making. | × × In the absence of published criteria there cannot be certainty as to how the chief executive will judge appropriateness, safety and suitability and the like. | Does not meet criteria. |
| **Administrative criteria for approvals** | — The criteria have been well consulted on (in 2005 and 2015) so are likely to promote quality decision-making, providing they are adhered to and do not change. Administrative criteria can be more easily changed than regulatory, so effectiveness could go up or down depending on any change. | — The compliance costs fall on the organisations or people applying for approval and on the approver (MPI). Providing the criteria do not change, the compliance costs should be the same whether they are administrative or regulatory. Administrative criteria can be more easily changed, so costs could go up or down. | × Given the significance of approvals in managing risks it is arguable that the criteria should be legally binding. | × Certainty is reduced given that the criteria could be changed at any time without the formal requirement for consultation (as is required for a regulation). | Does not meet criteria. |

| | Effectiveness (promotes food safety and suitability) | Administrative efficiency (does not impose undue compliance costs) | Proportionality (in relation to risk) | Certainty (on how businesses will be impacted) | Summary |
|---|---|---|---|---|---|
| **Regulations to set criteria for approvals** | ✓ The criteria have been well consulted on (in 2005 and 2015) so are likely to promote quality decisions. If the criteria are found to be inflexible or not relevant having them in regulations makes for a lengthy process to change them, but this would require consultation, and should provide a sound basis for any changes. | — The compliance costs should be the same whether the criteria are regulatory or administrative. | ✓ ✓ Setting the criteria in regulations is in keeping with the importance of approvals in managing risks. | ✓ ✓ Certainty is provided by making the criteria a legal requirement that cannot be changed without further consultation. | Delivers higher benefits than administrative criteria, mainly because of the durability and certainty provided by regulations, and the inability to change regulatory criteria without further consultation. The majority of submissions (2005 and 2015) supported criteria in regulations. |

## F: Assessment of options for setting maximum residue levels and managing food with residues

| | Effectiveness (promotes food safety and suitability) | Administrative efficiency (does not impose undue compliance costs) | Proportionality (in relation to risk) | Certainty (on how businesses will be impacted) | Summary |
|---|---|---|---|---|---|
| **Status quo: no regulations or guidance on setting and managing residues** | — Notices would still be issued regarding residue levels but these would be done without a specific regulatory framework. Given all notices come from the same authority, MPI, administrative process could provide consistency. | — In the absence of a specific regulatory framework, notices may impose undue restrictions. | × × Given the potential harm from residues it would be proportionate to have a regulatory framework for the making of notices. | × × There would be no certainty as to the relevant factors for decision-making, nor on content of notices. | Does not meet criteria. |
| **Regulations on setting and managing residues** | ✓ The proposed criteria to determine maximum limits are derived, in the main, from the existing New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards, and can therefore be expected to be effective. | — The proposals do not impose costs other than on MPI as the issuer of notices. | ✓ Provides for notices to be made to allow food sales and exemptions in certain conditions. | ✓ ✓ Provides certainty for regulators and businesses as to what must be included in notices. | Meets the criteria. |

## G: Assessment of options for addressing issues with imported food

| | **Effectiveness (promotes food safety and suitability)** | **Administrative efficiency (does not impose undue compliance costs)** | **Proportionality (in relation to risk)** | **Certainty (on how businesses will be impacted)** | **Summary** |
|---|---|---|---|---|---|
| **Status quo: no regulations or guidance on managing issues with imported food** | ✗ ✗ Importers and regulators would need to work things out as they go. | ✗ ✗ Costs and delays would arise as importers and regulators work out what to do on a case by case basis. | ✗ ✗ There would not necessarily be proportionality if importers and regulators work out what to do in a case by case basis. | ✗ ✗ Importers would not know what is required to provide for safety and suitability. | Does not meet criteria. |
| **G1: Regulations to establish general requirements for importers to have access to certain information for 4 years to enable traceability of imported food** | ✓ The information required covers all aspects of the lifecycle up until clearance. | ✓ Importers have flexibility about how they provide access to the information. They do not have to hold it themselves. | ✓ Although information requirements are the same for all importers, they are based on the risks posed by all imported foods | ✓ Importers know what is required. | Meets all criteria. Guidance will be developed to supplement the regulations. |
| **G2: Regulations to set storage, transport and handling requirements** | ✓ This targets particular risk areas in the import process. | ✓ Compliance costs will be highest for those who pose the greater risk. | ✓ Required actions will be determined by the type of food and therefore are proportionate to the risks posed. | ✓ Importers know what is required. | Meets all criteria. Guidance will be developed to supplement the regulations. |

| | Effectiveness (promotes food safety and suitability) | Administrative efficiency (does not impose undue compliance costs) | Proportionality (in relation to risk) | Certainty (on how businesses will be impacted) | Summary |
|---|---|---|---|---|---|
| **G3: Regulations for the management of not-cleared imported food** | ✓ This targets a particular risk area in the import process. | ✓ Compliance costs will be highest for those who pose the greater risk. | ✓ This targets a particular risk area in the import process. | ✓ Importers know what is required. | Meets all criteria. Guidance will be developed to supplement the regulations. |
| **G4: Regulations to categorise and manage imported food according to risk** | ✓ Setting categories based on risk and applying specific requirements to each category means effort is focused where it is most needed. | ✓ The proposed categorisation system has more robust criteria than the Food (Prescribed Foods) Standard 2007. This will enable better targeting of imported foods and reduce unnecessary intervention at the border. | ✓ ✓ The criteria will enable effective targeting according to risk. | ✓ Certainty is provided by categorisation. | Meets all criteria. Guidance will be developed to supplement the regulations. |

