Regulatory Impact Statement: Policy approvals - Facilitating export exemptions under the Food Act 2014 from New Zealand food composition and labelling requirements

Coversheet

Purpose of Document	
Decision sought:	*Analysis produced for the purpose of informing final Cabinet policy decisions.*
Advising agencies:	*The Ministry for Primary Industries*
Proposing Ministers:	*Minister for Food Safety*
Date finalised:	*1 November 2024*

Problem Definition

The current requirement to obtain export exemptions for foods for export that do not meet New Zealand composition and/or labelling requirements creates challenges for both the Ministry for Primary Industries (MPI) and exporters.

Exporters using exemptions consider the current approach creates unnecessary regulatory burden, is anti-competitive and is hindering export growth. The process is also costly for MPI and does not appropriately assign management of food safety and suitability risks to exporting food businesses.

Executive Summary

All food produced in New Zealand, including for export, must comply with the composition and labelling requirements of adopted joint food standards, and any New Zealand-specific food standards (such as the New Zealand Food (Supplemented Food) Standard).[1,2] Food that is exported must also comply with the importing country requirements. When these differ to New Zealand's requirements, operators must apply to the Ministry for Primary Industries (MPI) for an exemption from New Zealand's composition or labelling requirements, unless an existing exemption already applies.[3]

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[1] Sections 397(4) and 404 of the Food Act 2014.

[2] There are also primary processing requirements that ensure our food is safe and suitable for both New Zealand and overseas consumers and allow attestations for these attributes to our overseas markets.

[3] Dairy and honey producers do not need to apply for labelling exemptions, as there are existing labelling export exemption Notices. There is also a labelling exemption Notice for infant formula, with restrictions on permissions for health claims. Paragraph 75 outlines these in more detail.

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There are two mechanisms available in the Food Act to manage export exemptions: the currently used section 347 exemption process[4], and the power to make regulations under section 345.

The current section 347 exemption notice process requires applications for individual products to designated markets, on a case-by-case basis. MPI assesses the request against domestic, international, and importing country standards. Feedback from targeted and public consultation was that this process is time-consuming and limits exporter's ability to compete overseas resulting in lost commercial opportunities – particularly for the dairy and infant formula industry. Feedback also confirmed that this process mis-allocates some of the risk-management to MPI rather than the operator. The current process is not cost-recovered and is resource intensive for both MPI to assess and for businesses to prepare the required supporting evidential information.

Section 345 of the Food Act allows regulations to be made that generally exempt food exports from domestic composition and/or labelling requirements and to any destination.[5] Such an exemption may be subject to conditions. These conditions must be set in the regulations. To date, these regulations have not been made.

From June to July 2024, MPI publicly consulted on four options that would provide an exemption in regulations for all food exports from labelling and composition requirements and would require that certain conditions be met.

24 submissions were received. These included submitters from food and beverage businesses (a large proportion being from the dairy industry); natural health products sector; industry organisations; and third-party verifiers. Many submitters did not support any of the proposed options. They considered the proposed conditions attached to an exemption in regulations could result in increased regulatory complexity, restrict innovation, create trade barriers, enforcement challenges and financial barriers. Instead, 45% of submitters supported a new 'Option Five' proposed by dairy industry bodies and supported by dairy processing manufacturers and some wider food & beverage sector submitters.

Feedback from consultation and subsequent analysis has informed the preferred approach. This includes aspects of a proposed 'Option Five' put forward by some industry bodies and supported by most dairy sector submitters. In summary, the preferred approach is staged, with Stage One being to introduce section 345 regulations that provide:

a) an exemption from the composition requirements of any adopted joint food standards or domestic food standards,[6] for all animal products for export produced in accordance with a Risk Management Programme (RMP), subject to conditions;

b) an exemption from the labelling requirements of adopted joint food standards or domestic food standards for infant formula for export, with conditions or exceptions that reflect those currently applied to infant formula under the *Animal Products Notice: Labelling Requirements for Exports of Dairy Based Infant Formula Products*

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[4] These exemptions are gazetted in the Food Act Notice: Food for Export – Exemptions from Domestic Compositional Requirements.

[5] Section 345 regulations may also exempt food that is to be exported from the requirements of regulations made under section 383 and notices made under section 405.

[6] These exemptions apply to food intended for export to a destination other than Australia.

