REGULATORY IMPACT STATEMENT 2009 – A REFORMED FOOD REGULATORY REGIME

In October 2006 the New Zealand Food Safety Authority (NZFSA) prepared a Regulatory Impact Statement (RIS) for the policy decisions that reflected the Domestic Food Review (DFR) and the consultation that had been completed between 2002 and 2006. The 2006 RIS was updated in June 2008 to include information on the proposed transition, the number of food businesses and more recent foodborne illness data.

That RIS is available on the NZFSA website http://www.nzfsa.govt.nz/policylaw/publications/regulatory-statements/index.htm and the Treasury website: http://www.treasury.govt.nz/publications/informationreleases/ris/premay2008.

This 2009 RIS analyses the marginal change that will be achieved by two specific options following on from the analysis that has already been completed and underpins the drafted Food Bill.

EXECUTIVE SUMMARY

The DFR, undertaken over a four year period from May 2003, documented a number of problems with New Zealand's current food regime. These included:

- a significant and rising incidence of foodborne illness among the New Zealand population; and
- three different food regimes and three separate regulators operating simultaneously, with resulting poor lines of accountability and unnecessary confusion, inconsistency, duplication and complexity.

The total cost to New Zealand society from foodborne illness, due to a number of foodborne pathogens, is estimated to be \$86 million per annum¹. Approximately 90% of this cost is attributable to lost productivity due to absence from the work force.

The DFR identified that there is confusion about when government is involved; there are a significant number of businesses who are unaware of the legislation they must meet to ensure the food they sell is safe and suitable; and uncertainty regarding who administers the legislation. These factors alone lead to non-compliance, unnecessary regulatory costs, and significant and unnecessary compliance costs.

Significantly for an export led recovery for New Zealand, the domestic food regulatory regime is the platform for exports. The New Zealand domestic standard is used as the basis for negotiating equivalence arrangements with our trading partners. This minimises the excessive importing country requirements that may be imposed but which do not go to food safety.

¹ ESR: Risk Ranking – Estimates of the Cost of Foodborne Disease for New Zealand – Peter Cressey and Dr Rob Lake, March 2008. The \$86 million represents direct health-care costs (i.e. GP consultations and medications); direct non-health-care costs (i.e. travel costs to and from a GP consultation or a hospital); and indirect non-health-care costs (i.e. costs to society due to lost production resulting from illness. This is based on the estimated costs due to lost production from work missed by employed people only).

If no government action is taken, businesses and Territorial Authorities will face increased costs of future measures that would be undertaken by Territorial Authorities to ensure compliance with the existing regime. Such measures had been largely stopped by Territorial Authorities because of the expectation that new food legislation was on the horizon.

In October 2006, policy proposals for the drafting of a Food Bill were agreed based on the analysis for the DFR and the completed consultation. A draft Food Bill was prepared based on the then agreed policy. A regulatory impact statement was prepared for the draft Food Bill and is attached at Appendix 1.

In April 2009, Cabinet agreed, in principle, to the continued work on a Food Bill subject to the completion of a regulatory review of two identified options, a limited amendment to the Food Act; and a revised Food Bill. The proposed Food Bill has been included in the Government's Regulatory Review Programme (regulatory review) for 2009.

The regulatory review of the two options reviewed seven areas:

- compliance costs;
- international best practices;
- consistency and equity of chosen regulatory requirements;
- risk based versus a prescriptive regime;
- the seamlessness and coherence of the proposed regime;
- impacts on trade and commerce in food and associated products; and
- the level of resource required and the impact of timing of each option.

The regulatory review has been completed and the results of the review concluded that a revised Food Bill is the preferred option for progressing the reform of the food regulatory regime. Option E would provide improved food safety within a comprehensive framework. Changes to revise the Food Bill can be achieved within a 6-8 month timeframe, at which point the Food Bill would be ready for introduction to the House. There will be less pressure on government resources to improve the drafted Food Bill because the work on drafting and testing aspects of the new food regime that has already been done can be used. A copy of the regulatory review report is attached as Appendix two.

This regulatory impact statement specifically covers changes anticipated from the two options. The original regulatory impact statement supporting policy for the drafted Food Bill is not being revisited and is relevant to the policy at that time.

ADEQUACY STATEMENT

The Regulatory Impact Analysis Team has reviewed this Regulatory Impact Statement and considers that it accurately reflects the analysis undertaken in relation to the proposal and contains the required information.

STATUS QUO AND PROBLEM

Food production in New Zealand stands out among food-producing OECD nations as a dominant contributor to the country's manufacturing production, gross domestic product, export intensity and trade balance. The food sector comprises 35,000 to 40,000 businesses (depending on definition) and up to 200,000 additional part-time food premises.

Food production provides jobs for 20% of the working population, with the retail value of food and beverage being \$13.8 billion per annum², with food service valued at \$5 billion per annum. New Zealand's food sector accounts for at least 10% of our Gross Domestic Product.

NZFSA has specific functions as New Zealand's primary food regulator. The NZFSA is required, among other things, to administer all food legislation and food safety and suitability matters. NZFSA also has to deliver on two closely aligned areas:

- reducing the incidence of foodborne illness in New Zealand; and
- providing a coherent and seamless food regulatory programme.

Currently most food is regulated under the Food Act 1981. Other food is regulated under the Animal Products Act 1999, the Wine Act 2003, the Agricultural Compounds and Veterinary Medicines Act 1997 and regulations under these Acts. Most premises are covered by the Food Hygiene Regulations 1974, and are inspected by Territorial Authorities who enforce the Regulations. Some businesses are however exempted from the Food Hygiene Regulations 1974 because they have voluntarily chosen to operate under a food safety programme.

In 1996 an amendment was made to the Food Act 1981 to allow food businesses to become exempt from the Food Hygiene Regulations 1974 if they voluntarily adopted a food safety programme. Food safety programmes, are a risk based tool, which are audited by third parties. Food safety programme requirements are enforced by Public Health Units and NZFSA. A variety of food businesses currently operate using food safety programmes such as supermarkets, manufacturers and franchise operators.

All persons preparing food for sale or selling food, including imported food, are additionally required to comply with the Food (Safety) Regulations 2002 and Food Standards (including the joint Food Standards Code for food labelling and composition). These requirements are variously enforced by Public Health Units, third parties and NZFSA.

The DFR covered food safety and suitability of food for its intended use. 'Suitability' covers composition, labelling, identification and condition of food but does not include matters that are directly related to the food's safety or matters that are related to the food's quality requirements for commercial reasons. An example of food that is unsuitable is food that is in a condition that is offensive or so perished as to affect its intended use but generally excludes quality issues (e.g. floury apples).

In parallel, NZFSA initiated an Imported Foods Review. Changes to improve the import regime are key amendments proposed for the new Food Act. These changes include the registration of importers and a border system that is responsive to the risk of the food being imported.

The DFR identified that the current domestic food system suffers from:

- duplication, overlaps and gaps in laws and consequential costs for food businesses;
- confusion about when (and at which level) government is involved;
- inconsistent controls in some areas;
- unnecessary complexity in the structure of responsibilities and in the legislative framework of controls;

² Food and Beverage Task Force (August 2006)

- lack of practicality of some controls;
- inconsistency in the regulatory impact on businesses, including unnecessary regulations that do not go to food safety issues;
- lack of clarity and consistency about how much facilitation and guidance NZFSA, as the principle regulator, will provide;
- ill-defined roles of key players with the food regulatory regime;
- lack of common understanding of good hygienic practice and other key concepts; and
- the absence of sufficient risk assessments in the food sector.

The DFR identified that the food regulatory regime urgently needs to be improved. In October 2006 the Government agreed to policy proposals for the drafting of a Food Bill. A draft Food Bill was prepared based on the then agreed policy. The public policy objective was to provide an efficient, effective and risk-based food regulatory regime that manages food safety and suitability issues. A regulatory impact statement was drafted for the Food Bill (Appendix one).

The regulatory framework in the drafted Food Bill aimed to reduce the prescriptive nature of the current regime, and move to an outcomes-based regulatory system by introducing a risk-based regime based on three tools:

- food control plans (regulatory),
- national (including monitoring) programmes (regulatory), and
- food handler guidance (a non-regulatory, educative tool).

The two options considered in this RIS do not change the shift from a prescriptive regime to an outcomes-based regulatory system.

In April 2009 Cabinet agreed, in principle, to the continued work on a Food Bill subject to the completion of a regulatory review of two identified options a limited amendment to the Food Act (Option C) and a revised Food Bill (Option E).

The problem outlined by this regulatory impact statement is the decision that needs to be made to be able to choose between the two options.

OBJECTIVES

The overarching public policy objective is to consider how the regulatory (and non-regulatory) risk management tools can be more effectively used to provide an efficient, effective and risk-based food regulatory regime that manages food safety and suitability issues; and to meet the Government's objectives of providing improved business certainty and reducing compliance costs.

The policy objective addressed in this paper is to determine whether the option of a limited amendment to the Food Act 1981 or the option of a revised Food Bill best meets the overarching public policy objective.

BACKGROUND TO OPTIONS

The Government has agreed in principle to continue work on a Food Bill subject to a review of two specific options for progression. A copy of the Regulatory Review Programme report is at Appendix two

The two options have been developed to ensure that the Government's objectives of providing improved business certainty and further reducing compliance costs are met, while maintaining the outcomes that will be achieved by the drafted Food Bill, including lowering the incidence of foodborne illnesses. Business certainly will be improved through food businesses having increased awareness of the legislative requirements relevant to their food business.

To achieve this, for both options, it is proposed that the regulatory and non-regulatory tools will be used in the same way. This means that for both options the common factor is the proposal to use these tools to improve the food regime and improve food safety outcomes. It is proposed to use the lesser regulatory tool, national programmes for a greater number of food businesses than originally envisaged for both options. National programmes would now be for those businesses that present low to medium food safety risks. It is also proposed that a schedule is included in the resultant Food Act that clearly sets out what tool (regulatory, non-regulatory, educative) food sectors will be required to use to provide certainty to food businesses.

The diagram below (figure 1) shows the change in the way food businesses are proposed to be regulated. In the current regulatory environment under the Food Act 1981 almost all businesses are regulated via the registration of premises and prescriptive regulation.

The significant change to this regulatory framework for a revised Food Bill or a limited amendment to the Food Act 1981 is the proposal to use national programmes prescribed in regulations as the primary risk management tool for a larger number of food sectors.

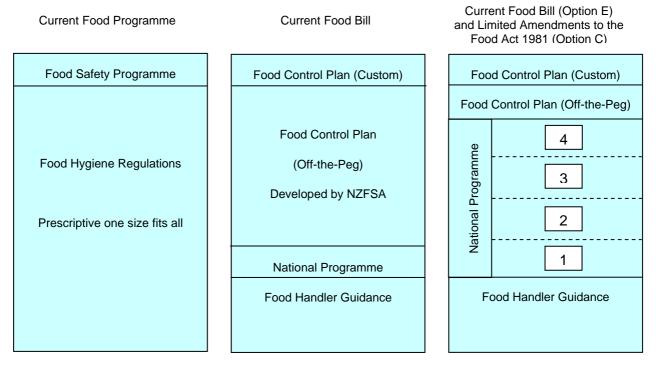


Figure 1:

Scheme of Legislation

National programmes will be able to be implemented at a reduced cost for businesses compared to food safety programmes, the Food Hygiene Regulations 1974 and food control plans. This is because while food controls plans can be tailored to manage risk

posed by particular business types, there is limited ability at a regulatory level to influence the priority and scope of the particular requirements individual businesses must meet.

The scope of national programmes will be around the minimum regulatory requirements that a food business will need to comply with to assure food safety. A national programme will include the core elements of food safety that will deliver the minimum requirements necessary to achieve the objective of safe and suitable food. Because the national programmes are prescribed in regulation there will be a higher level of transparency and scrutiny to ensure good regulatory practises are maintained.

The provision of four levels of national programmes provides an opportunity at a regulatory level to differentiate regulatory requirements faced by groups of businesses based on risk, impact on consumers, expected compliance rate and cost benefit. For example, businesses posing lower risk will face less regulatory requirements than those that pose higher risks. For lower risk businesses this will result in less regulation to comply with, and a corresponding reduction in verification requirements and registration costs. By including a schedule in the resultant Food Act, which sets out clearly the specific tool a food business must operate under, will increase business certainty of what is required of them.

The ability to create industry-specific specifications will be used to amplify national programmes, if required. Guidance material may also be made available to sectors that are subject to national programmes.

The diagram below (figure 2) illustrates how the proposed revised regime will match a businesses food safety risks with the degree of regulatory control and the expected level of compliance costs.

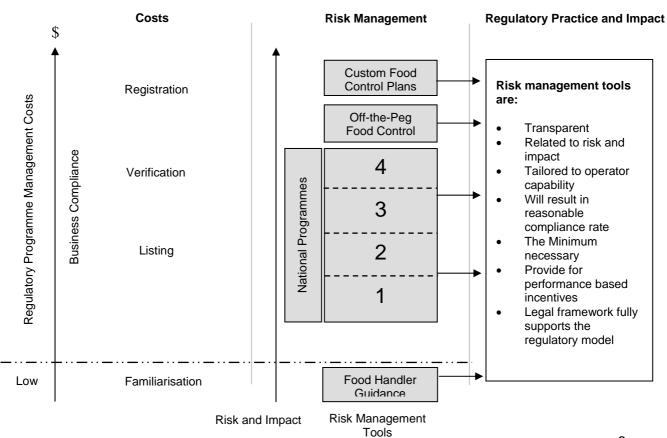


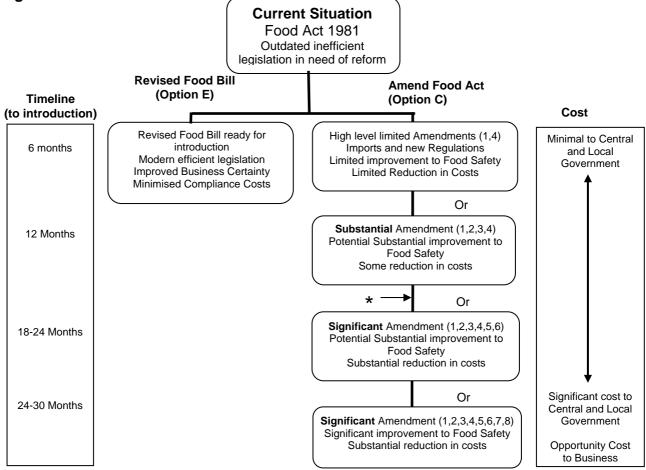
Figure 2:

Both options for reform can, to varying degrees, meet the objective of an efficient, effective and risk-based food regulatory regime that manages food safety and suitability issues. However, there are differing costs, timelines and regulatory and legislative implications for each option. These differences are represented in the chart below (figure 3).

The length of time that will be needed to complete the consultative processes, prepare and provide policy proposals to Government, and undertake the drafting of a limited amendment to the Food Act also needs to be considered.

A revised Food Bill could be finished in the same time and cost as a minor limited amendment to the current Food Act 1981 and would better achieve the public policy objectives. This is because the Food Bill is largely drafted, and changes to revise the Bill to extend the use of national programmes, and consequential changes would not require significant drafting effort.

Figure 3:



* Point at which at "Limited" amendment becomes a significant amendment. Note – the sub options in Figure 3 for Option C are mutually exclusive.

ALTERNATIVE OPTION - LIMITED AMENDMENT TO THE FOOD ACT 1981 (OPTION C)

This option gave consideration to the 'fundamental' aspects of the DFR that would need to be changed in order to support a limited amendment of the current Food Act 1981 and the associated regulations to improve and enhance the current food regulatory regime. It requires the identification of the 'fundamental' aspects of the DFR that could be undertaken to make a significant improvement to food safety and suitability. These are:

- 1. an enhanced Import Regime
- 2. mandating risk-based tools
- 3. clarifying the New Zealand Standard
- 4. repealing and replacing the Food Hygiene Regulations 1974
- 5. providing increased auditor capacity
- 6. revised penalties
- 7. an enhanced enforcement regime
- 8. improving the alignment across New Zealand's food legislation.