## I: Assessment of options to establish infringement offences

| | Effectiveness (promotes food safety and suitability) | Administrative efficiency (does not impose undue compliance costs) | Proportionality (in relation to risk) | Certainty (on how businesses will be impacted) | Summary |
|---|---|---|---|---|---|
| **Status quo: no regulations to create infringement offences** | × The absence of infringement offences for less serious non-compliance reduces the effectiveness of the compliance and enforcement system. Prosecution is often assessed as too time-consuming and expensive, while overuse of warnings reduces incentives to comply. | × Prosecution for minor non-compliance would impose costs for the regulator and the business that may be disproportionate to the seriousness of the offence. | × The absence of infringement offences reduces the opportunities for proportionate responses to less serious offending. | × Businesses would face the uncertainty of prosecution and sentencing if convicted. | This options does not meet the criteria. |
| **Regulations to establish infringement offences as proposed** | ✓ Compliance and enforcement is enhanced when minor non-compliance is dealt with swiftly as is possible with infringement fees. | ✓ Businesses and regulators face less costs compared with prosecution. | ✓ Infringement offences allow for proportionate responses to less serious offending. | ✓ Infringement offences provide certainty as there is a fixed fee. | Meets all criteria. |

## J: Assessment of transition options for businesses already operating under a risk-based measure

| | Effectiveness (promotes food safety and suitability) | Administrative efficiency (does not impose undue compliance costs) | Proportionality (in relation to risk) | Certainty (on how businesses will be impacted) | Summary |
|---|---|---|---|---|---|
| **Status quo: no regulations to set transition periods** | This is not possible as the Act clearly anticipates that regulations will establish transition periods based on food sectors (section 413(4)). | | | | |
| **Regulations to require businesses operating a voluntary risk-based measure to transition with their sectors** | ✓ Moving the highest risk sectors to the new regime in the earlier periods provides for effective management of food safety and suitability. | × This may be seen as imposing undue costs on businesses by not recognising their voluntary efforts through the benefit of extra flexibility. | × Does not take account of the lower risk of these particular businesses within their sectors. | ✓ Both the businesses and the regulators have certainty as to when transition is required. | Meets effectiveness and certainty criteria. |
| **Regulations to allow these businesses operating a voluntary risk-based measure to either transition with their sector (generally in period 1 or 2) or transition by the end of period 3** | ✓ Once the Act comes into force these businesses are deemed to be operating under a food control plan, so they will be subject to verification and compliance action in accordance with that risk based measure even before they formally transition. | — Provides maximum flexibility to these businesses to manage their transition costs. It may be less efficient for the regulators as they will not be able to plan so well for transitions. | ✓ Assuming these businesses present a lower risk, allowing them to transition in their own time is proportionate to risk. | × There is less certainty for the regulator as to when a business will decide to transition. | Has slightly higher net benefits overall. Certainty is lower for the regulators, (MPI and territorial authorities). This can be managed through the regulators' ongoing relationships and communications with these businesses. |

## Cost impacts on businesses

40. Appendix B provides estimated compliance costs for food businesses. These estimates are subject to a number of limitations as described in Appendix B. The factors that will have most impact on the costs a business faces will be:
    a. The extent to which the business is already performing well.
    b. The extent to which it may need to change as a consequence of transition to the Food Act. The change could mean either an increase or a decrease in costs, but it will mean the costs are more proportionate to the risks the business poses.
    c. The ongoing verification costs, which will be lower for well performing businesses due to reduced frequency.

## Consultation

41. The MPI *Public Discussion Paper No: 2015/01 Proposals for regulations under the Food Act 2014*, was released in January 2015, with submissions invited until 31 March 2015. We held 26 consultation meetings in eleven locations. Eleven of these meetings were specifically with territorial authorities, twelve were public meetings and three meetings were with representative groups from territorial authorities, the food and beverage industry and the education sector. In total over 700 people attended a consultation meeting. 148 written submissions were received.

42. The responses were generally positive, with many suggestions for additional matters to be included in regulations. Consultation responses to the various proposals have been noted throughout this RIS. Where relevant the text notes proposals changed due to submissions and our further consideration of the issues.

43. Given the complexity and scale of these regulations, we will seek Cabinet agreement that exposure drafts be shared with the Territorial Authority Steering Group and the Food and Beverage Forum before they are finalised. MPI has worked closely with these two groups in the development of the Food Act and its regulations. These two groups were also provided with exposure drafts of the Food Bill as it moved through its Parliamentary stages. We will also carry out further consultation with affected parties on proposals for tertiary notices later during 2015.