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and Formulated Supplementary Food for Young Children.[7] This includes particular labelling requirements relating to nutrition and health claims;

c) an exemption from the labelling requirements of any adopted joint food standards or domestic food standards for all other foods for export (not including wine), with no conditions; and

d) an exemption from the labelling requirements of the Dietary Supplement Regulations (with no conditions) for all dietary supplements, and an exemption from the composition requirements of the Dietary Supplement Regulations for those dietary supplements regulated as animal products produced with a RMP (with the same conditions proposed for (a)).[8]

Subsequently, under Stage Two, the proposed composition exemption under section 345 could be extended to include other, non-animal product foods. This is expected to require changes to the Food Act and its regulations, to introduce export controls, provide for official certification, and support exemptions for food exports under the Food Act.

The staged approach would enable regulations to be put in place relatively quickly for animal product operators, noting the dairy industry is our largest export earner[9] and the primary user of the existing export exemption system. Additionally, the animal products sector is already well regulated for exports under the Animal Products Act 1999 (APA) and has a long history of navigating the requirements of overseas markets. In contrast, the Food Act lacks export controls and mechanisms to manage the proposed requirements on exporters, operators or manufacturers. It allows these issues to be addressed at a later stage, without delaying implementation of an improved pathway for animal products.

If Cabinet approves the preferred approach, the proposed section 345 regulations (Stage One) would be introduced in the first half of 2025.

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Limitations and Constraints on Analysis

Due to the significant issues that the dairy industry considers result from the current exemption requirement, the Minister for Food Safety committed to introducing changes by the end of 2024.

This timing imperative meant changes to primary legislation, international standards and market access arrangements were out of scope of the options proposed for public consultation. Out of scope were proposals to:

- amend primary legislation, such as the Food Act or the Animal Products Act – noting this would require substantive legislative change and complexity, and entail longer lead time to develop and implement compared to proposals to establish regulations under the Food Act;
- amend the Australia New Zealand Food Standards Code or domestic food standards;
- change the availability of market access documentation under the Animal Products Act;

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[7] Animal Products Notice: Labelling Requirements for Exports of Dairy Based Infant Formula Products and Formulated Supplementary Food for Young Children: https://www.mpi.govt.nz/dmsdocument/43741-Animal-Products-Notice-Labelling-Requirements-for-Exports-of-Dairy-Based-Infant-Formula-Products-and-Formulated-Supplementary-Food-for-Young-Children

[8] This is subject to a 'lift and shift' of the Dietary Supplement Regulations 1985 to the Food Act 2014

[9] Current total dairy export revenue is forecast at $25.8 billion for the year ending 30 June 2025.

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- provide exemptions for food for export for personal use that is not traded; and/or
- amend the Export Assurance system. MPI consulted on options for modernising our export assurance system from July to September 2022. This can be found on the MPI website here: https://www.mpi.govt.nz/export/exporting-from-nz-how-it-works/mpis-role-in-exporting/modernising-our-export-legislation-for-food-and-fibre-products/.

Alongside the status quo, the options for regulatory change to the current approach for export exemptions are limited to the proposed creation of new regulations under section 345 of the Food Act. The Food Act provides two mechanisms for export exemptions: sections 345 and 347. To date, MPI has utilised the section 347 individual application process and regulations under section 345 have not been made.

The scope of any exemptions regulations under section 345 is limited to exported food that does not meet New Zealand's labelling and/or compositional requirements, or the requirements of regulations made under 383 or notices made under section 405. This includes food exported for sale by manufacturers and third-party exporters, including those selling food via Cross-Border E-Commerce (CBEC).

The data and evidence used in developing this proposal is limited to feedback provided to MPI in response to formal public consultation and from targeted consultation with parts of the dairy sector (and some of the wider food and beverage sector). This includes information (both qualitative and quantitative) provided to us in submissions from individuals, industry bodies, and food and beverage sector companies. Due to time and data constraints, it was not possible to fully analyse the monetised costs in the cost benefit analysis.