Under this option there are a number of different combinations of the proposed amendments identified in figure three above that could be selected to improve the current Food Act 1981. The combinations could be determined by what might constitute a 'limited amendment' that still delivers significantly improved food safety and suitability.

In considering the combination of 'fundamental' aspects that would comprise a limited amendment, it was recognised that there is a point when the selected aspects represent a substantive amendment, not a limited amendment. If a larger combination (or all) of the 'fundamental' aspects of the DFR were considered these would push a limited amendment into being a substantive amendment. Doing more than a limited amendment would represent a resource commitment of the same level as (or more than) the preferred Option E.

Analysis of Option C identified that only imports, new regulations, a range of risk tools (including non regulatory) and clarifying the application of the base New Zealand standard for food safety can be achieved before it starts to tip that balance. Beyond this point, i.e. seeking to include audit/verifier capacity provisions, revised penalties, enhanced enforcement provisions and improved alignment across New Zealand's food legislation would be a substantive amendment.

If all of the DFR 'fundamental' aspects were included there would be a greater need to merge new concepts and styles with the existing outdated and archaic legislation. Choosing all of the DFR 'fundamental' aspects under Option C does not make this option equivalent to what can be achieved under the preferred option. There would be gaps in the framework from merging older style legislation with the current drafting style; aspects like the clarification of the role of regulators and stronger appeal processes and Territorial Authority bylaws would not have been addressed. The advantage of drafting a new Act that has a clear framework, purpose, consistent language, and coherent style becomes a compelling alternative.

High level amendments to the Food Act 1984 to enhance the import regime and replace the Food Hygiene Regulations 1974 may be able to be achieved for a lower cost to central and local government than a revised Food Bill. However, the opportunity cost to businesses and consumers is higher in so far as reductions in compliance costs and improvements to food safety will be limited.

The additional length of time needed to progress this option correlates to an increase in resource and cost required from central and local government to develop the amendment proposals. The opportunity cost of this is lost cost savings to central and local government and to businesses. Society will also face the costs of continued high levels of food borne illness resulting from the delay in achieving improved food safety outcomes.

The risk of this option is that a limited amendment of the Food Act 1981 will create greater confusion for both food businesses and regulators because the amendment would contribute to an already disjointed legislative framework. The merging of old legislation with a new drafting style will not provide a cohesive framework to deliver on food safety outcomes. Managing this risk would be a challenge for food businesses and regulators; there will be a need to ensure that as far as possible the purpose and intent of the legislation is clarified.

Why an amendment to the Food Act 1981 is not the preferred option

The reasons why this is not the preferred option are:

- it would require more time and effort to give effect to achieving some, but not all, of the benefits identified in the preferred option;
- central government, local government and food businesses will continue to face unnecessary compliance costs that are associated with the current Food Act regime during the additional time taken to effect change;
- consumers would have to wait longer for an improvement in food safety;
- additional resources and cost to central and local government are required to achieve a similar outcome to the preferred option;
- while limited combinations of the option can be delivered for a similar cost and effort as the preferred option the outcome in terms of improved food safety and reduced compliance costs would be inferior; and
- the amended Food Act will remain based on an outdated and archaic legislative framework.

PREFERRED OPTION - REVISED FOOD BILL (OPTION E)

This option introduces a revised Food Bill from that developed over the last two years, which includes changes to improve certainty for business and further reduce compliance costs.

Regulatory Framework

Under the legislative framework, for the proposed regulatory regime, the Food Bill will clearly set out the duties, roles and high level outcomes for food businesses, the Minister, the Chief Executive and Territorial Authorities. Sitting under the Food Bill will be limited regulations that expand on the high level food safety outcomes and provide for national programmes.

Specifications will be provided to expand on the national programmes for specific sectors or to explain what is needed to achieve the high level outcomes when it is not feasible for each individual business to have this information (e.g. for honey harvesters, information would be available about the maximum allowable level of Tutin that is permitted in honey before the honey is too toxic for human consumption). Specifications will also expand on the basic requirements for food control plans. Food handler guidance will work effectively as an exemptions process. The diagram below sets out the design of the legislative framework for the Food Bill.

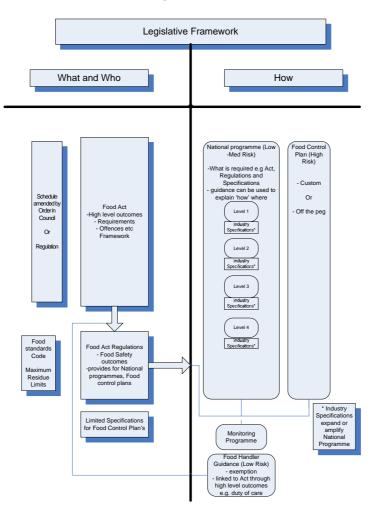


Figure 4 – Legislative Framework for Option E

A summary of the proposals contained in the drafted Food Bill and their regulatory impacts is contained in the appended regulatory impact statement (Appendix One).

The drafted Food Bill's objectives are to:

• restate and reform the law relating to dealings with food; and

- achieve the safety and suitability of food for sale by instituting risk-based measures in order to –
 - o minimise and manage risks to public health
 - o promote and protect public health
- require persons who deal with food to take responsibility for the safety and suitability of food.

The drafted Food Bill imposes the primary duty on persons who deal with food to ensure that the food is safe and suitable.

The drafted Food Bill provides for three types of risk management tools:

- food control plans
- national programmes
- food handler guidance.

A decision on the management tool that is most appropriate for a particular sector will take into account factors such as risk, the likely impact of an adverse food safety event, economic efficiency, the capability of regulated parties to develop and implement the tools, and the likely compliance rates. This means that the most efficient and effective approach can be taken to manage food safety and suitability issues in particular food sectors.

The revised Food Bill will make use of the lesser regulatory tool, national programmes for those businesses that present low to medium food safety risks and developing a schedule in the Food Act that clearly sets out what tool (regulatory, non-regulatory, educative) food sectors will be required to use to provide certainty to food businesses and further reduce compliance costs.

The revised Food Bill will provide for national programmes to be developed across four levels based on the level of risk and the degree of complexity associated with the activities undertaken by a sector. For example, manufacturers are proposed to be subject to a Level 4 national programme because they have complex processes and higher risks to manage. The four levels of national programme would ensure flexibility within the food regulatory regime to cover a range of activities from simple to more complex, and a range of food safety risks from lower to higher, that must be managed by food businesses without the cost of going to individual plans.

National programmes would not be pseudo food control plans, and would not be used to impose unnecessary regulation and/or increased registration and verification on food business operators. They would remain a lesser tool, setting out high level outcomes as minimum requirements that a group of food businesses or food sectors must meet to assure food safety. There would be no individual tailoring available to businesses covered by a national programme. Such differences could only be accommodated by an individual food control programme. Food businesses covered by a national programme (or food handler guidance) could still elect to develop their own individual food control plan for their own commercial reasons.

National programmes would not be written for each food sector but at each of the four levels would be supplemented by specific requirements for a particular sector where necessary.

National programmes are not intended to cover all food businesses that operate in New Zealand. They would not deliver the required food safety management at the top end or be cost effective at the lower end. There are higher risk, wide impact businesses (such as manufacturers of foods for high risk groups, and restaurants/takeaways dealing with a broad range of high risk foods on a daily basis³) that will continue to require food control plans. There are also the low risk, small impact 'kiwiana', activities (such as fundraising cake stalls and barbecues) that do not justify specific regulatory controls. For this latter group 'food handler guidance' is proposed.

For national programmes both the frequency and intensity of verification will vary. This variation will be dependent on the level of risk that is associated with a particular food sector or groups of food sectors. Both of these aspects provide for reduced costs to business.

Improved Business certainty

Improved business certainty is achieved through a proposed schedule in the revised Food Bill, which would clearly set out the specific tool a food business must operate under. The requirements of each national programme will be prescribed and clearly specify the regulatory requirements for each level of programme. Greater transparency and justification, including the requirement for consultation and regulatory impact analysis, is achieved through use of regulations to prescribe national programmes.

Reduced Compliance Costs

Under the revised Food Bill the numbers of businesses that are proposed to move from the Food Hygiene Regulations to a food control plan will decrease from an estimated 32,000 maximum down to an estimated maximum of 16,000.

This means up to 16,000 businesses that would have been regulated under an off-the-peg food control plan will now move from the Food Hygiene Regulations to operate under a national programme. Almost all of those businesses will face a reduction in compliance costs associated with:

- having less regulation to comply with;
- having greater certainty of regulatory requirements; and
- requiring less time and effort for transition.

Businesses that operate under a national programme will face costs associated with registration, verification and associated programme and compliance charges. However, those costs are expected to be less than those that would have incurred had those business operated under an off-the-peg food control plan as proposed in the drafted Food Bill.

Generally food businesses will benefit from reduced compliance costs and benefits will be achieved through only food safety requirements relevant to an individual food

³ This is based on the risk ranking work undertaken by NZFSA as part of the Domestic Food Review. Information on this can be found at: <u>http://www.nzfsa.govt.nz/policy-law/projects/domestic-food-review/risk-ranking/riskranking-methods.pdf</u>

business being imposed. A degree of national consistency can be achieved through the new regime; this does not exist at present. Territorial Authorities currently cost recover registration and inspection (verification) fees, which range from 10% to more than 100% of the fee being cost recovered; with the median being 66%. There will be a need for greater transparency to be provided to food businesses in respect of the fees that are charged to them.

It is expected that this initial cost will be decided by the local authority and is expected to be approximately \$50-\$100 for registration. The cost of verification for national programmes will depend on the level of national programme (risk posed), e.g. food verification (inspection) – based on hourly rate of \$100 per hour. On average this should be a 1-3 hr process costing \$100 - \$300.

There will be a rolling programme of verification based on four levels of national programme. All such businesses/premises will have an initial visit then verification frequency would be:

- Level 4 1 in 2 years
- Level 3 1 in 3 years
- Level 2 1 in 5 years
- Level 1 when a problem is raised.

A summary of those registration and verification charges are in the following table. More detailed costs are provided in the tables at Appendix 3 of the regulatory impact statement.

	Current Food Act	Drafted Food Bill	Revised Food Bill
	(Food Hygiene	(off-the-peg food	(national
	Regulations)	control plan)	programme)
Registration		\$100-\$150	\$50-\$100
Verification	Cost of both registration & verification range from \$50-\$1,880 per annum	\$100 to \$300 per annum	Level 4 \$100-\$300 every 2 years Level 3 \$100-\$300 every 3
			years Level 2 \$100–\$300 every 5 years Level 1 \$100–\$300 on investigation

Registration and Verification Costs for National Programmes

Current costs are derived from an NZFSA survey of Territorial Authorities completed at the beginning of the review. Allowing for known fee increases since the survey was completed NZFSA estimates that Territorial Authorities currently collect around \$6.5 million in fees and charges for food safety activities. A simple average is \$285 per business. However, there is a range in annual charges from \$50 to \$1,880.

The cost estimates for the proposed Food Bill are derived from the functions Territorial Authorities will perform e.g., registration and verification, plus some compliance activity and an estimate of the likely representative time, cost and effort to perform those functions. NZFSA is expecting the regulatory cost of the proposed regime to be no more than current costs. Under the revised Food Bill the expectation is that costs (on average) will be lower than current costs.

The new regime allows standardisation of verification, and provides for performance based verification whereby good operators are rewarded with less frequent and intense verification visits (reducing compliance costs for the food business). The rolling programme of verification will also reduce the costs for food businesses that have a national programme.

Steps that have been taken to minimise compliance costs

NZFSA will minimise compliance costs by applying the most suitable management tool to each business type. The majority of businesses will be provided with a national programme or an off-the-peg food control plan that is already evaluated and provided with guidance on how to tailor the plan to accommodate any special features. In addition, NZFSA will supply a wide range of guidance materials.

The extended use of national programmes is proposed as the risk management tool for a larger number of food sectors. The use of national programmes combined with lesser registration requirements and reduced frequency of verification all contribute to significant cost savings for businesses from the existing regime.

The revised Food Bill provides for a greater alignment between the risk a business poses and the regulatory control it is under. In general, high risk businesses will be required to have a food control plan, low to medium risk business will operate by using the national programme, and very low to low risk businesses will be required to have food handler guidance. Exceptions will occur when a particular sector is so small that the cost of the Government providing a national programme greatly outweighs the net cost of that industry developing their own food control plans. Appendix four, sets out the level of regulatory and non regulatory control that will apply to specific sectors.

In determining which tool applies to a particular food business sector NZFSA has completed work on establishing the most appropriate tool for various sectors based on a cobination of factors including food safety risks, existing regulatory requirements and the commonality between sectors. Based on this analysis, food businesses have been slotted into the tools, this will form a list in a schedule to the Food Bill that sets down what tool applies to each food business sector.

NZFSA has conducted trials of two of the off-the peg food control plans. The first trial was with 'corner' dairy retail businesses⁴ who are a hard to reach group of small businesses that do not generally have experience of management systems. The response from participants in this trial was positive, with many endorsing the food control plan documentation for effectiveness, relevance, simplicity and ease of understanding. The template has been designed to provide relevant, simplified food safety information to

⁴ The trial was conducted before the proposed changes to how the regulatory tools will be applied to food businesses. It is anticipated that most 'corner' dairy retail businesses under the revised Food Bill would be subject to a national programme.

food business operators, a copy of one of the pages from the food control plan is at Appendix five.

The second and third trials tested the food service food control plan in five areas of New Zealand in conjunction with the Hospitality Association of New Zealand and the Restaurant Association of New Zealand. Both trials involved a range of food businesses across the food service sector. The second trial also focused on Territorial Authorities working closely together to share information and deliver a more consistent regulatory service across a region. At the conclusion of the trials there were many businesses that indicated that the food control plan had become an integral part of their business, and they could identify the benefits of using the tool.

In August 2008 the food service sector (restaurants, café's etc) template food control plan was launched through the Voluntary Implementation programme. This was an NZFSA initiative that was strongly supported by Territorial Authorities to continue the work of the DFR. The results of this programme have been positive; 68 Territorial Authorities have agreed to participate and more than 500 businesses have voluntarily signed up to use the off-the-peg food control plan so far. The results of the earlier trials and the Voluntary Implementation Programme have been be used to make improvements to the efficiency and effectiveness of the regulatory tools.

The proposal to schedule in legislation the specific tool a food business must operate and use and a regulation making processes for changing those tools, as well as the prescribing in regulation of national programmes will enable a higher level of transparency and scrutiny over regulatory risk management decisions. The requirement for consultation and regulatory impact analysis will assist in ensuring that that compliance costs are minimised.

NZFSA will organise a graduated transition programme that will enable government and industry to manage and spread the cost of transition (see below).

IMPLEMENTATION AND REVIEW

Those high risk businesses that were identified for transition into the new regime under the Food Bill will still be required to operate using a food control plan. Those sectors that were identified for transition in years 3-5 will mostly be subject to a national programme. The greater use of national programmes will mean that of an estimated 35,000 to 40,000 food businesses, up to 24,000 food businesses will be required to have a national programme and the remainder will mostly be required to have food control plans.

NZFSA will need to develop national programmes prior to implementation. National programmes will need to be consulted on with affected food businesses to ensure that the content, scope and usability is appropriate and manages the food safety risks of the food business. The development of national programmes will provide clarity about the look of the national programme and how it will work. Work that has been completed under the Voluntary Implementation Programme on food control plans can be drawn on to contribute to national programmes. This is because there are generic aspects that are applicable to all food businesses such as safe food handling practices and sickness policy.

A graduated transition programme will enable a managed approach to implementation. It is proposed that transition takes place over a five year period. This length of time will

give Territorial Authorities and food businesses enough time to adjust to the new expectations and develop graduated local implementation strategies.