## Conclusions and recommendations

44. Based on the analysis above, we make the following recommendations.

45. **A: Registration: food control plans and national programmes**

    A1 Regulations to support evaluation of custom food control plans by requiring:

    a. evaluators to undertake an onsite assessment of the business, unless the MPI chief executive waives this requirement;
    b. food business operators to provide evidence to the evaluator that certain products or processes are safe;
    c. evaluators to include prescribed content in their evaluation reports; and
    d. evaluators to endorse both the evaluation report and the food control plan to certify that the plan has not been modified since the evaluation.

A2 Regulations to require businesses subject to food control plans to provide information about the physical boundaries of their premises and the activities undertaken within these premises.

A3 Regulations to set the duration of national programme registration at 12 months.

A4 Regulations to establish the territorial authority (TA) as the registration authority for national programme businesses. A mobile business must register with the TA where its business address is located. A business that operates in more than one TA district will have the option of either registering each part of the business individually with the relevant TA or the whole business with MPI:

A5 Regulations to allow the registration authority to annualise the registration of national programme businesses to align with the financial year end.

46. **B: Verification: food control plans and national programmes**

B1 Regulations to set verification frequencies as outlined below.

| **Food sectors subject to:** | **Initial verification of existing businesses** | **Initial verification of a new business** | **Verification variation** | |
|---|---|---|---|---|
| | | | **Maximum frequency** | **Minimum frequency** |
| **Custom food control plans** | Within 6 months of registration | Within 3 months of registration | 3 months | 18 months |
| **Template food control plans** | Within 1 year of registration | Within 1 month of registration | 3 months | 18 months |
| **National programme Level 3** | Within 6 months of registration | Within 1 month of registration | 3 months | 2 years |
| **National programme Level 2** | Within 1 year of registration | Within 1 month of registration | 3 months | 3 years |
| **National programme Level 1** | Within 1 year of registration | Within 1 month of registration | Nil unless a situation arises | |

Regulations to provide for performance-based verification so that after initial verification:

a. Businesses subject to a food control plan will start at 12 months frequency and move to 18 months if the business receives two consecutive acceptable verification outcomes.
b. Businesses subject to national programme level 3 will start at 2 years, level 2 will start at 3 years, and level 1 will start at no routine verification. These businesses will move to more frequent verification if the verifier recommends this to the registration authority on the basis of unacceptable verification reports.

Regulations to set criteria to determine verification frequency as follows:

a. confidence in management;
b. food safety behaviour;
c. the effectiveness of process controls;
d. the effectiveness of environmental controls; and
e. compliance history.

B2: Regulations to specify the following aspects of the verification process:

a. **Verifiers' duties to inform the operator** of any deficiencies found, the likely outcome, and timing for the next verification visit.
b. **Verifier to negotiate and confirm corrective actions** with the operator if the verifier detects non-compliance.
c. **Verifier to assign an outcome** with an indicative list of relevant factors to take into account.
d. **Verifier to provide a written report to the operator**, and the report is to include specified contents.
e. **Business operator to have the right to request a reconsideration of a verification decision**.
f. **Verification of multi-site businesses** may be flexible after initial verification of each premises or site.
g. **Verifier to report to MPI**, including making reports and outcomes available to MPI as reasonably necessary, and informing the MPI chief executive of any 'critical non-compliance' as soon as possible.
h. **Operator verification** required of all of operators working under a custom food control plan.

47. **C: Safety and suitability: food control plans and national programmes**

C1 Places where food is produced, processed and handled: Regulations to require food business operators to ensure places are:

a. designed, located and constructed to enable food safety and suitability to be achieved; and
b. maintained to facilitate cleaning and sanitising, and prevent contamination of food.

C2 Supporting systems: Regulations to require food business operators to control pests, manage waste, use appropriate chemicals and maintenance compounds and ensure appropriate use of water.

C3 Facilities, equipment and essential services: Regulations to require food business operators to ensure that:

a. Facilities, equipment, and essential services are constructed and maintained to enable safety and suitability of food and operated in a manner that does not exceed their capacity.
b. Adequate drainage and liquid and solid waste disposal systems are provided.

Regulations to require all food business operators under national programmes to ensure that:

a. Adequate cleaning facilities are provided.
b. Laundry activities are appropriate.
c. Appropriate hygiene facilities and amenities are available.
d. Equipment used to control the temperature of food is optimal and maintained.
e. Equipment is appropriate to control harmful or undesirable micro-organisms.
f. Air quality and ventilation is maintained, and adequate lighting is provided.
g. Adequate facilities for the storage of food, materials and cleaning equipment are provided.
h. Equipment used with food, and for cleaning places is fit for intended use.
i. Vending machines only dispense food that is safe and/or suitable.