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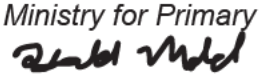
Responsible Manager(s) (completed by relevant manager)
Dr Donald Ward *Manager* *Food Regulations Policy* *Ministry for Primary Industries*  *1 November 2024*

Quality Assurance (completed by QA panel)	
Reviewing Agency:	Ministry for Primary Industries (MPI)
Panel Assessment & Comment:	The MPI Regulatory Impact Analysis Panel has reviewed the Regulatory Impact Statement (RIS) attached to this Cabinet paper and considers it partially meets the Quality Assurance criteria. The Panel considers the RIS is as clear and concise as possible, complete, and consulted on with stakeholders. The Panel notes that analysis of the problem and options is constrained by a lack of time for analysis and review (including the costs and benefits of the proposed options). This limits the degree to which the convincing criterion can be achieved.

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Section 1: Diagnosing the policy problem

What is the context behind the policy problem and how is the status quo expected to develop?

1. New Zealand food exports are a significant contributor to the economy. Food export earnings are projected to reach $57.7 billion in 2025. Of this, the dairy industry (the primary users of the current export exemption process) is the largest contributor with total dairy export revenue forecast at $25.8 billion for the year ending 30 June 2025.[10]

2. As the authority that regulates the safety and suitability of food for sale in New Zealand and for export, MPI aims to ensure that the health and safety risks from food are managed, and that consumer health and wellbeing are protected. We also support access to export markets.

3. All food produced for sale in New Zealand, including for export, must comply with the composition and labelling requirements of the Australia New Zealand Food Standards Code (the Food Standards Code), certain New Zealand-specific food standards, as well as regulations made under section 383 and notices made under section 405 of the Food Act. These standards form the primary requirements for attesting our exported food is safe and suitable to overseas markets.[11]

4. Food that is exported must also meet the importing country's requirements. These requirements can differ from New Zealand's requirements for composition and/or labelling, in which case the food to be exported must be made exempt from New Zealand requirements.[12] The current exemption framework involves either that:

   a) food operators must apply for an exemption from New Zealand requirements under section 347 of the Food Act; or

   b) dairy and honey products to be exported meet labelling export exemption notices under the Animal Products Act 1999 (APA) (this includes infant formula, with restrictions on permissions for health and nutrition claims).

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Export exemption mechanisms under the Food Act

5. There are two mechanisms available in the Food Act to manage export exemptions: the currently used section 347 individual exemption process,[13] and the power to make regulations under section 345.

[10] MPI Situation and Outlook report, June 2024.

[11] Section 397(4) provides that a person who manufactures or prepares food for sale in New Zealand, or sells food in New Zealand, or imports food into, or exports food from, New Zealand must comply with the requirements of the adopted food standard in relation to that food.

[12] Foods that are exempted are not able to be sold in New Zealand or Australia.

[13] These exemptions are gazetted in the Food Act Notice: Food for Export – Exemptions from Domestic Compositional Requirements.

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Section 347

6. Section 347 of the Food Act provides the ability to exempt exported foods from domestic requirements when an exporter makes a request.[14] An exemption is limited to considering a particular food product and the intended overseas market(s) it is exported to. Any changes to the composition of the food to meet evolving market requirements, as is common, may require a separate request.

7. Before granting such an exemption, the Food Act requires the Director-General of MPI to:

   a) be satisfied that the exemption is necessary or desirable to facilitate access to an overseas market or to overseas markets; and
   b) be satisfied that, if appropriate, the risks in relation to the safety and suitability of food are managed by an applicable risk management programme or regulated control scheme under the APA or any other applicable risk-based measure; and
   c) take into account the requirements of the overseas market or overseas markets to which the food is to be exported.

8. MPI assesses the request against domestic, international, and importing country standards. If relevant and in the absence of clear importing country standards, MPI provides a high-level safety assessment of the proposed constituent in the product for the intended population. Some exports also need a statement from MPI that they meet specific export requirements.

9. Due to existing labelling exemption notices under the APA, almost all exemption requests relate to composition, for food produced to an importing country standard which differs from New Zealand standards. Compositional factors might differ due to the importing country permitting (or not permitting) the use of certain ingredients or substances (for example, vitamins, minerals, additives, processing aids, fat, and protein). Very few exemption requests have been rejected.

10. To date, food exporters operating under the APA have been the primary users of exemptions as they require export certification/official assurances to accompany product. This is beginning to change and more businesses operating under the Food Act are requesting exemptions in order to obtain certification. s9(2)(g)(i) [redacted].

Section 345

11. Section 345 of the Food Act enables regulations to be made exempting food that is to be exported from all or any adopted joint food standards or domestic food standards, in the case of food intended for export to a destination other than Australia, as well as from regulations made under section 383[15] and notices made under section 405.[16] A regulation under section 345 can apply to any destination market and set any

[14] In 2020, MPI received and processed 32 individual applications for export exemptions, 21 applications in 2021, and 15 in 2023.