NZFSA will continue to take principal responsibility for all regulatory functions, including investigations and in assessing food control plans submitted for registration. Their contracted roles will include some or all of the following activities:

- contribute to the development of standards and implementation tools and education;
- systems audit;
- certain food control plan pre-registration activities;
- non-compliance investigations in specific (limited) areas beyond Territorial Authority responsibility;
- enforcement;
- emergency response, including recalls;
- monitoring and surveillance;
- facilitation of training (industry and businesses);
- foodborne illness response (as provided for under the Health Act); and
- education of consumers.

Territorial Authorities will have the regulator functions for the registration, compliance and enforcement of off-the-peg food control plans and some national programmes; a responsibility to deliver food handler guidance to ensure safe and suitable food is delivered by very small food-selling operations and a choice (provided they gain the required competency recognition) to have a role in verifying custom-made plans.

Territorial Authorities will also have an ongoing role in external verification including an exclusive right to conduct verification processes in the case of less complex businesses i.e. businesses that:

- have an off-the-peg food control plan;
- operate exclusively within a single Territorial Authority jurisdiction (except for

mobile businesses, where the lead would be taken by the Territorial Authority

where the mobile operator primarily operates); and

• have a limited scope of operation and sells directly to the consumer.

Throughout the implementation of the Voluntary Implementation Programme, NZFSA has been working with participating Territorial Authorities to develop their capability to undertake verification (one of the key shifts for Territorial Authorities) and enforcement activities. This work has set in place the platform that will be used for the new food regime.

Monitoring and enforcement will be done by both Territorial Authorities and NZFSA. NZFSA has been working with Territorial Authorities participating in the Voluntary

Implementation Programme to provide Food Act officer training to enable enforcement activities to be more effectively undertaken.

The NZFSA Compliance and Investigations Group will undertake audit checks of the food regulatory regime to ensure that the system is effective and achieving the desired outcomes of improving foodborne illness and food safety compliance.

NZFSA and Territorial Authorities will maintain an ongoing review programme of the implementation and operation of the new legislation. An example of this is the existing programme of review of the trials of the off-the peg food control plans with the food service sector (restaurants, café's etc) through the Voluntary Implementation programme. The results of the trials have been used to inform future policy development and implementation strategies and to make improvements to the efficiency and effectiveness of the regulatory tools.

CONSULTATION

The options discussed in this RIS were considered by the NZFSA / Local Government New Zealand Territorial Authority Steering Group (TA Steering Group). A meeting was held with the TA Steering Group in May 2009 to discuss the options, and following the development of the Regulatory Review Programme report a draft of that report was provided to them via email for comment. Some members of the TA Steering Group have also sought the views of other Territorial Authorities that are part of their regional cluster group prior to commenting to NZFSA.

The TA Steering Group gave consideration to both options C and E, and expressed the view that it was important that a reform of the food regulatory regime should be comprehensive. They expressed a desire to ensure that regulatory changes had sufficient 'teeth' within the law to enable them to monitor and enforce compliance appropriately. This would be achieved through option E and the enforcement tools that would be available in the new legislation, such as improvement notices through to prosecution.

The TA Steering Group were strongly supportive of a revised Food Bill, and agreed that a shift to a greater use of national programmes to reduce compliance costs and provide certainty to food businesses is a sound approach.

NZFSA has also consulted with the Food Retailers and Food Service Advisory Forum & Manufacturers and Processors Forum. A verbal update on the progress made on the Food Bill and possible reform was given to the members of the two forums at a joint meeting on 18 June 2009. Comments expressed by members were about the general frustration that the progression of the Food Bill is further delayed, and a desire to get the Food Bill into the Select Committee process as soon as possible. Following the meeting, the draft Regulatory Review Programme report was circulated to the forum via email. The comments received on the report were in support of a revised Food Bill.

The Small Business Advisory Group (facilitated by the Ministry of Economic Development) has also been consulted via email. One member from this group provided comment indicating that Option E looked to be the quickest to implement.

Consultation was also undertaken with the Ministries of Health, Economic Development, and Agriculture and Forestry, the Department of Internal Affairs, the State Services Commission and the Treasury. Generally departments were supportive of the regulatory

review and the recommendation that option E should be chosen to progress the Food Bill.

The Cabinet paper, regulatory review report and RIS were also provided to the Department of Prime Minister and Cabinet for information.

In terms of specific comment, the Ministry of Health was concerned that not enough emphasis had been placed on the public health outcomes that would be achieved from revised legislation. NZFSA is of the view that the public health outcomes i.e. minimising and managing risks to public health and protecting and protecting public health are part of the purpose of the drafted Food Bill. These outcomes have not been changed.

The Department of Internal Affairs queried whether food safety is an area where local discretion is desirable, and whether the proposed regime would be better served by central agency implementation through regional offices. NZFSA is of the view that these concerns were addressed during the DFR, with Territorial Authorities agreeing that they wished to maintain a role in food safety. Territorial Authorities possess local knowledge of food businesses operating within their district, they can respond quickly if an incident arises within their district; they already employ Environmental Health Officers who can deliver on food safety activities. It would not be cost effective to set up implementation through regional offices controlled by central government. NZFSA agrees with and supports the ongoing involvement of Territorial Authorities in food safety activities for New Zealand.

Appendix One

Domestic Food Review - Regulatory Impact and Compliance Cost Statement – October 2006, updated June 2008

Can be found at <u>http://www.nzfsa.govt.nz/policy-</u> <u>law/publications/regulatory-statements/domestic-food-review-</u> <u>regulatory-impact-statement.htm</u>

Regulatory Review Programme 2009

Food Bill – regulatory review of two options: a Limited Amendment to the Food Act 1981 (and associated regulations) (Option C) or the Revision of the Food Bill to provide certainty to food businesses and reduce compliance costs (Option E)

Executive Summary

- The proposed Food Bill has been included in the Regulatory Review Programme for 2009. Government has already agreed in principle to continuing work on the Food Bill. To further the Food Bill's progress, Government has requested the New Zealand Food Safety Authority (NZFSA) conduct a review of two specific options.
- 2. The two options are a limited amendment to the existing Food Act 1981 and associated regulations (Option C), and a revision of the Food Bill (as drafted) to more broadly use national programmes as the main regulatory tool, with a view to providing certainty to food businesses and to reduce compliance costs (Option E). Analysis of both options has been undertaken against Terms of Reference that were prepared for the two options as part of the Regulatory Review Programme 2009. Ministers English and Hide have approved the Terms of Reference.
- 3. Depending on the extent of aspects selected to comprise Option C, both Options could deliver similar cost minimisation and reductions for food businesses. Additionally, food businesses will make savings under both Options by only having the necessary requirements being applied to their food business operations, not having to comply with the non-safety related requirements of the Food Hygiene Regulations 1974 and possibly not having specific regulatory requirements to meet at all.
- 4. Society will benefit from an improved food regulatory regime from both options but it is the time and resource requirements to effect change that will have the most significant impact on costs. Again, depending on the aspects selected to comprise Option C, the Option could provide for improved food safety taking four to six months to consult on proposals to undertake a limited amendment of the Food Act 1981. However, depending on how 'limited' the amendment to the current Food Act 1981 is, the process could take up to three years.
- 5. Costs to Government would be incurred by the resources required to complete the consultative and policy processes for an amendment. For businesses, the

costs would be the requirement to continue operating using outdated legislation that imposes compliance costs that go beyond food safety until the amendment is enacted.

- 6. Option E would also provide for improved food safety within a comprehensive framework. There would be a need to consult on the transition of food sectors to the new revised tools; however this can be done at the same time as drafting changes are made to the revised Food Bill. It is anticipated that redrafting the Food Bill to extend the use of national programmes, and consequential changes across the draft, would take between six and eight months. At the conclusion of that period the revised Food Bill would be ready for introduction to the House.
- 7. Comparing both options (as set out in a table in paragraph 116), the cost of Option E would be significantly less than Option C because less time and resource would be needed to undertake the proposed revision to the Food Bill.

Introduction

- 8. NZFSA has specific functions as New Zealand's primary food regulator. NZFSA is required, among other things, to administer all food legislation and food safety and suitability matters. NZFSA also has to deliver results in two closely aligned areas:
 - Reducing the incidence of foodborne illness in New Zealand; and
 - Providing a coherent and seamless food regulatory programme.
- 9. NZFSA commenced a Domestic Food Review (DFR) in May 2003. The DFR covered all food sold in New Zealand, whatever its source and whatever the processes by which it reached the point of sale. At point of entry into New Zealand, all imported food falls within the scope of the regulatory regime that applies to New Zealand food.
- 10. Food produced in New Zealand for export (i.e. that at no stage enters the New Zealand food supply) did not fall within the ambit of the DFR. However, it is important to note, that food produced in New Zealand for export must meet the same standards of safety and suitability that apply to food for consumption in New Zealand.
- 11. The DFR was largely completed in October 2006. The conclusion of the DFR was that the current food regulatory regime was in urgent need of improvement. A background summary of the DFR is at Addendum A.
- 12. In response to the proposed changes identified during the DFR work, and the conclusion that improvement was urgently needed, the development of a new Food Bill commenced in February 2007. The current Food Act 1981 is a prescriptive approach to food safety drafted in the late 1970s. A single major amendment was made in 1996 that grafted on skeletal provisions for a voluntary risk based tool, a food safety programme. These provisions are not sustainable for the food regime in the long term.

Regulatory Reform Programme 2009

- 13.A Food Bill has been included in the Government's Regulatory Review Programme for 2009. The Cabinet Economic Growth and Infrastructure Committee considered five options (A to E) for proceeding. It agreed in principle to continued work on a revised Food Bill subject to the completion of a regulatory review of its two preferred options that addressed the need to improve business certainty and further reduce compliance costs:
 - Option C undertake a limited amendment to the Food Act 1981 (and associated regulations), or
 - Option E introduce a revised Food Bill.
- 14. Terms of Reference for progressing changes to the domestic food regulatory regime were submitted to the Minister of Finance and the Minister for Regulatory Reform on 24 April 2009. The Terms of Reference (Addendum B) proposed that a review be undertaken of the Food Act 1981 and Food Hygiene Regulations 1974 that would specifically consider the two selected options, Options C and E.

Review of the Options

- 15. The Terms of Reference required the fundamental differences between the current food regime and the two selected options to be assessed across seven areas:
 - compliance costs;
 - international best practices;
 - consistency and equity of chosen regulatory requirements;
 - risk based versus a prescriptive regime;
 - how seamless and coherent is the proposed regime;
 - impacts on trade and commerce in food and associated products; and
 - the level of resource required and the impact of timing of each option.
- 16. The assessment of options draws on the areas identified by the DFR and recommended as needing amendment. Both options need to also consider the time and resource commitments that central and local Government will require to be able to deliver the food safety regime. The areas recommended for amendment provide the basis for analysing Options C and E to improve the food regime. These areas may comprise either a limited or significant amendment to food legislation.
- 17. If the DFR recommended amendments were undertaken, they would significantly improve the current food safety regime. These amendments are described as the 'fundamental' aspects and include the following:

- 1. provision of an enhanced imported food regime;
- mandated risk based tools (both regulatory and non-regulatory or educative) and a shift in onus of responsibility for food safety from Government to food business operators;
- 3. clarification of the New Zealand Standard as the platform for all food sold within, and exported from, New Zealand;
- 4. replacement of the Food Hygiene Regulations 1974 with regulations that are outcome based and enabling;
- 5. provision for increased audit capability and the Territorial Authority role;
- 6. improvement of penalty provisions;
- 7. improvement of the enforcement regime; and
- 8. improvement to the alignment of New Zealand food legislation.
- 18. There are other changes that would go towards the provision of a comprehensive package of changes to address the problems raised during the DFR. These are currently included in the drafted Food Bill and include: providing for mandated education and training requirements which would remove the need for various Territorial Authority bylaws that have been created to address this gap and improve consistency; performance requirements for Territorial Authorities; greater clarification of the role of regulators (i.e. the Minister, the Chief Executive and Territorial Authorities); stronger appeal processes; and prerequisites for the provision of a national grading system for retail services.
- 19. The other changes referred to in paragraph 18 are not seen to be the 'fundamental' aspects that would improve the current food safety regime. These changes are areas that could be included in a more comprehensive legislative change package, or could be added as enhancements to a more limited package at a later stage. These changes are necessary for a comprehensive and nationally consistent approach. Many Territorial Authorities have provided for some of these via bylaws.
- 20. One of the 'fundamental' aspects, mandated risk based tools (both regulatory and non-regulatory or educative) that shift the onus of responsibility for food safety from Government to food business operators, has been reviewed on the basis of experience under a voluntary programme run as part of DFR and the cost of compliance. This new approach could be used in either Option C or E and is described below before consideration is given to the two Options.

Risk based tools - reducing cost of compliance

21. The DFR work to date has centred on the application of a regulatory food control plan tailored to each food business. Two lesser tools were developed for special or exceptional circumstances: national programmes and food handler guidance. A change to make the national programme the rule rather than the exception, has

emerged from NZFSA's work on an 'off-the-peg' template food control plan for the food service and catering sector, and a request from Government to consider further reducing compliance costs. It is clear that for many medium to lower risk sectors, there are generic or core requirements, designed to deliver on the objective of safe and suitable food that could form the basis for a national programme. These could be supplemented by specific requirements for a particular sector.

22. Both business certainty, and reduced compliance costs, could be satisfied by giving primacy to national programmes instead of the current food safety programmes (in the Food Act) or food control plans (in the drafted Food Bill) especially for medium risk/medium impact food businesses. National programmes would be the first or central option for regulatory control instead of individual food safety plans (as is currently available in the Food Act) or food control plans (as has been developed to date under the DFR and in the drafted Food Bill). By making this change, a greater number of food businesses could start in the new food regime under a national programme rather than on individual plans.

Expanded use of national programmes

- 23. National programmes would need to be developed across four levels based on the level of risk and the degree of complexity associated with the activities undertaken by a sector. For example, specific manufacturers are proposed to be subject to a Level 4 national programme because they have complex processes and higher risks to manage. The four levels of national programme would ensure flexibility within the food regulatory regime to cover a range of activities from simple to more complex, and a range of food safety risks from lower to higher, that must be managed by food businesses without the cost of going to individual plans.
- 24. National programmes would not be pseudo food safety programmes or food control plans. They would remain a lesser tool, setting out high level outcomes as minimum requirements that a group of food businesses or food sectors must meet to assure food safety. There would be no individual tailoring available to businesses covered by a national programme. Such differences could only be accommodated by an individual food control programme. Food businesses covered by a national programme (or food handler guidance) could still elect to develop their own individual food control plan for their own commercial reasons.
- 25. National programmes would not be written for each food sector but each of the four levels would be supplemented by specific requirements for a particular sector where necessary.
- 26. National programmes are not intended to cover all food businesses that operate in New Zealand. They would not deliver the required food safety management at the top end or be cost effective at the lower end. There are high risk, wide impact businesses (such as manufacturers of foods for high risk groups, and restaurants/takeaways dealing with a broad range of high risk foods on a daily basis) that will continue to require individual plans. There are also the low risk, small impact 'kiwiana', activities (such as fundraising cake stalls and barbeques)

that do not justify specific regulatory controls. For this latter group 'food handler guidance' described below is proposed.

27. For national programmes, there will be a range of both frequency of verification and the extent of elements requiring verification (i.e. the intensity of the checks). Both of these aspects relating to verification provide for reduced costs to business. The frequency and intensity of verification will be dependent on the level of risk that is associated with a particular food sector or groups of food sectors. This is discussed further in paragraphs 35 to 40.

Food safety programmes/food control plans

- 28. There are a number of food sectors that have very few operators because of their size or the unique processes/products etc that they do/make. There are also businesses dealing at the high risk/high impact end of the food chain; sectors where there is a high diversity of products and food activities; and food businesses that process foods with a high potential for foodborne illness either for the general population or for highly susceptible population groups. These businesses and sectors would still need an individualised food safety programme or food control plan. Examples of such businesses are super markets and food service on-site catering. Food safety programmes and food control plans that are individually developed by a food business operator would still need to be evaluated prior to being registered. Evaluation is the step that ensures the processes described in the plan deliver the food safety and suitability outcomes sought by the regulator.
- 29. NZFSA is already providing guidance materials for businesses to assist them in developing their own food safety programmes or food control plans. NZFSA has also developed an off-the-peg (template) food control plan for businesses in the food service and catering sector, and may continue down this pathway for groups of businesses or sectors that are to be subject to this tool. This would be particularly the case where it was more economic (for businesses) for Government to undertake development and evaluation.