C4 People: Regulations to require food business operators to ensure that all people at any place where food is produced or processed and handled use an appropriate hygiene routine that does not compromise the safety and suitability of food, that people that carry illness are precluded from handling food, and that appropriate clothing is worn.

C5: Food ingredients and food related accessories: Regulations to require food business operators to ensure that:

a. Food ingredients and food-related accessories that are used in the processing and handling of food are safe and suitable.
b. Packaging does not become a hazard to food.
c. Food can be traced from the supplier, within the business and to the next recipient in the supply chain (other than the final consumer).
d. The food business has a procedure that enables the recall of food and the reporting of the recall to the MPI chief executive.

C6: Production, processing and handling: Regulations to require food business operators to ensure that:

a. Food does not contain biological, chemical, and physical hazards or extraneous objects, material, or substances.
b. Food that is transported is safe and/or suitable for its intended use.

C7: Documents, records and reports: Regulations to require food business operators to ensure that records are kept that enable the operator, MPI chief executive, a food safety officer or a verifier to readily ascertain that the business is meeting its regulatory obligations.

C8: Corrective action: Regulations to require food business operators to take corrective actions and keep records of such actions.

C9: Reporting: Regulations to require food business operators to report to their verifier any breach that resulted in unsafe food that can cause injury to human life or public health.

C10: Competency and training: Regulations to require food business operators to ensure that persons working at food business have the necessary competencies or skills to carry out their tasks.

48. **D: Recognition of agencies, persons and classes of persons**

D1 Regulations to set the following core requirements for recognised agencies:

a. a documented Quality Management System;

b. management of technical competencies; and
c. management of potential conflicts of interest.

Regulations to require a recognised person to demonstrate that they meet specified competencies in respect of skills, experience and knowledge.

D2 Regulations to require agencies and persons seeking recognition to evaluate custom food control plans and/or verify businesses operating under these plans to hold a current accreditation to ISO 17020 to demonstrate that they meet core requirements. Agencies and persons seeking recognition to verify businesses operating under other risk measures must demonstrate to MPI that they meet the core requirements.

D3 Regulations to set requirements for the renewal of recognition as follows:

a. Confirmation that required accreditation remains current, or that the agency can continue to demonstrate the core management and other requirements relevant to its level of recognition.
b. Confirmation that the person continues to meet requirements.
c. Assessment of performance during the previous period of recognition.
d. Consideration of any changes to the 'fit and proper' status of the recognised agency or person.
e. Payment of any prescribed fee.

D4 Regulations to establish performance standards and requirements to ensure that recognised agencies and recognised persons continue to meet their statutory obligations and remain fit to be recognised and provide their recognised functions.

D5 Regulations to provide that only recognised agencies or persons may provide independent evaluation functions.

49. **E: Approvals of documents, materials, facilities, persons or classes of persons**

E1 Regulations to set the following criteria that the chief executive must take into account before issuing an approval:

a. improves credibility and confidence;
b. improves efficiency;
c. improves clarity and transparency.

50. **F: Food standards**

F1 Regulations to establish:

a. Criteria to determine maximum residue levels.
b. The information to be included in notices issued by the MPI chief executive to set maximum residue levels.
c. The conditions of sale for foods containing residue of agricultural compounds.
d. The circumstances where a food containing a residue may be exempt from the conditions of sale.

51. **G: Imported food**

G1 Regulations to establish general requirements for importers to have access to certain information showing how the safety and suitability of imported food is managed, to maintain access for 4 years, and to provide that food safety officers may require records to be translated into English.

G2 Regulations to establish storage, transport and handling requirements.

G3 Regulations to set requirements for managing imported food that is not cleared at the border.

G4 Regulations to categorise and manage imported food according to risk, specifically to:

a. Establish categories of imported food: high regulatory interest food and increased regulatory interest food.
b. Provide for the MPI chief executive to prepare a categorisation report showing which food fits in which category.
c. Require 'high regulatory interest' food to be cleared at the border, subject to certain evidence requirements.
d. Specify requirements for managing 'increased regulatory interest' food.
e. Require that any sampling and testing of imported food must be at an approved laboratory, with a food safety officer to determine whether and how often such sampling and testing is required.

G5 Regulations to provide that importers may be subject to verification if deemed necessary by MPI if information from other sources, including compliance action, indicates that this is necessary. If required, verification will take place according to a schedule determined by MPI as the registration authority.

52. **H: Exemptions** No regulations for exemptions are proposed at this time.

53. **I: Infringement offences**

Regulations to establish infringement offences with a fee of $450, for:

a. importing for the purpose of sale while not being registered;
b. failing to register a food control plan; or
c. failing to register under a national programme if required to do so under the Food Act.

Regulations to be made to establish infringement offences for breaches of certain requirements in the Australia New Zealand Food Standards code, with infringement fees of $300, $450 or $650 depending whether the offence is assessed as of low, medium, or high seriousness.

54. **J: Transition**

**J1 Specify the introductory period:** Regulations to be made to set the start date for the operation of the various transitional provisions and the date for the repeal of the Food Act 1981 to be 1 March 2016.