[15] Section 383 of the Food Act allows the Governor-General to, by Order in Council, on the recommendation of the Minister, make regulations and notices about standards in relation to food.

[16] Section 405 of the Food Act allows the chief executive to issue notices setting requirements or specifying matters permitted by the Act, or permitted by a provision of the Act.

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conditions. These conditions must be set in the regulations. To date, these regulations have not been made.

How is the status quo expected to develop if no action is taken?

12. Demand for exemptions is driven primarily by market demands, including changes to importing country requirements, and exporters' business improvement and development needs. This makes predicting future demand difficult, however, demand may increase because:

    a) dairy companies are increasingly expanding their product portfolios into mixed and non-animal products and other innovative products (for example, infant formula, modified milk powders, nutrition, and protein formulas), which will require more complex exemptions under the Food Act; and

    b) while requests from the non-dairy sector are currently less common, these are increasing with the growth in the 'other processed foods' sector (for example, new compositional and innovative foods such as functional beverages).

13. Existing notice exemptions are becoming complicated and unwieldy to follow and can become misaligned with new market requirements over time.

14. Historically, food exporters outside the dairy infant formula and related products markets rarely seek exemptions. Limited information is available as to why this is. However, there is likely to be a lack of awareness among food and beverage exporters of the Food Act requirements. Some Food Act verifiers may not directly check for exemption requirements. It is possible that the public consultation MPI held in June/July 2024 as part of these proposals may have increased awareness of the current requirement to seek exemptions under section 347.

15. If the status quo is maintained, MPI would seek to further clarify and publicise the requirements relating to export exemptions, which may lead to greater demand for exemptions. This would continue to have cost and resource impacts for MPI (and/or MedSafe) in assessing these applications. Implementation of some operational improvements and a cost recovery mechanism would likely be required.

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What is the policy problem or opportunity?

16. In the discussion document for public consultation on options for export exemptions under the Food Act, we outlined the identified shortcomings of the current export exemption process and sought feedback on what impacts it is having on businesses' ability to export, including to compete and meet customer requests.

17. Feedback received from submitters recognised some benefits of the current requirement, including that it is familiar and that existing exemption Notices are effective and provide companies with a list of published exemptions. Some submitters noted that existing exemptions in notices (in particular, the dairy export labelling exemption notice[17]) allow nutritional and health claims. It was also noted that no market failures have been attributed to existing labelling exemption Notices.

[17] Animal Products (Exemption from Labelling Standards for Dairy Product and Dairy material Intended for Export) Notice

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18. However, the majority of submitters identified negative impacts resulting from the current requirement to obtain an exemption. These included that it creates unnecessary regulatory burden, is anti-competitive and is hindering export growth. These issues are expanded on below.

The current process potentially results in lost commercial opportunities

19. Currently, dairy and infant formula producers are the main sector relying on export exemptions. In representations by members of the dairy industry, and in targeted engagement with established MPI forums, some exporters reported foregoing commercial opportunities because of the current requirement to obtain individual exemptions. Some local manufacturers also said they cannot compete with their overseas competitors (including from Australia and the EU) who do not need to obtain food export exemptions, resulting in lost market share. Overseas businesses/importers are also reportedly discouraged from seeking New Zealand manufacturing because of the exemption requirement and have been known to shift opportunities to other countries (including Australia).

20. These impacts were highlighted by submitters about the current approach:

- Delays product launch/registration and hinders speed to market.
- Is not agile/lacks flexibility, and does not enable New Zealand to keep pace with the fast changing and competitive global food supply chain.
- Is overreach by the New Zealand government into other countries' regulatory jurisdictions, exemptions are uncommon globally and exports should deliver what the importing country wants.
- Restricts exports and is an unnecessary trade barrier imposed on exporters.
- New Zealand requirements are not understood by commercial partners and can result in lost commercial opportunities.
- Does not align with international approaches which do not require export exemptions.

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21. Dairy industry organisations noted that the current process has a major impact for New Zealand dairy exporters, particularly in more nutritionally specialised products. Some submitters provided specific examples of estimated loss in sales due to product launch being delayed (product registration certificates cannot typically be started until exemptions are granted), but are not discussed here due to commercial sensitivity. Other submitters noted they had had to turn away customers and business opportunities as a result of the requirement and time taken to process exemptions.