Food handler guidance

30. Food handler guidance is intended to be educative, non-regulatory information for food businesses of low risk/low impact. The guidance would provide them with sufficient basic information on safe food practices to deliver food safety in a narrow range of activities. Food handler guidance would cover basic hygiene information like good hand washing, how to avoid cross contamination of food, and safe storage of food. This tool would be freely available to the 80,000 to 200,000 food 'events' that operate across New Zealand on a daily and/or weekly basis each year.

Registration aspects

31. National programmes would have a range of registration starting points for food businesses based on the food safety risks being managed by the food business. These will range from self registration, third party registration, to registration with NZFSA or Territorial Authorities. Previously only registration with NZFSA or Territorial Authorities had been proposed.

- 32. Self registration provides capability for the food business operator to register their business on an approved system for minimal cost. Such a system will provide for food business operators to be able to register and list their business, together with relevant business information such as the scope of the food business activities. This will be important to regulators, both central and local government, to be able to undertake compliance checks of food businesses that are operating in New Zealand.
- 33. Third party registration considers existing data capture systems that may be associated with a sector or generally, for example, the horticulture sector has information on their members that may be used; this would reduce costs and minimise the duplication of systems. Direct registration with Territorial Authorities or NZFSA would be used if either of the other two options (self registration or third party registration) was not able to be undertaken, or was not appropriate. Costs associated with each of the three options for registration would need to be on an actual and reasonable rate.
- 34. Registration, whether it is self registration, third party registration, or registration with NZFSA or Territorial Authorities, is mandatory and is necessary to enable regulators to have awareness of the food businesses that are operating across New Zealand so that compliance activities can be managed. Territorial Authorities and NZFSA will both need to have knowledge of food businesses that are operating and there will be a need to avoid unnecessary duplication of systems.

Verification aspects

- 35. There are a variety of food sectors that operate in New Zealand and verification requirements should be designed to accommodate the variability that exists, and the food safety risks that need to be managed. For food sectors where the risks are very low, verification may only be initiated if a problem is reported (which may trigger an investigation) regarding the food activities, effectively a zero verification position. For other food businesses, where the risks are medium to high, verification will range from once every two years or once every three years; and for those food businesses where significant food safety issues need to be managed annual verification would apply. Annual verification would apply, at least initially, to those food businesses that operate under a food control plan.
- 36. Most food businesses operating under a national programme would be subject to a rolling verification programme. Such a verification programme would mean a reasonable sample of food businesses covered by a specific national programme would be selected for verification each year. This could be between 20-40% of businesses within a specific national programme. Rationale for starting from this position is that there is a high turn over of food businesses, estimated at a third, and the need to ensure reasonable confidence levels that the system is working.
- 37. Depending on the results of the verification for a specific national programme the percentage of businesses verified could be increased or decreased. The rationale for starting from high position is that there is a high turn over of food businesses

(estimated at around 25% annually) and the need to ensure reasonable confidence levels that the system is working.

- 38. With the proposal for verification to be subject to a rolling programme, there will be a need for regulators to undertake an occasional 'scoping check' of a food business in the year, or years, that the verification is not being done to ensure that the national programme is fit for purpose. This would be done to ensure that the scope of the food business has not changed significantly from what has been registered (self registered).
- 39. For example, a corner store dairy may self-register their national programme and indicate that they are selling shelf stable products. A year later, the food business operator innovates and decides to now also make fresh sandwiches that have higher food safety risks that need to be managed. This shift in scope of their national programme would require the food business operator to have awareness of aspects such as safe food storage requirements, food handling aspects, and the avoidance of cross contamination.
- 40. All food control plans would remain subject to an annual verification, with the provision for food businesses that were good performers (i.e. consistent and with a high level of compliance) to benefit from performance based verification. Performance based verification rewards good operators by reducing their verification frequency.

The package of risk based tools

- 41. Addendum C sets out how the risk-based regulatory and non-regulatory tools would fit together and how greater use of the national programme could be achieved to reduce compliance costs. Details of the types of sectors that would fall into a certain category, whether registration or self registration was appropriate, the standards and requirements applicable to the sector and information on the level and frequency of verification are also included.
- 42. There are distinct differences across the three tools that might be available, i.e. the food safety programme/food control plan, the four levels of national programme and food handler guidance. Addendum D provides an indication of the tool that specific sectors might be subject to under this revised approach. Business certainty could be provided by setting out this information publicly, making it clear which sectors were intended to be covered by which tool and, in the case of national programmes, which level of tool applies.
- 43. A list of food sectors that might be subject to national programmes could be included in a schedule under the amended or revised Act, depending on which Option is chosen. Similarly, those sectors that would be subject to food handler guidance (educative material), could also be listed in a schedule. Business certainty would be assured. In respect of registration requirements and the frequency of verification, these aspects could be achieved by prescribing them in the regulations to further provide certainty to food businesses.
- 44. Compliance costs for businesses covered by national programmes, compared to food safety programmes or food control plans, would be reduced because of the flexibility in registration and the reduced frequency of verification. Compliance

costs of low risk/low impact food activities would be even lower because they would not be subject to specific food regulatory controls. The primary link for them would simply be an obligation to deliver safe and suitable food.

Option C

Description of Option C

45. Option C is a limited amendment of the Food Act 1981 (and associated regulations). It requires the identification of the 'fundamental' aspects of the DFR that could be undertaken to make a significant improvement to food safety and suitability. Government has not placed any parameters around which 'fundamental' aspects should be included in a limited amendment. The following table assesses the proposed amendments identified in paragraph 17 and summarises key potential benefits and problems of each for an Option C package.

1 Enhanced Import Regime	
An enhanced imports regime as set out in the Food Bill could be included in an amendment.	
Identified benefit	Potential problem
The focus would be on better management of food and related goods entering New Zealand based on their risk, rather than just on prescribed, high risk foods. This would require specifically dealing with importers as a core food sector group.	If there are no risk based tools available, then an alternative regulatory tool would need to be developed for application in the import regime.
Features would include targeted regulatory controls and setting out a positive list of duties for importers. A specific 'imports' regime would need to be built requiring importers to have systems and procedures in place for the traceability of imported products.	
Applying duties would greatly enhance the ability of NZFSA, and importers themselves, to be responsive in circumstances such as those associated with the import of "White Rabbit" confectionary that was found to contain high levels of melamine in 2008.	

2 Three risk-based tools mandated to cover all food operations

The current food safety programmes could be enhanced and mandated (they are currently voluntary) and supplemented by two less costly tools: National Programmes to provide generic cover for defined food sectors; and Food Handler Guidance (non-regulatory, educative material) to cover the lower risk/least impact activities such as fundraisers like cake stalls and barbeques. This would reflect the revised approach described in paragraphs 21-44.

Identified benefit	Potential problem
Risk-based tools are less prescriptive than inspection-based regimes. A range of tools provides flexibility, especially for small operations and small business and avoids the 'one size fits all' approach. The best tool would be used relevant to the needs and scope of a specific food	Risk-based tools require other components within the legislative regime framework to enable them to work effectively. Changes to include risk-based tools cannot be phased or piecemeal, and would require amendments throughout the whole legislative framework.
sector.	The Food Act 1981 does not address the food production side of the food chain which may
Most importantly, risk based tools shift the onus of responsibility for delivering safe and suitable food from Government to operators.	be an issue when applying tools to these sectors such as the horticultural sector.

3 Clarifying the New Zealand Standard

Clarifying that all persons who sell food, including importers, producers, processors and handlers, whether it is for the domestic or export market, are subject to the Food Act unless specifically exempted is important to New Zealand's reputation both domestically and internationally. Omission of this clarification in the Food Act 1981 is a particular weakness and creates unnecessary uncertainty for businesses. Definitions such as 'food' and 'food business' could be updated as part of this clarification.

Identified benefit	Potential problem
Clarifies the businesses that are to be regulated and the standard that they are expected to meet. This will help ensure national consistency.	The definitions as they are currently drafted in the Food Bill would need to be reworked to fit within the Food Act 1981 schema.
Addresses the changing environment within which food is sold, such as internet sales, innovative ingredients and processes and new technologies.	

4 Food Hygiene Regulations 1974

The Food Hygiene Regulations would need to be completely reviewed with the prospect of the majority being repealed and replaced. They are out of date and have not kept up with changes in eating habits (such as outside dining and buffet dining); food preferences (such as ethnic foods and special preparations); technology or environmental developments. They are unwieldy and often ignored, creating potentially significant legal issues.

Identified benefit	Potential problem	
Less prescriptive and more outcomes focussed regulations would be developed.	If there are no risk based tools available then any revised regulations would still have a significant prescriptive component to them.	
Parts of the regulations that are not able	The Food Hygiene Regulations were initially created by the now repealed Food and Drug	

· · · · · ·	Act 1969. They were a poor fit to the Food Act in 1981. They will remain a poor fit unless repealed and replaced.
Businesses would benefit from reduced compliance costs that are currently imposed to meet the often non-food safety aspects of the existing regulations. Only necessary requirements to address food safety outcomes would be regulated.	More outcome based regulations require different powers in the Food Act 1981 that specifically address food safety aspects of food production.

5 Providing increased audit capacity

A three tier 'Regulatory Model' is currently applied across all food legislation except the bulk of the Food Act 1981. It is fundamental to our export regime and is widely accepted internationally. It defines Government involvement in the food sector and consists of three participants: the regulator (Government), the auditor/verifier and the industry operator.

The three participants assume complementary roles and responsibilities which, when combined, enable the regulatory model to function as a robust and effective system. In New Zealand, it protects and enhances New Zealand's position as a trusted supplier of safe, "fit for purpose" and truthfully labelled food for some domestic and all international consumers.

Identified benefit	Potential problem
If risk based tools are included in any amendment then provision is needed for TAs to undertake audit/verification of these risk based tools just as they inspect the current prescriptive requirements.	If provision is not made for TA involvement in audit/verification, there is the prospect of a shortage of available auditors/verifiers to audit food businesses and ensure they were delivering on their responsibilities to provide safe and suitable food.
Providing TAs with an area of exclusivity to audit/verify certain risk based tools in their region guarantees audit capacity for the system. Over time, as audit capacity develops, exclusivity could be reviewed.	

6 Penalties

The penalties need to be significantly increased. Judicial comment in recent cases brought before the courts indicates dissatisfaction with the current range of penalties available.

Identified benefit	Potential problem	
A more appropriate range of penalties could be implemented that align the Food Act with other food related legislation.	Does not address the core problem of improving food safety. If taken in isolation this single amendment would be seen as a short term remedy.	

7 Enforcement The enforcement regime is out of date and needs to be reviewed in light of the development of the Search and Surveillance Bill and the more extensive use of infringement regimes. **Identified benefit** Potential problem Not all offences would be able to Changes would modernise and expand on existing adapted into a modern be enforcement powers to ensure that these are the best framework because the schema available in the modern food environment. of the Food Act 1981 is a major limitation. Introduction of an infringement regime and other enforcement tools that may be used from improvement notices to imprisonment provides an escalation The archaic language and approach to enforcement that does not currently exist. outdated drafting style of the Food Act 1981 means the This would provide an enforcement regime that would offence provisions currently integrate with the new Search and Surveillance Bill drafted in the Food Bill would regime. need to be completely re-written. 8 Improve the alignment across New Zealand's food legislation

The alignment of New Zealand's food legislation is considered a priority by both NZFSA and the food industry. Any amendment to the Food Act 1981 should attempt to address this as far as possible.

Identified benefit	Potential problem	
	used in 1981. An attempt was made in 1999 with a	

- 46. There are a number of different combinations of the proposed amendments identified in paragraph 17 that could be selected to improve the current Food Act 1981. The combinations will be determined by what might constitute a 'limited amendment' that still delivers significantly improved food safety and suitability.
- 47. The following table sets out some possible combinations of the 'fundamental' aspects, a summary analysis of the subsequent relative impacts on the Food Act 1981, effectiveness for food safety and costs and benefits (least/limited/marginal, some, substantial or significant).

Amendments by number from paragraph 16	Brief description	Extent of amendment and likely impact on food safety and cost of compliance
1, 4	Imports and new Regulations	Least amendment – likely to be around 20% change to Act Limited/marginal food safety improvement and limited/marginal reduction in costs
All of the above plus 2 and 3	Imports and new Regulations PLUS range of risk tools (including non-regulatory) and clarifying application of the base New Zealand standard for food safety	Substantial amendment – likely to be around 35% change to Act Potential for substantial food safety improvement and some reduction in costs
All of the above plus 5 and 6	Imports, new Regulations, range of risk tools (including non-regulatory) and clarifying application of the base New Zealand standard for food safety PLUS audit/verifier capacity provisions and revised penalties	Significant amendment – likely to be at least a 50% change to Act Potential for significant food safety improvement and substantial reduction in costs
All the above plus 7 and 8	Imports, new Regulations, range of risk tools (including non-regulatory) and clarifying application of the base New Zealand standard for food safety, audit/verifier capacity provisions and revised penalties PLUS enhanced enforcement provisions and improved alignment across New Zealand's food legislation	Significant amendment – likely to be in excess of 70% change to Act Significant food safety improvement and substantial reduction in costs

48. Ministers have already rejected a proposal to only amend the Food Hygiene Regulations 1974 on the basis that it would deliver an inferior system and very limited food safety improvement, (EDI Min (09) 5/11 refers).

- 49. Proceeding with 'fundamentals' 1 and 4 only, (importer regime and revised regulations), delivers a marginal improvement in food safety (mostly focussed on imports) and marginal reduction in costs (by removing food regulation provisions that do not contribute to food safety). Even so, because of the need to 'fit' an improved import regime into the current Food Act design; amendments would be needed across the entire Food Act requiring around 20% of the Act to be amended. A lesser combination of the proposed amendments could also be considered, but these would need to be aspects that are not interconnected and which could be changed without too much impact on other parts of the Act. Such specific changes would be limited in their ability to address an overall improvement to our domestic food regulatory regime.
- 50. Proceeding with 'fundamentals' 1, 2, 3 and 4 only (importer regime, revised regulations, risk based tools and clarifying the New Zealand standard to apply) has the potential to substantially improve food safety and result in some reduction in costs for industry and Government. This would result in around 35% of the Food Act 1981 being amended. This could be more of a comprehensive legislative change rather than a limited amendment and may leave the Act in a piecemeal state, with a combination of old (1981) and new (2009) provisions and drafting styles.
- 51. Proceeding with 'fundamentals' 1 to 6 (importer regime, revised regulations, risk based tools, clarifying the New Zealand standard to apply, audit/verification and penalties) is an integrated package. The proposed changes are interconnected and collectively build the foundation for a risk-based food regime. Amendments 1 to 6 represent a significant change to the Food Act 1981 and would equate to at least a 50% change to that legislation, but like proceeding with 'fundamentals' 1 to 4, it may leave the Act in a piecemeal state.
- 52. Proceeding with 'fundamentals' 1 to 6 challenges both the idea of a 'limited amendment' and the cost-benefit for Government of attempting an amendment rather than drafting a new bill in it's entirety. At this point it may be potentially impracticable, and more resource intensive, to make significant amendments to an existing Act than to recast the Act in its entirety. It could be more efficient and effective to make the same changes through the development of a new bill and reap the benefits of a more coherent Bill, as opposed to a piecemeal combination of old and new.
- 53. Proceeding with 'fundamentals' 1 to 8 (importer regime, revised regulations, risk based tools, clarifying the New Zealand standard to apply, audit/verification, penalties, enforcement and alignment across all New Zealand food legislation) is most likely beyond the scope of a limited amendment.
- 54. Improving the enforcement regime provisions is a significant change, which by itself would push a proposed limited amendment beyond the concept of being limited. As an alternative, if Option C was to proceed with fewer 'fundamentals' consideration could be given to amending the enforcement and penalty provisions once the first limited amendment of the 'fundamental' aspects, i.e. aspects 1 to 4 in paragraph 12 above, are enacted. This would effectively push the enforcement changes out for a period of three years or more.