**J2 Specify the transition timeframes and schedules:** Regulations to be made to:

a. set transition periods for food sectors; and
b. allow businesses already operating under a risk-based measure to either transition with their sector (generally in period 1 or 2) or transition by the end of period 3.

**J3: Timeframe for registration applications:** Regulations to require transitioning businesses to apply for registration under the Food Act 2014 no later than 3 months before the end of the transition date that applies to their sector.

# Implementation

55. The proposed regulations must be in place by commencement of the Food Act on 1 March 2016. Implementation will be supported by targeted communications with particular groups, as well as information made generally available through, for example, the MPI website. A key part of this communications programme will be a web-based 'Where Do I Fit?' tool. This tool will be available to all food businesses to assist them to determine, for their specific circumstances, where they fit in the risk management framework. We will continue to work with sector groups, industry leaders and territorial authorities on the guidance to support implementation.

56. Given the very high number of businesses covered by the Food Act and the wide variation in the nature and size of these businesses, there is a risk that not all businesses will know what is required and when. To address this we are doing implementation surveys of food businesses to gauge their awareness and knowledge of the new requirements, as well as their willingness to comply and their confidence in their ability to do so. This will inform our delivery of information and guidance around the requirements.

57. Some businesses in the education and health sectors have been exempt or partially exempt under the Food Hygiene Regulations 1974. We are working with the Ministry of Education and the Ministry of Health to reduce the duplication between their respective regulatory regimes and the Food Act so that the costs and impacts on these businesses can be minimised and their transition eased. It is, however, important that these businesses provide safe and suitable food, as they often serve vulnerable populations (very young children, the elderly and those in poor health who have a high risk of susceptibility to foodborne illness).

58. Within MPI we have a cross-organisational implementation programme which is preparing for all aspects of the implementation. As well as the development of the regulations, this programme covers issues such as the development of tertiary notices, and guidance. Information systems management, monitoring and evaluation, and compliance strategies are also part of the programme. The focus is not only on developing these components, but also on ensuring that they are developed in an integrated way so that they will work together effectively and efficiently.

59. Both MPI and territorial authorities have regulatory functions under the Food Act and will be required to act as registration authorities and as enforcement agencies. The implementation of the infringements regime will involve both MPI and the territorial authorities. (For any particular business the registration authority is also the enforcement authority). Both MPI and the territorial authorities have considerable experience with existing infringement regimes. MPI compliance officers administer

infringement schemes under the Fisheries Act 1996 and the Biosecurity Act 1993. Territorial authorities have experience with infringements under statutes such as the Resource Management Act 1991 and the Building Act 2004. Implementation will build on this experience, and will be supplemented by training and guidance provided by MPI in conjunction with territorial authorities. This will include use of MPI's 'Voluntary, Assisted, Directed, Enforced' compliance model (VADE). This model supports use of the best possible intervention, taking account of the level of potential or actual harm and the barriers to compliance or motivations for non-compliance.

## Monitoring, evaluation and review

60. The Food Act requires a review of the statutory recognition of territorial authorities as verifiers. Under section 138, the MPI chief executive must review the operation of section 137, which directly recognises territorial authorities as the sole verifiers of food businesses that operate under a template food control plan issued by the MPI chief executive, that operate entirely within the district of the territorial authority, and that primarily sell food directly to consumers. This review must be conducted as soon as practicable after the expiry of the Act's introductory period, and must be reported to the Minister for Food Safety within six months. The report must consider whether the provisions of section 137 should be retained, amended or repealed. We are identifying key performance indicators for this function, and will put in place a monitoring framework so that relevant information is gathered from commencement on 1 March 2016.

61. In addition to this statutory requirement, we will be working both prior to and during the implementation period to monitor the impact of both our initiatives and those of territorial authorities to ensure stakeholders are aware of the changes being introduced by the Food Act and its regulations and notices. Stakeholders include operators of food businesses, food safety officers and verifiers. Where we identify barriers to effective implementation, such as low levels of understanding amongst food businesses, we will reassess the tools and guidance used to date, and consider how best to make improvements.

62. As noted above, we are doing implementation surveys to gauge businesses' knowledge, and their willingness and confidence in their ability to comply. These factors are key indicators, and we have identified some further key indicators for monitoring of food sectors, which we will finalise over the coming months. These further indicators are likely to focus on things such as:
    a. the extent that operators see benefits in the requirements;
    b. the percentage of the sector registered with the correct risk based measure;
    c. the average annual cost of compliance;
    d. the percentage of verification reports resulting in critical non compliances; and
    e. the number of compliance actions undertaken as a percentage of the total businesses.

63. The indicators will be monitored through the use of market research with food operators, and through quantitative data collected from both MPI and territorial authorities' operational systems. For each food sector, a baseline will be established prior to the applicable transition period. The change will then be monitored at regular intervals.

64. We are also considering how we will work with verifiers and food safety officers to monitor their functions. The detail and approach to this has yet to be finalised.