22. Submitters from the natural health products industry noted that the current process does not permit export exemptions for dietary supplements at all, which they said meant the industry was losing NZD$500 million in export trade per annum.

The current process creates regulatory burden

23. The current process is resource intensive, costly and time consuming for food exporters. Applicants are required to disclose evidential information to support each individual application, which are often required to cover multiple markets, address several product differences, or are time-critical. Submitters gave a range of timeframes for obtaining exemption application approvals, ranging from three months, over six months, up to one year. Many submitters noted that it creates a competitive

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disadvantage by creating an unnecessary and burdensome regulatory process/red tape and restricts the ability to innovate.

24. From MPI's perspective, the current process requires MPI to carry out a thorough assessment of individual applications. The timing of exemption requests is sporadic and driven by commercial imperatives outside MPI's control, making work planning and resource allocation difficult. The current exemption process is not currently cost-recovered and is resource intensive for those MPI teams involved in assessing applications.

25. The mandatory considerations that must be taken into account to decide exemption outcomes are broadly defined under the Food Act. However, feedback from submitters identified that there are variations in the process, interpretations and criteria MPI applies when assessing or granting exemptions. For example, one dairy company noted that MPI does not always accept express permissions of the overseas market and this conflicts with the overseas competent authority. Another company noted that the current requirement to obtain an exemption creates a 'chicken and egg' situation between MPI official assurances to support product registration, and product registration in market – which they said can be difficult to obtain without first having applied for an exemption.

26. Some submitters noted that exporters of foods outside the dairy and honey sectors rarely seek exemptions, either due to lack of awareness or time constraints, which was felt to unevenly distribute regulatory burden amongst food manufacturers.

Current use of export exemptions has limited effect

27. The current exemption setting relies on exporters approaching MPI with specific requests. MPI can only provide exemptions on a case-by-case (i.e. product by product) basis. An exemption can only cover a specific food, constituent and the intended overseas market it is exported to. This limits its utility for food exporters.

28. Food exporters outside the dairy infant formula and related product markets rarely seek exemptions. Limited information is available as to why this is. However, there is likely to be a lack of awareness among food and beverage exporters of the Food Act requirements, and Food Act verifiers are not required to directly check for exemption requirements. MPI has more recently received some applications from outside the dairy infant formula sector; it is possible (but unconfirmed) that this is due to increased awareness of the exemption pathway following public consultation on this proposal. One export industry submitter suggested that further analysis would be beneficial as to why there is limited uptake of the current exemption process by businesses operating under the Food Act.

Responsibility for ensuring safety and suitability of exported food lies with exporters/manufacturers

29. A cornerstone of New Zealand's highly regarded model for food safety is that food businesses, including exporters, manage their own food safety and suitability risks, with appropriate oversight of their risk management systems and processes by independent auditors and verifiers. Many submitters commented that the existing regulatory framework for operators of risk-based measures should provide the basis for exporters

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to self-assess product compliance with the relevant importing country requirements (where they exist).

30. The MPI ownership of the individual exemption process, which includes consideration of any potential food toxicity and nutritional risks arising from certain ingredients added to products, sees MPI assume some responsibility for the exempted products being safe and suitable for the end consumer. This responsibility should lie with food manufacturers or exporters to have the systems and processes in place for ensuring safety of their products and demonstrating compliance with relevant requirements (including importing country requirements).

31. Further, food compositional requirements have become complex and variable across different countries. New Zealand requirements do not always cover different situations and product categories. This makes it increasingly impractical for MPI to identify requirements and resolve individual exports exemptions and keep pace with changing overseas standards.

The stakeholders

32. Key stakeholders in this issue are the current and potential future users of export exemptions under the Food Act. To date, dairy product manufacturers have been the primary users of export exemptions. Although the dairy industry represents the majority of the current users of export exemptions, these exemptions are applicable to the wider food and beverage sector. In particular, exemptions may be required by processed food manufacturers, who seek to meet different importing country requirements for composition and/or labelling. The number of non-dairy processed food exporters utilising exemptions is increasing, with more businesses operating under the Food Act requesting exemptions to obtain certification.