- 55. Consideration then needs to be given to an obligation for all New Zealand legislation, which has enforcement powers, to be aligned with the recently introduced Search and Surveillance Bill. This would push the need to review and/or update enforcement provisions in the Food Act 1981 to be of greater priority than anticipated.
- 56. The Law Commission, Ministry of Justice and the Parliamentary Counsel Office have met with NZFSA to discuss amending the Food Act 1981 to bring it into line with the Search and Surveillance Bill. With the future of the Food Bill still to be confirmed, minor amendments to the Food Act 1981 are included in the Search and Surveillance Bill. However, these changes do not adopt the Search and Surveillance regime in its entirety due to the difficulties of grafting these onto the Food Act 1981 in its current form. Further consideration would need to be given to additional changes to the Food Act 1981, to reflect the full ambit of the Search and Surveillance regime, if the decision is made to undertake a limited amendment of that Act.
- 57. The greater combination of 'fundamental' aspects that are introduced into the existing Food Act, the more there is a need to merge new concepts and styles with outdated and archaic legislation. The advantage of drafting a new bill that has a clear framework, purpose, consistent language, and coherent style becomes a compelling alternative.
- 58. Discussions with the NZFSA/Local Government New Zealand convened Territorial Authority Steering Group regarding the combination of 'fundamental' aspects for Option C resulted in Territorial Authorities indicating that they favour all of the proposed amendments in paragraph 17 and more (particularly a national grading scheme). The relationship of these eight 'fundamentals' is seen by Territorial Authorities to create the bare minimum of a core package for a significantly improved food regime.

Assessment of Option C against the Terms of Reference

59. The following paragraphs (59 to 81) specifically address the areas of review identified in the Terms of Reference in respect of Option C. Each is assessed with reference to the decisions that might be made under Option C.

Prescriptive regime versus risk-based

- 60. The current Food Act 1981 is prescriptive and is a command and control environment that is driven by regulators telling food businesses what they must do to provide safe and suitable food. Food businesses are, in the main, inspected annually and the operators instructed by the regulator on improvements or changes they need to make to address concerns raised during that annual inspection.
- 61. Currently, the Food Hygiene Regulations 1974 prescribe a number of requirements that a food business must meet that do not go to food safety. For example many premises are delayed from opening because of issues around the

non-provision of coving⁵ or what the Environmental Health Officer considers inappropriate floor coving. This would have no effect on the safety of food but is a 'registration' requirement. Delays in opening, to address these type of registration improvements, results in ongoing costs for food businesses (rent etc), with no income being generated. Some of the changes identified by the Environmental Health Officer during the annual inspection, and highlighted for improvement, do not go to food safety issues. A summary of the aspects of the Food Hygiene Regulations 1974 that impose unnecessary requirements and increase compliance costs on food businesses is at Addendum E.

- 62. Determining how prescriptive (command and control) or risk based (responsibility is with the food business operator) Option C is, will also influence the impact on food safety and the cost of compliance. Under the proposed 'fundamental' aspects', the introduction of a range of mandated tools, revised regulations, an importer regime and clarification of the New Zealand standard would be a good step towards a risk based management regime, improved food safety and reduced costs.
- 63. A range of regulatory (and educative) tools will avoid a 'one size fits all' system. Appropriate tools could then be applied to sectors that best reflect the activities within the sector and the food safety risks that need to be managed. If risk based tools are not mandated then some interlinked 'fundamental' changes would not be viable or would not make sense in terms of their purpose.

Degree of consistency and equity across food sectors

- 64. Depending on the chosen combination of 'fundamental' aspects a reasonable degree of consistency and equity across food sectors may be achieved. If the regulatory tools are mandated, and are based on the management of food safety risks by food businesses, then the ability to apply the same rules nationally, i.e. from Kaitaia through to Invercargill, would be far more likely to occur. For example, a national programme could be supplemented so as to apply to a certain sector and to businesses in that sector throughout New Zealand. Requirements and guidance would be tailored and standardised so that both businesses and Environmental Health Officers in Territorial Authorities know with certainty what is necessary.
- 65. Territorial Authority bylaws that have been imposed to address gaps in the primary legislation, and are not addressed through the limited amendment, would remain in place and need to be complied with by food businesses. This may create some inconsistencies across food sectors, for example, a number of Territorial Authorities have bylaws for food safety training, Option C does not address this gap.

⁵ Coving relates to the curved surface between the floor and the wall.

Seamlessness and coherence of the regime

- 66. The degree of seamlessness and coherence that would result from a limited amendment will be dependent on how easily two different styles of legislative drafting can be meshed together. A limited amendment would require consideration to be given to how an archaic Act (not drafted in plain English) can sustain the new legislative changes (drafted in the modern, plain English style). How successful this melding together will be depends on how interconnected the chosen 'fundamental' aspects are, and how those amendments impact across the entire shape of the Food Act 1981. For example, provisions for risk-based tools (both regulatory and non-regulatory) would lead to revised regulations specific to food safety, with aspects that do not go to food safety being removed. This would contribute towards a more coherent and seamless regime.
- 67. Food business operators would still have to comply with the Food Act 1981, revised Food Hygiene Regulations 1974, the existing Food (Safety) Regulations 2002 and the Food Standards Code (for labelling and composition aspects). Territorial Authority bylaws would also need to be complied with where necessary.

Comparison with international best practices

68. Provided that mandated risk based tools were part of the mix for a limited amendment, the proposed changes would begin to bring the Food Act 1981 into line with international practices for ensuring food safety. Food safety systems that operate in Canada, England/Wales, Scotland, Northern Ireland and the Australian States of Victoria, New South Wales and Queensland were analysed by NZFSA as part of the DFR. The food safety systems in these countries are all risk based and focus on the management of food safety risks by the food business operator.

Compliance Costs

- 69. The provision of a range of risk based tools, and the avoidance of a 'one size fits all' system, will reduce costs for food businesses because they would only be required to meet the obligations relevant to the tool they will operate under. For example, if the risk based tools include national programmes (as elaborated on in paragraphs 23-44), reduced costs could be achieved by removing non-safety related aspects, reducing registration requirements, and reducing the frequency of verification for food businesses that would operate under national programmes.
- 70. Revoking the existing Food Hygiene Regulations 1974, and drafting new regulations that were outcome based, and relevant to food safety, would also reduce compliance costs for food businesses. The regulations would be relevant to food safety outcomes and not include compliance requirements that go beyond food safety such as requiring that no ceiling shall be less than 2.4 metres above the floor⁶. The remedial obligations that food businesses would be subject to would be relevant to the activities they were undertaking within their food business.

⁶ First schedule of the Food Hygiene Regulations 1974.

71. It should be noted that food businesses will face compliance costs associated with trying to interpret and comply with legislation that does not have a clear purpose. When legislation is not clear and coherent, the degree of accessibility and consistency that is being sought is compromised and may lead to ineffective and inefficient legislation being imposed.

Impacts on trade and commerce

- 72. Clarifying the obligations and role of the food business operator as the person with primary responsibility for food safety and suitability puts the operator in greater control of their business, increases their awareness of their food safety obligations and therefore improves commerce. Under the proposals, if risk based tools are mandated, food business operators will have greater ownership and responsibility for their food business. Food business operators will be able to be more proactive in how they meet their obligations and respond to food safety problems that arise within their food business, instead of being reactive. The food business operator will have the flexibility to plan and comply in a manner that is the most cost effective for their food business.
- 73. Under a Voluntary Implementation Programme, run by NZFSA over the past year (since May 2008), risk based tools called food control plans have been made available for use under the current Food Act 1981 (as food safety programmes) to build familiarity with prospective tools that might be used in the future. Feedback from food businesses who are participating in the Voluntary Implementation Programme has been encouraging and positive, with a number of businesses appreciating the level of awareness that they have achieved because of the shift of responsibility to them as owners/operators. The verification (audit) visits focus on the activities they are doing within the food business to deliver safe and suitable food.
- 74. The current legislation requires the food that is sold at sausage sizzles and stalls at markets selling cakes, pickles and jams is prepared in premises that are registered (unless an exemption applies). The exemption is from being registered, not from the obligations of the Food Hygiene Regulations 1974 or the Act. Often these types of stalls do not meet this prescriptive requirement and are technically non-compliant with the Food Act 1981 regime, and are technically acting outside of the law.
- 75. Introducing risk management tools, including the provision of food handler guidance (non regulatory, educative material), will provide a more appropriate and pragmatic tool for managing the risks associated with these occasional practices. Food handler guidance will legitimise the undertaking of these iconic, but technically unlawful, activities and help to build an improved food safety culture.
- 76. The current food safety regime is confusing for food businesses that have to be cognisant of the range of obligations that they must comply with. The structure is unnecessarily complex.

Resource requirements

- 77. The level of resources required, and how the timing of Option C will impact on central and local government and on industry depends on the combination of 'fundamental' aspects selected to proceed. Even though the components have been subject to consultation, the consultation was on a whole revised food regime package. A limited amendment may require further consultation. This process could take up to six months to complete to include the development of a discussion paper, a consultation period, completion of the analysis of any submissions received and recommendations made to Government on how to proceed.
- 78. In terms of drafting, it would be difficult to uplift aspects of the currently drafted Food Bill and insert that drafted text directly into the Food Act 1981 because amending language will be required and the new wording is not necessarily a natural fit with the different schema of the Food Act. The drafted Food Bill has been written as a coherent package with correlations and interconnections between the provisions and parts and using the modern drafting style in plain English and as a stand alone Act. The drafting of proposed amendments to the Food Act 1981 would need to blend new provisions into an existing and different schema and blend the old style of drafting with the modern style.
- 79. The Food Act 1981 schema is complex and disjointed compared to legislative schemas of today. It does not clearly articulate the purpose or scheme of the legislation, and the 1996 amendment adds to the disjointedness by inserting a risk-based component to legislation predicated on prescription. A limited amendment would need to manage the disjointedness of the Food Act 1981 with the proposed 'fundamental' changes to ensure that the resulting legislation delivered a food safety regime that could be understood by both those subject to the legislation and the users of the legislation, i.e. regulators. As noted above, this may be a more complex, and therefore more significant amendment, than was anticipated and would therefore require greater resource (central and local government), and an extended period of time, to progress.
- 80. As also noted above, the extent of legislative change would determine how the Food Act 1981 would need to be redesigned and restructured. It is likely that a new part or parts could be drafted to accommodate a limited amendment if it only contained new concepts that did not already exist in the Food Act 1981. However, many aspects, such as regulatory tools (the basics of one tool are in the Food Act 1981 as a voluntary option for businesses) are already provided for and may be able to be revised to provide for the mandating of, and inclusion of additional tools. Any new part(s) would need to include definitions to accommodate the specific proposal introduced by the new part. Fitting the new part(s) into the existing Food Act would also need to consider factors such as the 1981 drafting style, and the current plain English drafting style.
- 81. The length of time that would be needed to complete the consultative processes, prepare and provide policy proposals to Government, and the drafting of a revised Act may take between 18 months and three years to complete. The progression of an amendment to the Food Act 1981 through Parliament also depends on the amendment's priority on the legislative programme. The costs associated with

the entire process would need to be achieved from Vote: Food Safety baseline funding.

Option E

Description of Option E

- 82. Option E introduces a revised Food Bill that, as with Option C, better delivers on business certainty and reduced compliance costs for food businesses. Both requirements of business certainty and reduced compliance costs could be satisfied by giving primacy to the proposed regulatory tool, national programmes as described in paragraphs 13 to 44.
- 83. The 'fundamental' aspects of the DFR identified for change in paragraph 17 have all been included in the existing Food Bill (as drafted). The drafted Food Bill has also carried over those aspects of the existing Food Act 1981 that have been working well, which equates to approximately 20% of that Act and includes provisions that would go a long way to removing the need for Territorial Authority food bylaws.
- 84. The significant change for a revised Food Bill would be the intention to use national programmes as the risk management tool for a larger number of food sectors. Under the Food Bill as currently drafted, the three tools have been provided for, but food control plans (regulatory) are central, with national (including monitoring) programmes (regulatory), and food handler guidance (a non-regulatory, educative tool) as exceptions.
- 85. In determining which tool would best apply to a particular food sector NZFSA used a risk-ranking model. The idea, under Option E, is to better align the costs associated with the implementation of risk management tools with the actual food safety risks posed by a specific food sector that needs to be managed. Under the new food regulatory regime all food businesses would be subject to one of the three tools (food control plans, national programmes or food handler guidance) with national programmes being the central tool and starting point for most food businesses. The decision on which tool will be used by specific sectors is based on a combination of factors such as food safety risks, existing programmes (i.e. codes of practice); and the degree of commonality between sectors.
- 86. Under the proposed transition for the Food Bill (as currently drafted) it was anticipated that most of the 35,000 to 40,000 food businesses that operate in New Zealand would be required to have a food control plan, with national programmes and food handler guidance being the exception to the rule. For the revised Food Bill, a substantially larger number of food businesses would be able to use a national programme. This shift would mean that approximately 60% of food businesses would fall into this category, where as it was only up to 20% before. These food businesses would face reduced registration and verification costs. Addendum D provides an indication of the tool that specific sectors would be subject to under the revised Food Bill.
- 87. The following table lists a selection of food businesses, together with an indication of the regulatory tool that might apply, the type of registration, the degree of

verification they might be subject to, and whether they would be required to be registered with NZFSA or Territorial Authorities.

Food Business	Proposed Tool	Verification frequency	Listed or registered
Sells only shelf stable products e.g. Farmers Retail Co. that sells sweets, chocolates, etc	National programme – Level 1	Verification only initiated if a problem is reported. This may trigger an investigation.	Self-registered
Raw Milk Gate sales	National programme – Level 2	Verification at least once in every 5 years	Self-registered or 3 rd party registration
Importer	National programme – Level 3	Verification at least once in every 3 years.	Listing (self registration) currently required
Retail bakery, more than bread	National programme – Level 4	Verification at least once in every 2 years	3 rd party registration or registration with Territorial Authority or NZFSA
Food Service General	Food Control Plan (using template provided by NZFSA)	Annual verification – would be performance based where compliant food businesses would have less frequent verification checks and non-compliant food businesses would be subject to increased verification checks.	Registered – Territorial Authority or NZFSA
Fundraisers, sausage sizzles	Food Handler Guidance	Not applicable, however has duty to provide safe and suitable food.	Not applicable.

88. It is proposed to include criteria in the revised Food Bill for determining if a national programme is appropriate in relation to those sectors not already set out in the Bill's schedule. The ability to amend a schedule of national programmes would be achieved by amendment by Order in Council.

89. Under the DFR, a five year transition plan had been consulted on and published. Most of the sectors scheduled for years one and two were the high risk/high impact or quite singularly unique businesses that were expected to be subject to individual food control plans. Subject to review, those food sectors that were due to transition in years three, four and five would largely change to national programmes. National programmes may also be applicable to some sectors in years one and two of transition. Addendum D sets out how the new transition of sectors for the revised Food Bill might apply. It is estimated that up to 60% of food businesses across the five year transition period would now be subject to national programmes.

Assessment of Option E against the Terms of Reference

Prescriptive regime versus risk based

- 90. Option E would continue the risk based regime originally proposed where responsibility is placed on the food business operator to provide safe and suitable food, thereby promoting a culture of continual vigilance in respect to food safety and suitability. The proposed risk based regime enables decisions and actions to be based, wherever practicable, on specific knowledge of risks to human health and in response to identifiable hazards. This means that low risk food activities would incur a reduced regulatory burden, rather than be subject to the current disproportionate regulation that exists under the 'one-size fits all' approach. This option also revokes the existing Food Hygiene Regulations 1974 and looks to replace them with outcome based regulations that are relevant to food safety.
- 91. The revised Food Bill would continue the modern drafting style that is more accessible to those persons who are subject to or use it, and have lower compliance costs for food businesses than Option C. The revised Food Bill would set out the roles and duties of regulators and food businesses. It would also allow for the upward movement between risk based instruments. Comparability between individual food control plans and other individualised risk based programmes is intended across New Zealand's food legislation, which may lead to consequential savings for food businesses through the avoidance of duplication.