65. Alongside this formal monitoring, we will continue to have regular and ongoing communications with stakeholders, including territorial authorities and industry associations. These interactions will provide ongoing feedback on effectiveness and contribute to identifying what is going well and any areas of concern.

# APPENDIX A: CLASSIFICATION OF FOOD SECTORS INTO RISK-BASED MEASURES

The Food Act 2014 divides food businesses into sectors and assigns the sectors to particular risk-based measures: food control plans, national programmes level 3, 2 or 1, or exemption from a risk-based measure. Section 21 explains the classification of food sectors for the purpose of assigning applicable risk-based measures. The classification of food sectors is based, among other things, on the level of risk that the activities of the food sector pose to public health in terms of the safety and suitability of food. The food sectors subject to each risk-based measure are set out in Schedules 1 and 2. The food sectors that are assessed as posing the lowest level of risk are classified in schedule 3, and are not required to operate under a risk-based measure.

Food businesses must operate according to the risk-based measure that applies to their sector. A business may opt to operate under a food control plan even if it is in a food sector classified under a lower level of risk. A business may not, however, operate under a risk-based measure that is applicable to lower risk sectors.

The schedules that set out the sectors and the applicable risk-based measure may be amended by regulation. Permitted amendments include altering the risk-based measure applicable to a particular food sector by removing or adding that sector to a schedule or moving the sector within a schedule. Any such changes must take account of the need to achieve the safety and suitability of food for sale, and the likely effect of the changes on the efficiency of the food sector and the economic impacts on the sector. Consultation is required to precede any such changes. (Section 22).

When the Food Bill was developed food sectors were assigned to the particular risk-based measures through use of a combination of risk ranking and prioritisation models drawn from Australian and Canadian food safety practices. The ranking process considered two key aspects:

- the inherent risk associated with particular foods, such as the type of food and the intended use by customer (assuming availability of a reasonable level of scientific or factual information); and
- the sector organisation or business practice factors that have an impact on food safety and suitability, such as food safety systems/structures in place (this information is less scientific).

Sector organisation or business practice factors considered in this model include the ability of a food sector to effectively implement regulatory change, and determining the best place in the supply chain for effective risk control.

# Food sectors and risk-based measures as defined in the Food Act 2014, Schedules 1, 2 and 3

| Food control plan | National programme level 3 | National programme level 2 | National programme level 1 | Not required to operate under a risk-based measure |
|---|---|---|---|---|
| **Approximate numbers under each risk-based measure (2013 estimates)** | | | | |
| **20 000** | **2 200** | **780** | **17 200** | |
| Food retailers that prepare or manufacturer and sell food | Brewers, distillers and manufacturers of vinegars, alcoholic beverages, or malt extract | Bakeries that prepare or manufacture bread or bread derived products only | Extractors and packers of honey | Accommodation providers: food for up to 10 guests |
| Food service sector | Manufacturers of non-alcoholic beverages | Food service provided to preschool children (including children under 5 years of age) in a centre-based service setting | Producers of horticultural food and horticultural packing operations | Accommodation providers: snacks or breakfasts |
| Manufacturers of commercially sterilised food products | Manufacturers of fats or oils for human consumption | Manufacturers of confectionery | Manufacturers of sugar or related products | Home-based early childhood education services |
| Manufacturers of dairy products | Manufacturers of food additives, processing aids, vitamins, minerals and other nutrients intended to be added to food | Processors of nuts and seeds | Retailers of hot beverages and shelf-stable manufacturer packaged food only | Early childhood education service providers who undertake minimal food handling only |

| Food control plan | National programme level 3 | National programme level 2 | National programme level 1 | Not required to operate under a risk-based measure |
|---|---|---|---|---|
| Manufacturers of food for vulnerable populations | Processors of grain | Manufacturers of crisps, popcorn, pretzels, or similar snack products | Retailers of manufacturer-packaged ice cream, iced confectionery, and iced desserts | Fishing vessel operators who supply food to crew |
| Manufacturers of fresh ready to eat salads | Processors of herbs or spices | Manufacturers of dried/dehydrated fruit or vegetables | Transporters or distributors of food products | Food trading: once a year |
| Manufacturers of meals and prepared foods | Retailers that handle food (but do not prepare or manufacture food) | Manufacturers of shelf-stable condiments (including sauces, spreads and preserves) | | Food service sector: catering of specified nature |
| Manufacturers of meat, poultry or fish products | Manufacturers of dry mix products | Manufacturers of shelf-stable grain-based products | | Food service sector: clubs organisations, and societies (internal) |
| Manufacturers of non-shelf stable sauces, spreads, dips, soups, broths, gravies or dressings | | Manufacturers of water-based products including ice, iced confectionery and desserts | | Food service sector: clubs, organisations, and societies (external) |
| Manufacturers or processed egg products | | Retailers of manufacturer-packaged chilled and frozen food (excluding ice cream, iced confectionery, and iced | | Horticultural producers: direct sales of own produce to consumers |

| Food control plan | National programme level 3 | National programme level 2 | National programme level 1 | Not required to operate under a risk-based measure |
|---|---|---|---|---|
| | | desserts) | | |
| Manufacturers of vegetable proteins or other protein products | | Manufacturers of frozen fruit or vegetables | | Retailers or direct sellers of shelf-stable, manufacturer-packaged food only |
| Wholesale bakeries | | | | |