33. As the regulator or competent authority, MPI is also a key stakeholder. Currently, MPI receives a relatively small number of exemption applications per annum (15-20), but these can be time consuming and resource intensive for MPI teams, with assessment times ranging from three months to one year.

34. Other stakeholders are the evaluators, verifiers or recognised agencies involved in verifying and evaluating the systems and processes manufacturers have in place to support export exemptions (issued under section 347). If the proposed regulations under section 345 are made, this will require verification of the proposed conditions that would enable operators to be eligible for exemptions.

35. Some of the information gathered from sector stakeholders was through proactive industry representations to Ministers or at established MPI forums. Information was also sought through targeted engagement with dairy industry representatives and, separately, with recognised agencies.

Stakeholder views on the problem

36. Cabinet approved the release of a discussion document for formal public consultation over six weeks in June/July 2024, on proposed options for export exemptions from New Zealand composition and labelling requirements under the Food Act.

37. In total, 24 submitters provided comments on the proposed options for export exemptions from New Zealand composition and labelling requirements.

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38. Submitters included food and beverage businesses, third-party verification and accreditation bodies, and industry organisations.

39. While most submitters were from the dairy industry, the diverse range of food and beverage export businesses were well-represented with submitters from the dairy product manufacturing, seafood processing, meat product manufacturing, and other food product manufacturing, as well as other from the natural health products sector (including manufacturers of dietary supplements and supplemented foods). All submitters were New Zealand-based.

Table 1: Representation of industry sectors in submissions received

Sector	Number of submitters*	Percentage of submitters
Dairy product manufacturing	11	46%
Other food product manufacturing	4	17%
Natural health products (including dietary supplements and/or supplemented foods)	3	13%
Seafood processing	2	8%
Meat product manufacturing	1	4%
Alcohol beverage industry	1	4%
Third party verification and audit	1	4%
Export industry	1	4%
Total	24	100

*Note: some submitters identified with more than one sector; only one sector per submitter has been included in this table.

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40. Overall, dairy industry submitters agreed with the problem as described in the discussion document. Key points raised were that the current process is time-consuming, not aligned with international approaches, results in lost commercial opportunities and creates a competitive disadvantage.

41. Most wider food and beverage sector submitters commented that they either do not use, or have limited experience with, the current exemption process (e.g. because limited compositional standards are relevant to their products). Submitters from the natural health products (including dietary supplements) sector commented that they are not currently able to use the current exemption process (or any exemption pathway), which they view as a significant barrier to export for the industry. However, a number of these submitters still supported introducing a more enabling approach for exemptions in regulations, noting that it may be relevant in future (e.g. due to recent changes to allergen labelling requirements and new value-add products).

The problem does not disproportionately affect any populations groups

42. We do not consider that the problem as described above disproportionately affects particular population groups.

What objectives are sought in relation to the policy problem?

43. As noted above, the key problems with the current approach are that:

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- the current process and requirement to obtain export exemptions potentially results in lost export opportunities/creates a competitive disadvantage for New Zealand businesses;
- the current process creates burdensome regulatory process/red tape and restricts the ability for businesses to innovate;
- current use of export exemptions has limited effect (due to the current requirement to obtain individual exemptions for exports to particular market(s) and for particular product(s));
- in granting individual exemptions, MPI has assumed some responsibility and risk ownership for ensuring exempted exported foods are safe and suitable for the end consumer, when this responsibility could sit more appropriately with exporters/manufacturers.

44. The proposed regulatory changes seek to improve the exemption pathway to ensure:

a) food exporters are supported with trade facilitation and product innovation is enabled;

b) a food export exemption regime that is more efficient and agile and the integrity of our export systems are maintained as key enablers of market access; and

c) New Zealand food exports are safe and suitable for intended use and are informatively and truthfully labelled.

45. These objectives aim to balance the needs of food exporters seeking to comply with different overseas compositional and/or labelling requirements, against managing food safety risks and maintaining our export systems that support market access. The recommended option seeks to manage these competing objectives through a staged approach, recognising the APA provides export controls that the Food Act currently does not.

46. The Government aims to double the value of New Zealand exports in 10 years and reduce regulatory burden for businesses. This goal is supported by better facilitating the trade of safe food products to a broad range of markets without adding undue compliance costs.

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Section 2: Deciding upon an option to address the policy problem

What criteria will be used to compare options to the status quo?