Degree of consistency and equity across food sectors

- 92. One of the problems identified with the existing food regulatory system was the lack of national consistency in the application of regulatory controls imposed on food businesses. Territorial Authorities interpret and implement the existing legislation requirements in many ways; some take a more pragmatic approach and recognise that some existing requirements go beyond food safety. Other Territorial Authorities fully enforce the existing requirements including those provisions that impose unnecessary costs on food businesses that are not food safety related. This is both inconsistent and inequitable.
- 93. The development and enactment of a comprehensive legislative package, that addresses the existing gaps of the food regulatory regime and improves on the existing food regime, would address the consistency and equity problems that

currently exist. Improved certainty will provide businesses with greater certainty and enable food businesses that operate in multiple locations to comply with the legislation more efficiently and effectively.

Seamlessness and coherence of the regime

94. The revised Food Bill would achieve a high degree of coherence and seamlessness because the entire Food Bill would be drafted using a modern drafting style and would present as a package. The modern drafting style provides for the relationship between the purpose and scheme of the revised Food Bill and the parts of the legislation to be explicit so that it presents as a cohesive and comprehensive whole.

Comparison with international best practices

- 95. The decision to move towards risk based tools is in line with how food safety is being managed in many other countries and regions, and is how New Zealand manages exports. NZFSA researched and analysed how other countries and regions were delivering on food safety as part of the DFR. This included analysis of the food safety systems that operate in Canada, England/Wales, Scotland, Northern Ireland and the Australian States of Victoria, New South Wales and Queensland. These food safety systems are all risk based and focus on the management of food safety risks by the food business operator. They vary, however, in the amount of input that is expected of the food business operator.
- 96. It is the United Kingdom (UK) *Safer Food Better Business* programme that has formed the basis of proposals in the 'fundamental' aspects listed in paragraph 17 and adapted to suit the New Zealand food regulatory environment. This programme has proved very successful in the UK. In a recent UK survey, those food businesses that are operating under the *Safer Food Better Business* programme are able to identify the added value that it has contributed to their operations.

Compliance Costs

- 97. Similarly to Option C (depending on the combination of 'fundamentals' selected), Option E will result in compliance costs being minimised, and in many cases reduced consistent with the need for food to be safe and suitable. Option E will reduce compliance costs to food businesses through the provision of a coherent legislative framework that is easily understood and more accessible than Option C. The three regulatory tools provide different starting points and therefore different costs for different food businesses within the one food regulatory regime. The starting point for a food business will depend on aspects such as the level of risk associated with a food sector, and the existing systems that are already being used by food sectors (e.g. codes of practice).
- 98. The prescriptive Food Hygiene Regulations 1974 would be revoked and new outcome based regulations would be introduced. The new regulations would focus on food safety aspects only.

Impacts on trade and commerce

- 99. Similarly to Option C, Option E will provide for the role of the food business operator to be clarified in respect of their responsibility to assure food safety and suitability outcomes within their food business. An increased awareness of their food safety obligations improves commerce, and provides for greater ownership and responsibility of the food business for the food business operator. Like Option C, food business operators will be able to be more proactive in how they meet their obligations and respond to food safety problems that arise within their food business, instead of being reactive. They will also have flexibility to plan and comply in a manner that is the most cost effective for their food business.
- 100. As discussed in paragraph 73, businesses that have joined the Voluntary Implementation Programme have been able to see how the level of awareness they gain, because of the shift of responsibility, has improved how they undertake their business activities.
- 101. Legitimising iconic and occasional practices (i.e. sausage sizzles, stalls selling cakes, jams and pickles) with the provision of food handler guidance (non-regulatory, educative material) will also provide appropriate food safety advice to these operators. This will increase awareness for such operators regarding aspects like safe food storage, minimising cross contamination and good hygiene practices to improve food safety practices.

Resource requirements

- 102. Due to the advanced stage of the drafted Food Bill, it is anticipated that under Option E a revised Food Bill would be ready for introduction, if approved, within six to eight months. Time and resource would be required to revise the focus of the Food Bill to accommodate the shift to national programmes and to reflect consequential changes across the draft Food Bill. The changes would include creating a schedule of food businesses that would be subject to national programmes and food handler guidance being finalised. The registration and verification requirements would be set out in the Act by regulation.
- 103. Criteria would also be included in the legislation to provide for future decisions regarding the appropriateness of a national programme for food sectors, for example if there was a significant increase in risks to food safety for a specific sector there may be a need to require them to operate under a food control plan. Similarly, there may be food sectors that initially might be subject to using food control plans that over time demonstrate that a national programme is sufficient to manage the food safety risks of that sector.
- 104. Like Option C, the costs for Option E would need to be made from baseline funding. Funding of \$2.5million had been provided in the past two financial years to assist with the development of the tools required for implementation of a new food regulatory regime. The funding was used to develop and implement core aspects of the proposed food regulatory regime under the existing legislation with Territorial Authorities.

- 105. The Voluntary Implementation Programme was used to provide opportunity for food control plans to be voluntarily implemented by food businesses and for Territorial Authorities to assess the capability and time needed to introduce and register food control plans for businesses and to undertake verification checks. Additionally, under the Voluntary Implementation Programme NZFSA provided specific training to Territorial Authorities to assist them with gaining competency to undertake the registration and verification of food control plans.
- 106. Verification is a new role for Territorial Authorities and is a shift from their current inspection based process. The training provided a unique opportunity for the beginnings of a nationally consistent framework to be achieved so that future audit checks would be able to assess the performance of both food businesses, and Territorial Authorities, more equitably. The ability to provide an equitable system sets up many of the prerequisites for a national grading scheme.
- 107. With a revised Food Bill, reflecting a broader use of national programmes, there would be reduced costs for Territorial Authorities because it would reduce the need for Territorial Authorities to have capacity in-house to undertake annual verifications. Capacity for Territorial Authorities has been an ongoing issue due to the short supply Environmental Health Officers world-wide.
- 108. Additionally, setting the verification frequency for national programmes and the scope of verification would simplify what has to be done by Territorial Authorities.

Other matters considered for both options

- 109. The Legislation Advisory Committee (LAC) Guidelines, specifically the aspects of the guidelines dedicated to legislative design matters, will need to be considered for both Options to ensure that the chosen Option represents a comprehensive and cohesive package. Chapter 2 of the LAC Guidelines is about understandable and accessible legislation. The Guidelines note that when proposals are made to change or develop legislation both policy-makers and drafters have a responsibility to make it as understandable and accessible as practicable.
- 110. The Guidelines note that "legislative change should also give effect to the policy objectives in a way that will not cause unnecessary difficulties or complications for those who have to comply, and will not require recourse to the courts to resolve ambiguity, internal inconsistency, or conflict with other legislation or the common law".
- 111. There is a general view that if more than 40% of an Act is proposed for amendment then due consideration should be given to the merits of the drafting of a new Act in its entirety. Additional factors that may be taken into consideration will be the age of an Act and the drafting style that has been used and whether there will be a natural fit of the amendment into the Act.

Option C versus Option E

- 112. Option C and Option E both give consideration to legislative change. Amendments to existing legislation are more generally to be of a more limited nature. If a substantive amount of content in an Act is proposed for change it is often considered prudent to adopt new legislation due to the difficulties in meshing different drafting styles and language that can lead to disjointed legislation.
- 113. Option E will provide for a new Act that is of a superior quality than what could be achieved by amending the existing Food Act 1981. As a result of this, the compliance costs of Option E for food businesses will be less than Option C because the legislation will be more easily understood by food businesses, be more accessible, consistent and provide clarity about requirements.
- 114. The form of Option C, and therefore its comparability to Option E, depends on the number of 'fundamental' aspects that are selected to be progressed as a limited amendment. If the 'fundamental' aspects 1 and 4 are selected for Option C, within a four month period consultation on these proposals should be completed, at which point policy approval would be sought from Government and drafting of the amendment commenced. These latter stages would go out beyond six months and, if a greater number of 'fundamental' aspects are selected, it may take up to a further 2 ½ years to finalise amendments before an amended Act could commence.
- 115. A similar six to eight month timeframe for Option E would be sufficient time to consult and revise the Food Bill to reflect the extended use of national programmes and to make consequential changes across the legislation. At the conclusion of that six to eight month period the Food Bill would be ready for introduction to the House.

Time	Option C - what can be	Option E - what can be
Taken	achieved?	achieved?
Within 6 to 8 months	 If Option C comprised 'fundamental' aspects 1 to 4 (as per paragraph 12) there would be a requirement to consult. Consultation would be on: the proposal that risk management tools are mandated including food control plans, national programmes and food handler guidance; regulation making powers for 	drafted Food Bill to accommodate the broader use of national programmes described in Option E. Consultation on broader use of national programmes and the sectors that are to be covered by them will need to be undertaken in parallel. This will contribute to the schedule of sectors and their respective risk management

116. The following table provides an indication of what could be achieved for both Option C and Option E within certain time periods:

	 imported food to provide for an enhanced regime; a revision of the Food Hygiene Regulations 1974 and Food (Safety) Regulations 2002 to remove redundant and unnecessary provisions. This would lead to outcome regulations that go to food safety matters only; and 	that will be part of the new Act. A comprehensive Food Bill, that includes all of the 'fundamental' aspects of paragraph 12, would be ready for introduction to the House.
	 clarification of the New Zealand standard as the platform for all food sold within, and exported from New Zealand. 	
Up to 24 months	Following consultation, policy proposals would need to be submitted to Government for consideration. If approved then steps may be taken to the drafting of the amendment to the Food Act 1981. The drafting would need to consider the structure of the Food Act 1981 and the need to accommodate the proposed changes and the fitting of new (2009) amendments into an old (1981) framework.	The Food Bill proceeds through the legislative process, i.e. First Reading, Select Committee, Second & Third Readings etc. Food Bill enacted and transition of food sectors to the new regime commences.
24 months onwards	A new, limited amendment to the Food Act 1981 may be ready for introduction Those 'fundamental' aspects that have not been included in the	Implementation continues.
	limited amendment, i.e. aspects 5 to 8 in paragraph 12, would need addressing to be addresses at a later stage to bring the Food Act 1981 into line with modern practices.	

The cost of Option C and Option E

117. With the proposal that both Options will have risk based tools, as described in paragraphs 23 to 44, the compliance costs faced by food businesses will be

similar. There will be costs for verification and registration, which will be reduced dependent on the specific tool applied to a specific food sector.

- 118. Additionally, food businesses will make savings under both Options by only having the necessary requirements being applied to their food business operator. The risk management tool will be the reference for all of the regulatory requirements that need to be met by the food business operator to deliver on food safety. Similarly, the revision of the Food Hygiene Regulations 1974 to be only about food safety requirements will reduce unnecessary costs being imposed on food business. There are a number of regulations that are being imposed on food businesses that will no longer apply because they do not go to food safety.
- 119. Society will benefit from an improved food regulatory regime from both Option C and Option E. They will benefit from a nationally consistent regime that delivers on food safety and requires all food business operators to take responsibility for the food they sell to ensure it is safe and suitable. Greater awareness of food safety responsibilities by a food business operator will provide consumers with more confidence that all efforts are being made to minimise risk and reduce the incidence of foodborne illness. A regulatory system that introduces, and sets up, a national grading system will also provide a higher level of awareness of food business compliance.
- 120. The time and resource requirements are costs for Option C and Option E that need to be considered. These two aspects provide the point of differentiation between the two Options in terms of the end result, i.e. how much change can be achieved within the same time period and what local and central Government resource will be needed to do this. As noted in paragraphs 112 to 114, both options give consideration to legislative change.
- 121. Option C would provide for improved food safety and it would take four months to consult on proposals to undertake a limited amendment of the Food Act 1981. Following this, the steps of completing analysis of submissions and proposing policy to Government, and then drafting an amendment will take from six to eight months and up to three years to realise. Costs to Government would be incurred by the resources required to complete the consultative and policy processes for an amendment. For businesses, the costs would be the requirement to continue operating using outdated legislation that imposes compliance costs that go beyond food safety until the amendment is enacted. The costs of Option C are the resource and the extended period of time that is required to complete the necessary and good regulatory practice processes.
- 122. Option E would also provide for improved food safety within a comprehensive framework. There would be a need to consult on the transition of food sectors to the new revised tools; however this can be done at the same time as drafting changes are made to the revised Food Bill. It is anticipated that redrafting the Food Bill to extend the use of national programmes, and consequential changes across the draft, would take between six and eight months. At the conclusion of that period the revised Food Bill would be ready for introduction to the House.

123. Comparing both options, it is clear that the cost of Option E would be significantly less than Option C because less time and resource would be needed to undertake the proposed revision to the Food Bill.

Summary/Conclusion

- 124. Option C and Option E both provide opportunity for improvements to be made to the food safety regulatory regime. The significant and pending question is the degree of change that is sought, and how much of that change can be accomplished by either option. Both options will deliver a food regulatory regime that is an improvement on what already exists, however considering the cohesiveness, effectiveness and resource efficiencies of the different options will assist in reaching a decision on a preferred option.
- 125. It is the conclusion of this Regulatory Reform Programme Review that Option E should be pursued as the best option for improving the food regulatory regime because the revision of the Food Bill to include the broader use of national programmes can be achieved within a shorter time frame, there are costs that have already been sunk by government in drafting and testing aspects of the new regime, and there would be less pressure on government resources to improve an existing Bill. Significantly, Option E will deliver a comprehensive package that will provide for:
 - an enhanced imported food regime;
 - mandated risk based tools (both regulatory and educative) and a shift of the onus of responsibility from the Government to the food business operator;
 - the removal of the Food Hygiene Regulations 1974 and replacing them with regulations that are outcome based and enabling;
 - the clarification of the New Zealand Standard as the platform for all food sold within, and exported from, New Zealand;
 - increased audit capability and the Territorial Authority role;
 - improved penalty provisions;
 - improved enforcement regime (in line with the Search and Surveillance Bill requirements); and
 - an improved technical alignment of all food legislation.

Addendum A

Background summary of the Domestic Food Review

- There are three distinct food regulatory systems that currently operate in New Zealand; the Food Act 1981, Food Hygiene Regulations 1974 (made pursuant to the Health Act 1956 and the Food Act 1981) and Territorial Authority bylaws. These systems apply to food produced for the domestic market. For those food businesses who wish to export there are additional requirements that may also need to be met under other food legislation such as the Animal Products Act 1999 or the Wine Act 2003. Additional requirements may also be imposed by an importing country to meet overseas market needs.
- 2. Sitting alongside all three systems are two sets of food standards, New Zealand only standards, and those in the joint Australia New Zealand Food Standards Code (joint system). The joint system relates predominantly to the labelling and composition of food, and includes 'suitability' standards to address areas such as nutrition.
- 3. The New Zealand only standards cover matters that are outside of the scope of the joint system, and include maximum residue limits of agricultural compounds in food, food hygiene and food safety provisions (including high risk imported foods), and export requirements relating to third country trade.
- 4. The safety and suitability aspects of New Zealand's food regulatory regime have not been addressed together, because aspects of the system have been developed at different times. This has created complications for food businesses and uncertainty as to the respective roles of regulators at central and local Government level. The duplication and confusion has also led to additional and unnecessary costs being imposed on food businesses.
- 5. The various regulatory requirements and unclear administrative responsibilities create inconsistencies, interface issues, duplications and gaps throughout the food regulatory system in New Zealand. The system suffers from:
 - duplication, overlaps and gaps in laws and consequential costs for food businesses;
 - confusion about when (and at which level) Government is involved;
 - inconsistent controls in some areas;
 - unnecessary complexity in the structure of responsibilities and in the legislative framework of controls;
 - lack of practicality of some controls;
 - inconsistency in the regulatory impact on businesses, including unnecessary regulations that do not go to food safety issues;
 - lack of clarity and consistency about how much facilitation and guidance NZFSA, as the principle regulator, will provide;

- ill-defined roles of key players with the food regulatory regime;
- lack of common understanding of good hygienic practice and other key concepts; and
- absence of sufficient risk assessments in the food sector.