# APPENDIX B: ESTIMATED COMPLIANCE COSTS FOR FOOD BUSINESSES

As noted in the Agency Disclosure Statement, we have limited information as to the cost impacts of the proposed regulations on food businesses. Our best information comes from the regulatory impact analysis done to support the Cabinet decisions on the Food Bill in 2009, and the analysis that supported the cost recovery regulations for the Food Act 2014. See 'Regulatory impact statement 2009 — A reformed food regulatory regime' (http://www.foodsafety.govt.nz/elibrary/industry/Regulatory_Impact-Specifically_Covers.pdf) and 'Establishing cost recovery regulations to support the Food Act 2014' http://www.mpi.govt.nz/law-and-policy/legal-overviews/regulatory-impact-statements/. These documents are the sources for the information provided below.

The cost estimates below focus on the three key aspects dealt with in this RIS that will have cost impacts for food businesses. These are the requirements for registration, verification, and food safety and suitability. All of these are established by the Act rather than the proposed regulations. The proposed regulations are not, therefore, the reason that businesses face these costs, although the regulations expand on the basic framework provided by the Act, and as such have an impact on the size and nature of the costs.

There are, however, other key influences on the size and nature of the costs, in particular, the performance of the food business and the degree to which it is already operating to produce safe and suitable food. Ongoing verification frequency will be performance-based, so a well performing business will face the costs of verification at a lower frequency than under the current system where all inspections are annual. Another key driver of costs will be the extent to which a business will have to introduce new or upgraded processes, equipment or facilities to meet safety and suitability requirements. Where an existing business has good systems we do not expect this will require any further investment. Some businesses, especially those in the lower risk sectors, may need to spend less than they currently do as the new requirements are more attuned to their lower risk profile. As noted in the 'Implementation' section, there are some businesses in the education and health sectors have been exempt or partially exempt under the Food Hygiene Regulations 1974. We are working with the Ministry of Education and the Ministry of Health to reduce the duplication between their respective regulatory regimes and the Food Act regime so that the costs and impacts on these businesses can be minimised and their transition eased.

The Food (Fees and Charges Regulations) 2015 set MPI's charges for registration and verification. Most businesses will not, however, register with MPI, and MPI will only act as the verifier of last resort. Most businesses will register with their local territorial authority. Some businesses will be verified by the local territorial authority, and some will be verified by third parties (agencies and persons recognised under the Food Act

as possessing the relevant competencies for this function). Where registration and verification is provided by territorial authorities, they will set their own fees and charges. These may differ from those set by MPI so it is not possible to provide an estimate of these costs.[7] Similarly it is difficult to estimate the costs of verification provided by third parties. We have, however, provided some approximate figures based on assumptions about how long a verification may take and assuming the verifier's fees were similar to the hourly rate set for MPI.

## Compliance costs for businesses operating under a custom food control plan

| **Requirement** | **Food Act 1981 and Food Hygiene Regulations 1974** | **Food Act 2014** | |
|---|---|---|---|
| | | **Initial costs** | **Ongoing costs** |
| **Registration** | One off average charge of $1922 for evaluation and registration of a food safety programme. | **Registration with MPI is required by the Act**<br>MPI fee: $348.50 plus $155 per hour in excess of 2 hours. | **Annual renewal of registration is required by the Act**<br>MPI fee: $77.50 plus $155 per hour in excess of 2 hours. |
| **Evaluation of plan** | One-off charge of $10 000 - $20 000 paid to 3rd party experts for development and evaluation. The businesses with such plans tend to be large nationwide businesses such as supermarket chains. | **Required by Act**<br>One-off evaluation will be done by a recognised agency or person. Cost will depend on nature and complexity of plan, and on rates as negotiated between food business and evaluator.<br>Assuming evaluation takes between 5 and 15 hours, and the evaluator charges $155, total costs would be between $775 -$2325. | None unless need to register significant amendment to plan. |

[7] The Food Act requires that the territorial authority must have regard to the principals of cost recovery set out in the Act, must not recover more than reasonable costs incurred and must consult on these charges (section 205). The Act also provides MPI with a power to prescribe a framework or methodology for territorial authorities to apply when fixing fees (section 206). We have not proposed any such regulations at this stage. We will monitor the fees and charges set by territorial authorities once the Act comes into force.