47. We identified five criteria to enable assessment of the proposed options for public consultation. The criteria assessed the extent to which the options would address the issues with the current process and meet the proposed objectives:

1. **Facilitating food export trade and product innovation**
    - Food exporters need to be able to respond to market changes and opportunities in a timely manner. The primary objective is to facilitate this by minimising regulatory burden and making the Food Act exemption requirements simpler and more transparent.
    - This criterion assesses the extent to which the option will deliver this.

2. **Manages risks to food safety and suitability**
    - Making food that is safe to be consumed is a cornerstone of our food production sector wherever food is sold, domestically or in export markets.
    - Food must also be suitable for its intended purpose and population group – i.e. it must contain the right ingredients, at the right levels and the labelling (including claims made) must be appropriate.
    - Meeting the composition and labelling requirements of destination markets is essential to be able to successfully export food.
    - The responsibility for managing risks to food safety and suitability should lie with the operator and the exporter, with appropriate oversight by MPI via operators' risk-based measures.
    - This criterion assesses the extent to which the option would ensure operators and exporters identify and achieve compliance with the safety and suitability requirements of the overseas market and whether MPI is satisfied the operators and exporters can achieve this outcome.

3. **Manages risks to New Zealand trade and reputation**
    - New Zealand is a trading nation and the majority of our primary produce, including foods, is exported and makes a very large contribution to the economy.
    - Any problem in an overseas market with New Zealand produced food has the potential to have reputational and wider food trade risks for "New Zealand Inc".
    - MPI as the agency that oversees the food production system on behalf of New Zealand has a strong interest in ensuring that these wider risks are minimised.
    - This criterion assesses if the option could adversely affect "New Zealand Inc" in terms of our ability to sell food internationally.

4. **Cost effectiveness**
    - Does the option enable the efficient allocation of resources to deliver the service?
    - This criterion examines the costs and the value that the option will deliver, from the perspective of both the food industry and central government.

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5. **Equality considerations**

- The New Zealand food and beverage sector is very broad. It encompasses diverse industries that are at different stages of maturity, operate at different scales, produce foods that present different risk profiles and which occupy different positions on the value chain.
- This criterion considers whether the option will advantage or disadvantage a particular sector or sectors, or provide a level playing field for all.

48. Some submitters noted that the *Equality considerations* criterion needs to consider how that option provides opportunities for New Zealand exporters versus overseas exporters into the same market. Submitter feedback also noted that *Managing Risks to Trade and Reputation* should incorporate 'ease of trade' and 'agility to respond to market needs.' A suggestion was made that the criterion *Managing Risks to Food Safety and Suitability* could be weighted more heavily because by controlling for these, risks to trade and reputation should be managed by default. One submitter suggested that MPI consider whether safety and suitability criteria is adequately addressed already through other existing provisions. For example, for dairy product exports through relevant APA Notices that set out export and labelling requirements.

What scope will options be considered within?

49. The Food Act provides two mechanisms to create export exemptions from composition and labelling requirements: the section 347 individual exemption process, and the power to make regulations under section 345. For the reasons noted in the section on limitations and constraints, including that the Minister for Food Safety committed to introducing changes by the end of 2024, MPI is not proposing any amendments to primary legislation at this stage.

50. The scope of the proposed changes is limited to making regulations under section 345 of the Food Act. Section 345 allows regulations to be made that generally exempt food exports from:

a) adopted joint food standards or domestic food standards (in the case of food intended for export to a destination other than Australia),

b) regulations made under section 383; and

c) notices made under section 405.

51. Exemptions under section 345 may apply to exports to any destination, to specified destinations, or to any destination other than specified destinations. To date, no regulations have been made.

52. Non-regulatory options were considered but are not proposed as an option to enable export exemptions. MPI considers non-regulatory approaches would provide insufficient enforcement powers to manage risks relating to food safety, suitability, trade and/or reputation. The proposed regulations would set out the conditions businesses would need to meet in order to be eligible for export exemptions from New Zealand composition requirements. This would provide a clear formalised basis for setting government's expectations and to support the provision of official government assurances if businesses request them.

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53. As a result of stakeholder feedback, we have limited the scope of the options proposed in the Cabinet paper. We have also made some changes to the proposed conditions. These are outlined in the section below on Options.

Relevant experience from other countries

54. The proposed options seek to better align New Zealand's approach with that of our overseas trading partners, for example Australia, Canada and the EU. These jurisdictions enable trade by ensuring export commodities are fit-for-purpose and meet either domestic requirements for composition and/or labelling or importing country requirements.