Terms of Reference for progressing changes to the Food Bill

Regulation to be reviewed

1. Food Act 1981 and Food Hygiene Regulations 1974 - consideration of a limited amendment to the Food Act 1981 (and associated regulations) or a revised Food Bill that reflects the need to improve business certainty and further reduce compliance costs.

Lead Agency

2. New Zealand Food Safety Authority (NZFSA)

Problem Definition

3. To determine if a limited amendment to the current Food Act 1981 or a revision of the proposed Food Bill (that reflects changes to improve business certainly and further reduce compliance costs) is the most cost effective option to improve the efficiency and effectiveness of the current food safety regulatory regime.

Specific objectives for the Review

The proposed Food Bill

- 4. Under the proposed Food Bill the outcome intended for all businesses, including small and medium sized ones is that the regulatory measures applied will be the minimum required to achieve the desired outcome of safe and suitable food. This acknowledges that measures must be effective (i.e. will have a high compliance rate), and be at a reasonable and fair cost relative to the expected regulatory benefit. For a typical business that is compliant with existing requirements, overall regulatory and compliance costs should decrease.
- 5. A summary of the problems with the current regulatory system that were identified as part of the Domestic Food Review is at Attachment A (of the ToR).
- At their meeting on 1 April 2009, the Cabinet Economic Growth and Infrastructure Committee (EGI) agreed in principle, subject to the report referred to in paragraph 11 (of the EGI minute), to continue work on a revised Food Bill based on Option C or Option E.
- The report referred to in paragraph 11 is the terms of reference for progressing changes to the Food Bill as outlined under Option C or Option E. EGI Min (09) 5/11 refers. The two options are:
 - Option C making a limited amendment of the Food Act 1981 (and the associated regulations); or
 - Option E introducing a revised Food Bill that reflects changes to improve business certainly and further reduce compliance costs.

Option C versus Option E

- 8. Analysis of the fundamental differences between the current food regime and the two options proposed for a new food regulatory regime will need to be made.
- 9. The review of both options will consider the following:
 - to what degree will the current and proposed compliance costs imposed on the food sector be minimised, consistent with the need for food to be safe and suitable;
 - whether the food regulatory regime is prescriptive and based on a command and control regime or a risk based regime where the onus of responsibility is on the food business operator;
 - whether the chosen will option deliver regulatory requirements that can be applied consistently and equitably across food sectors;
 - how seamless and coherent the resultant food regulatory programme(s) will be;
 - how the chosen option compares with international best practices for food safety;
 - whether there will be an impact (positive or negative) on the trade and commerce in food and associated products; and
 - the level of resource required and how the timing of the options will impact on central and local Government and industry.

Option C

10. The Review of Option C will specifically:

- assess the feasibility of modifying the current prescriptive and inspection based approach with a view to removing unnecessary prescription and placing the onus of responsibility onto the food industry, including more flexibility as to how food safety requirements may be met;
- consider whether the above outcomes can be achieved by modifying the existing approach to food safety;
- give consideration to the estimated time and the level of resource that will be needed to develop and complete the policy to support a limited amendment, including allowing time for appropriate consultation to be undertaken;
- consider how the inconsistencies and associated costs of the current three regulatory regimes can be managed; and
- analyse how the proposed amendment can be incorporated into the format and style of the 1981 legislation while endeavouring to ensure that the intent of the legislation is easily understood by food businesses and regulators.

Option E

11. The Review of Option E will specifically:

- consider how national programmes (a regulatory tool under the proposed Food Bill) can be more broadly used for food businesses that prepare and sell food where the food safety risks are lower;
- identify a schedule of those food sectors that could be subject to national programmes, to provide certainty to food businesses regarding which tool (regulatory or non-regulatory) would apply to their sector;
- consider how the registration component and the frequency of verification will be implemented for national programmes to further reduce compliance costs.

Other matters to be considered

- 12. The Legislation Advisory Committee guidelines, specifically the legislative design matters, will need to be considered for both options to ensure that the chosen option represents a comprehensive and cohesive package.
- 13. Recommendations will be made to Ministers on each option, including the social and economic costs and benefits (effectiveness in achieving food safety outcomes), including the level of compliance costs that food businesses will face under each option.

Quality assurance mechanism

14. NZFSA will work with the following groups on this review:

- the Territorial Authority / Local Government Steering Group comprising representatives from six Territorial Authorities, of various sizes, as recommended by Local Government New Zealand (LGNZ). LGNZ also has a representative on this steering group. The members of this group provided technical and practical input into the policy process and the legislative impacts of the proposed Food Bill. This group has been established since October 2006.
- Food Retailers, Food Service, Food Manufacturing and Processors Advisory Forum - established to promote discussion with, and receive input from these private sectors on NZFSA's administration of the Food Act regulatory system. This forum was established in October 2007.
- The Small Business Advisory Group who will provide the perspective of small businesses.
- 15. Meetings will be held with these groups to discuss the merits of continuing work on a revised Food Bill under either Option C or Option E. The views of these groups will contribute to the decision making process.
- 16.NZFSA will consult with key Government agencies including the Ministry of Economic Development and the Treasury.

Timeframes

17. The review will be completed by the 30 June 2009 at which point a further Cabinet paper will be presented to EGI on Option C and Option E, with the preferred option for continuing work on a revised Food Bill.

Resourcing issues

18. Funding for the ongoing development of the proposed Food Bill will be made from within Vote: Food Safety.

Agencies consulted

- 19. The Ministry for Economic Development and the Treasury have been consulted with on these Terms of Reference.
- 20.1 am confident that the review will identify the option that will best deliver a feasible set of options for regulatory reform and recommendations (if reform is required) that will:
 - be the minimum necessary to achieve the regulation's objectives, having assessed costs, benefits and risks;
 - be as generic and as simple as the sector allows;
 - use self-regulatory approaches where appropriate;
 - be appropriately durable, predictable and adaptable;
 - where appropriate, accord with international best practice being mindful of our commitment to a single economic market with Australia;
 - minimise compliance costs imposed; and
 - aim to minimise adverse impacts on:
 - o innovation and investments;
 - o competition; and
 - o individual responsibility (with appropriate risk balance).

Hon Kate Wilkinson Minister for Food Safety

/ /2009

Attachment A (for the ToR)

Background Summary of the Domestic Food Review

- 1. The Domestic Food Review (DFR) commenced in May 2003 and covered all food sold in New Zealand, whatever its source and whatever the processes by which it reached the point of sale. At point of entry into New Zealand, all imported food falls within the scope of the regulatory regime that applies to New Zealand food.
- 2. Food produced in New Zealand for export (i.e. that at no stage enters the New Zealand food supply) did not fall within the ambit of the DFR. However, it is important to note, that food produced in New Zealand for export must meet the same standards of safety and suitability that apply to New Zealand food.
- 3. There are three distinct food regulatory systems that currently operate in New Zealand; the Food Act 1981, Food Hygiene Regulations 1974 (made pursuant to the Health Act 1956 and the Food Act 1981) and Territorial Authority bylaws. These systems apply to food produced for the domestic market. For those food businesses who wish to export there are additional requirements that may also need to be met under other food legislation such as the Animal Products Act 1999 or the Wine Act 2003. Additional requirements may also be imposed by an importing country to meet overseas market needs.
- 4. Sitting alongside all three systems are two sets of food standards, New Zealand only standards, and those in the joint Australia New Zealand Food Standards Code (joint system). The joint system relates predominantly to the labelling and composition of food, and includes 'suitability' standards to address areas such as nutrition.
- 5. The New Zealand only standards cover matters that are outside of the scope of the joint system, and include maximum residue limits of agricultural compounds in food, food hygiene and food safety provisions (including high risk imported foods), and export requirements relating to third country trade.
- 6. The safety and suitability aspects of New Zealand's food regulatory regime have not been addressed together, because aspects of the system have been developed at different times. This has created complications for food businesses and uncertainty as to the respective roles of regulators at central and local Government level. The duplication and confusion has also led to additional and unnecessary costs being imposed on food businesses.
- 7. The various regulatory requirements and unclear administrative responsibilities create inconsistencies, interface issues, duplications and gaps throughout the food regulatory system in New Zealand. The system suffers from:
 - duplication, overlaps and gaps in laws and consequential costs for food businesses;
 - confusion about when (and at which level) Government is involved;

- inconsistent controls in some areas;
- unnecessary complexity in the structure of responsibilities and in the legislative framework of controls;
- lack of practicality of some controls;
- inconsistency in the regulatory impact on businesses, including unnecessary regulations that do not go to food safety issues;
- lack of clarity and consistency about how much facilitation and guidance NZFSA, as the principle regulator, will provide;
- ill-defined roles of key players with the food regulatory regime;
- lack of common understanding of good hygienic practice and other key concepts; and
- absence of sufficient risk assessments in the food sector.

Economic cost of foodborne illness

- 8. There is a continuing significant incidence of foodborne illnesses in New Zealand. Every year in New Zealand there are about 18,000 cases of enteric (intestinal) illness notified, with over 1,000 of these resulting in hospitalisation, and up to five deaths.
- 9. A study by the Institute of Environmental Science and Research in 2008 on the economic impact of foodborne illness has shown that the total cost to New Zealand society due to foodborne campylobacteriosis, salmonellosis, listeriosis, STEC / VTEC infection, yersiniosis and norovirus infection is estimated to be \$86 million per annum.

Costs of the Status Quo

- 10.NZFSA and Territorial Authorities have taken a pragmatic approach to the enforcement of the current legislative requirements. This has meant that some, but not all, Territorial Authorities have not been enforcing the law in respect of requirements that do not go to food safety (but are required by the current legislation) in anticipation of a new food regulatory regime.
- 11. For example, there are many food selling activities that are part of the New Zealand way of life, i.e. sausage sizzles and stalls at markets selling cakes, pickles and jams. The current Food Hygiene Regulations require all food for sale to be prepared in premises that are registered unless exempted from registration. Exemption from registration is not exemption from the application of the Food Hygiene Regulations or the requirements of the Food Act 1981.
- 12. The reality is that a number of Territorial Authorities do not enforce the obligations of the Food Hygiene Regulations in relation to these iconic activities unless there is a real food safety problem, e.g. fermented sauces being sold. This is because it is simply not practicable or efficient for them to do so. If Territorial Authorities

actually enforced all of the requirements of the Food Hygiene Regulations, such activities would not be permitted to continue. Additionally, if a food business wanted to continue these activities the compliance costs associated with meeting the requirements would increase.

13. The decision to take this pragmatic approach is unlikely to be sustainable in the medium to long term future if the new food regulatory regime is put on hold.

Levels of Regulatory & Non-Regulatory control

Key to abbreviations:

- PBV Performance Based Verification
- RTE ready to eat
- YOPI Young, Old, People Immune-compromised

- (*) includes Territorial Authority involvement
- GOP Good Operating Practice
- HACCP Hazard Analysis Critical Control Point

Food Co	Food Control Plans												
Level	Examples	Regist	ration		Standards				Other Requi	rements		Ext Verifi	cation
	<i>NB.</i> Transition year shown in ()	Self	3 rd party	NZFSA	Generic Regs & Specs	Specific	GOP	HACCP	Records	Duties	Operator Verification	Initial	On-going
Food Control Plans (Including off-the-peg food control plans)	Retailers that process (high risk) Manufacturers (high risk) Including; FS – on-site catering (1) FS – off-site catering (1) FS – mobile (3)FS – general full on- licence (1) FS – general no full on-licence (2) FS – residential YOPI (2) FS – day care YOPI (2) FS – hospital YOPI (2) FS – IHR (2)Retail – butcher – RTE (3) Retail – makes to sell (3) Manuf – meat – RTE (3)	×	✓ or	opt 🗸	~	~	✓	✓ (NZFSA)	 Additional sector specific requirements GOP HACCP Systems 	✓ ++	√ ++	< 3 mth (unless already checked)	PBV by TA or other TPA at least annually

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National Programmes

	.												
Level	Examples	Regis	stration		Standa	rds			Other Requirements			Ext Verification	
	<i>NB</i> . Transition year shown in ()	Self	3 rd party	NZFSA	Generic Regs & Specs	Specific	GOP	HACCP	Records	Duties	Operator Verification	Initial	On-going
4	Manuf – meat – non RTE (3) Retail – butcher – non RTE (3) Retail – bakery, more than bread (4) Retail – handles and sells (mid risk) (3) <i>NB</i> . Default to here unless they make a case for another level	×	✓ or	opt 🗸	~	✓	~	×	- GOP - Systems	✓	√+	< 6 mth (unless already checked)	PBV by TA or other TPA at least 1 in 2 years
3	Manuf – frozen fruit & vege (5) Manuf – shelf stable condiments (5) Manuf –100% juice – short life (4) Manuf –(100% juice – short life (4) Manuf – 100% juice –extend life (4) Manuf – <100% juice –ext life (4) Retail – bakery, bread only (4) Hort – packing (3) Hort – producers – leafy veg & herbs (3) Hort – producer – berries, melons (3) Importers	✓ or	¥	×	¥	~	~	×	- GOP - Systems	~	*	< 1 yr (unless already checked)	PBV by TA or other TPA at least 1 in 3 years
2	Raw milk gate sales (2) Retail – includes readily perishable food (3) Distributor/Transport – readily perishable (4) FS – mobile (etc.) coffee/shelf stable only (3) Manuf – confectionery (4) All other Horticulture not mentioned elsewhere (3)	✓ or	~	×	✓ (opt out of some)	×	✔ (like FHG++)	×	- Inventory - Exception	×	×	< 1 yr (unless already checked)	PBV by TA at least 1 in 5 years
1	Retail – only sells shelf stable, manufacturer pre- packaged goods (3) Distributor/Transport – shelf stable (4)	~	×	×	✔ (opt	×	✓ (like	×	Nil specific	×	×	< 1 yr (unles already	Survey or when a

Level	Examples	Regis	Registration			Standards			Other Requirements			Ext Verification	
	<i>NB.</i> Transition year shown in ()	Self	3 rd party	NZFSA	Generic Regs & Specs	Specific	GOP	НАССР	Records	Duties	Operator Verification	Initial	On-going
	Manuf – ice and iced confection (5) Hort – very small producers (3)				out of many)		FHG)					checked)	problem occurs

FHG													
Level	Regist	ration		Standards			Other Requirements			Ext Verification			
	NB. Transition year shown in ()	Self	3 rd party	NZFSA	Generic Regs & Specs	Specific	GOP	HACCP	Records	Duties	Operator Verification	Initial	On-going
Food Handler Guidance	Sausage sizzles, school fundraisers, charity fundraiser or church bazaar	×	×	×	×	×	✔ (very basic)	×	×	✓ (must meet obligation of the Act to provide safe and suitable food)		×	×

Proposed Tools and Identified Sectors for Transition

Proposed Tool	Sectors NB. Transition year shown in ()	
Food control Plan (including off-the- peg food control plans)	 Food Service – on-site catering (1) Food Service – off-site catering (1) Food Service – general full on-licence (1) Food Service – general no full on-licence (2) 	 Food Service – hospital YOPI (2) Retail – butcher – RTE (3) Manufacturer – meat – RTE (3)
National Programme – Level 4	 Food Service – IHR (2) Manufacturer – meat – non RTE (3) Retail – butcher – non RTE (3) Retail – bakery, more than bread (4) Retail – makes to sell (mid risk) (3) 	NB . Default to here unless there is a case for another level
National Programme – Level 3	 Manufacturer – frozen fruit & vegetables (5) Manufacturer – shelf stable condiments (5) Manufacturer –100% juice – short life (4) Manufacturer –<100% juice – short life (4) Manufacturer – 100% juice –extend life (4) Manufacturer – <100% juice –ext life (4) 	 Horticulture – producers – leafy vegetables & herbs (3) Horticulture – producer – berries, melons (3) Importers Retail – bakery, bread only (4) Horticulture – packing (3)

National Programme – Level 2	 Raw milk gate sales (2) Distributor/Transport – perishable (4) Food Service – mobile (3) Food Service – residential YOPI (2) Food Service – day care YOPI (2) 	 All other Horticulture not mentioned elsewhere (3) Manufacturer – confectionery (4) 				
National Programme – Level 1	 Retail – only sells packaged goods (3) Distributor/Transport – shelf stable (4) 	 Manufacturer – ice and iced confection (5) Horticulture – very small producers (3) 				
Food Handler Guidance (non regulatory, educative tool)	Sausage sizzles, school fundraisers, charity fundraiser or church bazaar, small bed & breakfast operations, clubs with limited food preparations					

Food Hygiene Regulations 1974 Identified regulations that impose unnecessary costs on food businesses

The table below details some of the requirements contained within the Food Hygiene Regulations 1974.