| Requirement | Food Act 1981 and Food Hygiene Regulations 1974 | Food Act 2014 | |
|---|---|---|---|
| | | **Initial costs** | **Ongoing costs** |
| **Verification** | Annual charge – range from $900 - $5000. | **Act requires verification to be done by a recognised agency or person**<br>Cost will depend on nature and complexity of business, issues to be addressed etc., and on rates as negotiated between food business and verifier.<br>We assume that verification of a business operating under a custom food control plan would require the highest level of verifier skill and take longer than other verifications. 2009 estimate of costs was $500 to $5000. | **Required by Act, frequency set by regulation and subject to performance**<br>Well performing business: verification once every 18 months - $500 to $5000.<br>If verification identifies need for corrective actions, businesses will bear costs in fixing these issues, and may move onto a programme of more frequent verifications. |
| **Safety and suitability** | Unknown | Businesses will face initial costs of becoming familiar with the new requirements. MPI and territorial authorities are working together to provide information and assistance. The costs of developing and maintaining systems, faculties and processes to meet safety and suitability requirements will depend on the nature of the business, its size and the activities it performs. For existing well performing businesses, particularly those operating under a custom food safety programme, there should be little change. The new regulations will give them more flexibility to determine how they can continue to meet requirements. | |

## Compliance costs for businesses operating under a template food control plan

| Requirement | Food Act 1981 and Food Hygiene Regulations 1974 | Food Act 2014 | |
|---|---|---|---|
| | | **Initial costs** | **Ongoing costs** |
| **Registration** | One off average charge of $1922 for evaluation and registration of a food safety programme. | **Act requires these businesses to register with the local territorial authority**<br>Fees to be set by territorial authorities. | **Annual renewal of registration (required by Act)**<br>$77.50 plus $155 per hour in excess of 2 hours. |
| **Verification** | Annual charge – range from $900 - $5000. | **Act provides that in many cases verification will be done by the territorial authority, otherwise by recognised agency or person**<br>If done by a recognised agency or person cost will depend on nature and complexity of business, issues to be addressed etc., and on rates as negotiated between food business and verifier.<br>Assuming that the verifier's hourly rate is the same as that used by MPI in setting its cost recovery fees, and assuming a verification takes 2 to 3 hours, the costs of verification would be between $310 and $465. | **Required by Act, frequency set by regulation and subject to performance**<br>Well performing business: verification once every 18 months.<br>If verification identifies need for corrective actions, businesses will bear costs in fixing these issues, and may move onto a programme of more frequent verifications. |

| Requirement | Food Act 1981 and Food Hygiene Regulations 1974 | Food Act 2014 | |
|---|---|---|---|
| | | **Initial costs** | **Ongoing costs** |
| **Safety and suitability** | Unknown | Businesses will face initial costs of becoming familiar with the new requirements. MPI and territorial authorities are working together to provide information and assistance. The costs of developing and maintaining systems, faculties and processes to meet safety and suitability requirements will depend on the nature of the business, its size and the activities it performs. For existing well performing businesses, particularly those operating under a template food safety programme, there should be little change. The new regulations will give them more flexibility to determine how they can continue to meet requirements. | |

## Compliance costs for businesses operating under national programme

| Requirement | Food Act 1981 and Food Hygiene Regulations 1974 | Food Act 2014 | |
|---|---|---|---|
| | | **Initial costs** | **Ongoing costs** |
| **Registration** | Territorial authorities usually charge a single fee for both registration and inspection (verification).<br><br>This ranges from $50 to $1880. | **Required by Act. Registration authority set by regulations**<br>If register with MPI: $116.24 plus $155 per hour in excess of 2 hours.<br>If register with local territorial authority, fees to be set by territorial authorities. | **Annual renewal of registration (required by regulations)**<br>If register with MPI: $77.50 plus $155 per hour in excess of 2 hours.<br>If register with local territorial authority, fees to be set by territorial authorities. |
| **Verification** | | The Act provides that verification will be done by a recognised agency or person. Cost will depend on | **Frequency set by regulation and subject to performance** |

| Requirement | Food Act 1981 and Food Hygiene Regulations 1974 | Food Act 2014 | |
|---|---|---|---|
| | | **Initial costs** | **Ongoing costs** |
| | The range reflects the different cost recovery policies of territorial authorities. The range is 10% to 100% cost recovery, with a median of 66%. | nature and complexity of business, issues to be addressed etc., and on rates as negotiated between food business and verifier.<br><br>Assuming that the verifier's charge is the same as that used by MPI to set cost recovery fees if MPI acts as the verifier, and assuming a verification takes 1 to 3 hours, the costs of verification would be between $155 and $465. | National programme 3: well performing businesses will be verified once every 2 years.<br><br>National programme 2: well performing businesses will be verified once every 3 years.<br><br>National programme 1: well performing business will have no ongoing verification cost.<br><br>If verification identifies need for corrective actions, businesses will bear costs in fixing these issues, and may move onto a programme of more frequent verifications. |
| **Safety and suitability** | Unknown | Businesses will face initial costs of becoming familiar with the new requirements. MPI and territorial authorities are working together to provide information and assistance. The costs of developing and maintaining systems, faculties and processes to meet safety and suitability requirements will depend on the nature of the business, its size and the activities it performs. For existing well performing businesses, there should be little change, although it is possible costs will go down as the new requirements may be less onerous than the previous 'one size fits all' approach. The new regulations will give them more flexibility to determine how they can continue to meet requirements. | |