In certain instances, the Food Hygiene Regulations 1974 do not recognise alternative approaches to managing food safety, rather prescribing a 'one size fits all' approach. If some regulations are applied 'to the letter' by the Regulator, businesses face costs that either have little bearing on the safety of food, or are disproportionate to their level of food activity.

Reg.	Outline	Monetary resource	Time resource	Comment
4, 5	Registration process	Registration and inspection fee		Limited premises exemptions from registration requirements. Simple operations – e.g. sale of manufacturer pre-packaged goods only (biscuits, snacks, choc. bars etc.) subject to registration These very low risk businesses receive little value for their fee – generally a certificate only and perhaps a cursory visit
7	Notices to be displayed	Cost of notices in toilets, changing facilities, 'dogs not permitted' etc		
8	First Aid facilities	First aid equipment	Keeping first aid appliances and requisites clean	The regulations re-litigate requirements contained in other legislation
10	Restrictions on use of rooms and stalls as food rooms	Includes: 'No one to use as a food room any room or stall that is not used exclusively for the purpose of the food premises'		Precludes the use of home kitchens for simple home- based commercial food activities – ie baking bread, icing cakes. (However, Food Act precludes access to private dwellings)
12	Maintenance of wash hand basins	All wash hand basins to be maintained with hot and cold running water, or tempered water at minimum 38C		Lower temperature would suffice. Often confusion as well with requirements of Building Act for hot water and tempered supplies
15	Food Storage	Frozen food maintained at/below - 18C		No science behind this – maintaining hard-frozen would do

Reg.	Outline	Monetary resource	Time resource	Comment
19	Protective clothing	Provision of set of clean 'light coloured' protective clothing to workers each week		Requirement for light-coloured overall or smock does not necessarily suit today's food business environment where black is the new white.
26	Floor area for bakery	Requirement to provide minimum floor area for bakery. Not less than 3 sq metres per person or 9.5 sq m whichever is greater		Adds additional building or rental cost. Doesn't reflect risk or new equipment available today
27	Separate areas in deli	Requirement that certain operations be kept separate		Adds cost to business to provide separate preparation, storage and display areas/units. Risks can be managed in other ways
29	Eatinghouses (food sold for consumption on the premises)	No person to use any premises as an eatinghouse unless they conform with the requirements of Schedule 1, whether or not the premises are required by R4 to be registered	Convincing the TA of 'undue hardship' and obtaining an exemption certificate	Affects, for e.g. sports clubs providing food on match days
30	Special provisions for eatinghouses	 Requirement to get consent in writing from TA to increase floor space of dining room or decrease floor space of kitchen Immersing tea-towels and dish cloths etc in boiling water for 5 minutes every day 		Could be duplication with Building Act. Adds additional burden and cost. Not practical, time consuming and doesn't recognise alternatives.
33	Display in eatinghouses	Requirement to have worker in attendance to ensure customers are using utensils etc		Costly and impractical. Other staff can manage this as part of normal duties
35	Cleaning of utensils in an eatinghouse	Prescribes the use of a washing machine and water temperatures (60C for wash, 77C for rinse cycles) or a similarly prescriptive sanitising process involving 'immersion for 2 minutes in clean		Does not recognise low-throughput businesses (where domestic dishwasher might suffice), other (e.g. chemical) sanitising options

Reg.	Outline	Monetary resource	Time resource	Comment
		water at not less than 77C, the temperature being maintained by means of a gas ring, or steam or hot water jacket'		
38	Minimum floor area for eatinghouse	Requirement to provide minimum floor area for eatinghouse. Not less than 3 sq metres per person or 9.5 sq m whichever is greater		Adds additional building or rental cost. Doesn't reflect risk or new equipment available today
46(4)	Retail sale of meat and fish	No person shall use any stall for the retail sale of meat (unless it has been canned or cooked or is pre-packed poultry, sausages, cured ham or cured bacon)		Prevents retail sale of red meat cuts at a market stall
First Sched ule	Floors	'all angles between the floors and walls rounded off to a height of not less than 75mm from the floor'		'nice to have' but tends to be a point of over-focus
	Ceilings	'no ceiling shall be less than 2.4 metres above the floor'		Either precludes use of otherwise usable areas or requires unnecessary work to heighten ceiling
	Hot water supply	'hot water system having a storage capacity approved by an inspector'		Outwardly precludes use of a multipoint or continuous flow (instant) hot water system
		Hot water 'at a temperature of not less than 63C at all sinks and other equipment used for washing containers, utensils' 'at a temperature of not less than 83C for every other purpose'		Further confusion with Building Regulations. Costly installation and running
8	Changing facilities	Requirement to provide separate changing facilities for each sex if more than 4 persons		Costly and excessive. Doesn't reflect levels of risk or lack of risk i.e. applies to all registered businesses
10	Provision of wash	Requires specified numbers of		Doesn't reflect relative lack of risk where another

Reg.	Outline	Monetary resource	Time resource	Comment
	hand basins	basins		basin or sink might be acceptable or perhaps use of attached accommodation facilities
Other legisla tions	Building Act	Provision of toilets for customers		Adds undue cost and uses valuable space for provision of toilets even for small non-liquor eating- house's

Risk Management Tools, Business Compliance Costs – Comparison of existing Food Act 1981 regime, and proposed use of regulatory tools for an amended Food Act or a revised Food Bill

	Food Safety Prog	rammes (FSPs) / Food Control F	Plans(FCPs)	
	Food Act 1981 – current regime	Food Bill – 2008 drafted version	Regulatory tool (for amended Act or revised Food Bill) – proposed revision 2009	
Number of affected food businesses	3,000 FSP's	Between 16,000 and 32,000	Up to 16,000	
Development and Evaluation of a risk management tool	Food Safety Programmes – one off charge of between \$10,000 and \$20,000	Food Control Plans (FCP) –use of off-the-peg template would not need this step as developed and evaluated by NZFSA.	Food Control Plans (FCP) –use of off-the-peg template would not need this step as developed and evaluated by NZFSA.	
		No cost.	No cost	
		Custom FCP – developed by business for own use. May use aspects of the template or fully develop own FCP.	Custom FCP – developed by business for own use. May use aspects of the template or fully develop own FCP.	
		Between \$500 and \$20,000	Between \$500 and \$20,000	
Evaluation and Registration of a risk management	One off charges: FSPs - Public	Registration of an off-the peg template FCP - annual	Registration of an off-the peg template FCP - annual	
tool	Health Unit \$96 per hour – between 2 and 20 hrs	\$100	\$100	
	20110	Registration of Custom FCP	Registration of Custom FCP	
	NZFSA \$137.50 per hour – between 5 and	\$500 - \$1922	\$500 - \$1922	
	15 hrs Average cost: \$1922	Same as current costs for a full custom plan and decreasing if the plan is based in part on an off the peg FCP template	Same as current costs for a full custom plan and decreasing if the plan is based in part on an off the peg FCP template	
Verification – by Territorial	Annual charge - Ranges from	Off the peg FCP - annual	Off the peg FCP – annual ⁷	
Authorities, NZFSA or Third party auditors	\$900 to \$5,000	On average this should be a 2- 3 hr process: \$200 - \$300	On average this should be a 2-3 hr process: \$200 - \$300	
		Custom FCP - annual \$500 - \$5,000	Custom FCP – annual \$500 - \$5,000	
Cost range	Up to \$26,922	Expected average annual cost for an off the peg FCP: \$230 - \$250* Custom FCP up to \$26,922	Expected average annual cost for an off the peg FCP: \$230 - \$250* Custom FCP up to \$26,922	

⁷ Frequency may reduce, e.g. to biennial, if a business operator is consistently compliant and following good food safety practices. Also applies to Custom FCPs.

	Nation	al Programmes	
	Food Act 1981 – current regime	Food Bill – 2008 drafted version	Regulatory tool (for amended Act or revised Food Bill) – proposed revision 2009
Number of affected food businesses	23,000 – currently subject to Food Hygiene Regulations 1974	Up to 8,000	Up to 24,000
Annual registration and inspection by Territorial Authority. This is an all inclusive charge. Cost dependent on size of food business and the type of activity they are doing.	Cost of both functions range from \$50 to \$1,880	Annual registration by Territorial Authorities \$100 Verification (inspection) based on hourly rate of \$100 per hr. On average this should be a 2-3 hr process - \$200-\$300	Registration by Territorial Authorities and NZFSA or self-registration by food business \$50 - \$100 Verification (inspection) – based on hourly rate of \$100 per hr. On average this should be a 1-3 hr process. \$100 - \$300 Rolling programme of verification based on four levels of national programme. All have an initial visit then verification frequency would be: Level 4 – 1 in 2 years Level 3 – 1 in 3 years Level 2 – 1 in 5 years Level 1 – on complaint
Average Annual user charge per business	\$285**	Expected average annual cost \$230- \$250*	Expected average annual cost \$150-\$200 Reduces when verification frequency is prescribed by the level of the national programme.

* As with the current system, for the proposed and revised options there is likely to be a range of charges between Territorial Authorities. On average only 66% of costs are recovered by user charges, this is reflected in these numbers. The balance is funded by other Council review, e.g. rates. The proposed costs assume Territorial Authority funding continues at the same level.

** Costs are based on average Territorial Authority pricing

Food Handler Guidance											
	Food Act 1981 – current regime	Food Bill – 2 drafted versio		Regulatory tool (for amended Act or revised Food Bill) – proposed revision 2009							
Number of affected food businesses	fundraisers, galas and stalls at markets selling cakes, pickles and jams.										
	The Food Hygiene Regulations 1974 requ food for sale be prepared in premises that registered by Territorial Authorities, unless from registration. Exemption from registration exemption from the application of the Foo Regulations 1974 to their food activities. businesses can voluntary choose to use a programme. Many of these types of stalls do n prescriptive requirements of the Foo Regulations 1974, mainly because th produced in registered premises. The there are a large number of technical non with the Food Act 1981 regime and a people who are technically acting outside	t are s exempted ation is not od Hygiene Food a food safety ot meet the ood Hygiene hey are not result is that i-compliances a number of	costs regula these subje (educ Food legitin	e will be a reduction in the of obtaining and meeting ator requirements because food businesses would be ct to food handler guidance cative material). handler guidance would nise the undertaking of these but (technically) unlawful ties.							

Unregistered hospitals, childcare facilities, aged care homes or school tuck shops										
Food Act 1981 – current regime	Food Bill – 2008 drafted version amended Act or re Food Bill) – propos revision 2009									
Not required to be registered.	Only necessary requirements will be applied to businesses significantly reducing compliance costs.									
Territorial Authorities are unclear whether they should inspect, so variation exists with some businesses being inspected, and others not being inspected.	Business operators will have in one place reference to all the regulatory requirements that need to be met as well as documentation on how they will meet these requirements.									
For those that are inspected they currently face the same compliance cost as those businesses that are required to register under the Food Hygiene Regulations 1974.	 Hospitals – Food Control Plan Childcare facilities – National Aged care homes – National School Tuck Shop – National 	Programme Programme								
Some are paying annual inspection costs.										

⁸ Consultation will need to be undertaken with affected sectors regarding the appropriateness of the regulatory and non-regulatory tools under the revised Food Bill.

Levels of Regulatory & Non-Regulatory control

Key to abbreviations:

- PBV Performance Based Verification
- RTE ready to eat
- YOPI Young, Old, People Immune-compromised

- (*) includes Territorial Authority involvement
- GOP Good Operating Practice
- HACCP Hazard Analysis Critical Control Point

Food Co	Food Control Plans												
Level	Examples	Regist	ration		Standa	ırds			Other Requi	rements		Ext Verification	
	<i>NB.</i> Transition year shown in ()	Self	3 rd party	NZFSA	Generic Regs & Specs	Specific	GOP	HACCP	Records	Duties	Operator Verification	Initial	On-going
Food Control Plans (Including off-the-peg food control plans)	Retailers that process (high risk) Manufacturers (high risk) Including: Food Service (FS) – on-site catering (1) FS – off-site catering (1) FS – mobile (3) FS – general full on-licence (1) FS – general no full on-licence (2) FS – hospital YOPI (2) FS – International Health Regulations (2) Retail – butcher – RTE (3) Retail – makes to sell (3) Manufacturer – meat – RTE (3)	×	√ or	opt 🗸	~	~	✓	✓ (NZFSA)	 Additional sector specific requirements GOP HACCP Systems 	√++	√ ++	< 3 mth (unless already checked)	PBV by TA or other TPA at least annually

Nati	ional Programmes												
Level	vel Examples Registration				Stand	ards			Other Requirements			Ext Verification	
	<i>NB.</i> Transition year shown in ()	Self	3 rd party	NZFSA	Generic Regs & Specs	Specific	GOP	HACCP	Records	Duties	Operator Verification	Initial	On-going
4	Manufacturer – meat – non RTE (3) Retail – butcher – non RTE (3) Retail – bakery, more than bread (4) Retail – handles and sells (mid risk) (3) <i>NB</i> . Default to here unless they make a case for another level	×	✓ or	opt 🗸	~	✓	~	×	- GOP - Systems	✓	√+	< 6 mth (unless already checked)	PBV by TA or other TPA at least 1 in 2 years
3	Manufacturer – frozen fruit & vegetables (5) Manufacturer – shelf stable condiments (5) Manufacturer –100% juice – short life (4) Manufacturer –100% juice –extend life (4) Manufacturer – 100% juice –ext life (4) Retail – bakery, bread only (4) Horticulture – packing (3) Horticulture – producers – leafy vegetables & herbs (3) Horticulture – producer – berries, melons (3) Importers	✓ or	1	×	~	~	~	×	- GOP - Systems	~	~	< 1 yr (unless already checked)	PBV by TA or other TPA at least 1 in 3 years
2	Raw milk gate sales (2) Retail – includes readily perishable food (3) Distributor/Transport – readily perishable (4) FS – mobile (etc.) coffee/shelf stable only (3) Manufacturer – confectionery (4) FS – day care YOPI (2) FS – residential YOPI (2) All other Horticulture not mentioned elsewhere (3)	✓ or	~	×	✓ (opt out of some)	×	✓ (like FHG++)	×	- Inventory - Exception	×	×	< 1 yr (unless already checked)	PBV by TA at least 1 in 5 years
1	Retail – only sells shelf stable, manufacturer pre- packaged goods (3) Distributor/Transport – shelf stable (4) Manufacturer – ice and iced confection (5) Horticulture – very small producers (3)	~	×	×	✓ (opt out of many)	×	✔ (like FHG)	×	Nil specific	×	×	< 1 yr (unles already checked)	Survey or when a problem occurs

FHG													
Level	Examples	Regist	Registration						Other Requirements			Ext Verification	
	NB. Transition year shown in ()	Self	3 rd party	NZFSA	Generic Regs & Specs	Specific	GOP	HACCP	Records	Duties	Operator Verification	Initial	On-going
Food Handler Guidance	Sausage sizzles, school fundraisers, charity fundraiser or church bazaar	×	×	×	x	×	✓ (very basic)	×	×	✓ (must meet obligation of the Act to provide safe and suitable food)		×	×