55. For the most part these countries do not require individual exemptions from composition and labelling requirements for food exports. In some cases, certain requirements (largely record keeping and documentation) must be met. Where importing country requirements are silent, domestic food law applies unless the importing country expressly agrees or accepts the exported food. Auditors may check if products achieve compliance with importing country requirements.

Australia

56. In Australia, under the Export Control Act 2020, certain 'prescribed goods' for export (including animal products) should meet applicable Food Standards Code requirements for composition and labelling where required. However, they can be exported under importing country requirements if an exporter meets certain requirements as part of export registration (including identifying importing country requirements, checking that they are met and record keeping). Auditors can check if products achieve compliance with importing country requirements within their risk-based measure. Most processed foods are not subject to Australian export controls as they are deemed low risk, expected to meet food safety requirements, and can be exported without direct government oversight. Australia broadly does not provide specific labelling requirements for exported foods, other than requiring exported goods to not bear a false trade description. General consumer and food law applies to prohibit false and misleading conduct.

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Canada

57. In Canada, exported food must meet Canadian food standard requirements where the importing country requirements are silent. However, exporters must ensure that food for export meets the importing country composition and labelling requirements. Manufacturers of food that does not comply with Canadian food standards must keep written documentation of foreign country requirements.

The European Union (EU)

58. The EU sets out overarching principles and requirements for food, including food for export, in its General Food Law Regulation (Regulation (EC) No 178/2002)[18]. The

[18] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32002R0178

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implementing legislation under this food law is harmonised for EU member states. Article 12 of the EU General Food Law Regulation states that food exports must comply with the EU regulations unless it complies with the importing country requirements, or is otherwise requested by the importing country's competent authority. When food does not comply with EU regulations, the importing country must be made aware of the reasons and the food can still be exported if the importing country expressly agrees or requests this. The EU regulations also set out some general requirements including that exported food must not be unsafe or injurious to health.

What options are being considered?

59. The options proposed in the discussion document for public consultation were:

- Option 1: Retain the status quo (section 347)

Risk-based exemptions in regulations under section 345

- Option 2 – an exemption in regulations for all food exports, with certain specified conditions.
- Option 3 – an exemption in regulations for all food exports, with conditions for composition requirements (and potentially where health claims are made, or official assurances required), and a general labelling exemption.
- Option 4 – an exemption in regulations for all food exports, with conditions according to class of product or for particular export markets.

60. Options 2 to 4 provide variations of how exemptions in regulations made under section 345 could be applied, including the proposed requirements ('conditions') businesses would need to comply with to be eligible for exemptions.

61. These options were described in the Discussion Document for public consultation:

https://www.mpi.govt.nz/consultations/options-for-export-exemptions-from-new-zealand-composition-andor-labelling-requirements-under-the-food-act-2014/

62. The section below provides a brief description of all the feasible options we have considered and consulted on, why they are not being progressed and how consultation feedback has helped to develop the recommended option.[19] This is followed by analysis of the recommended option against the status quo.

Option One – Maintain the Status Quo

Key features of this option

63. The 'status quo' maintains the current situation.

64. The current section 347 process can be used to exempt food from the composition and/or labelling requirements under the Food Act, including the Food Standards Code and New Zealand specific standards. This includes food that is an animal material or

[19] An overview assessment of how options two, three and four compare with the status quo is attached at **Appendix Two**. The assessment has been updated since the discussion document was released, to account for submitter feedback.

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animal product under the APA, which must meet some requirements in the Food Act.

65. The current section 347 exemption process would remain the only pathway for all requests made by export food producers who require an exemption from domestic labelling and/or composition requirements.

66. Food exporters contact MPI who assess the request. Matters considered include:

- that the exemption is necessary or desirable to facilitate access to an overseas market or to overseas markets;
- if appropriate, the risks in relation to the safety and suitability of food are managed by an applicable risk management programme or regulated control scheme under the APA or any other applicable risk-based measure; and
- the requirements of the overseas market or overseas markets to which the food is to be exported.

67. An exemption must be specific to a particular market or markets and to a particular food, and may be subject to any conditions specified in the notice.

68. If the MPI individual exemption application is successful, the exemption is granted and an amended Notice covering the exemption is developed and may be gazetted (although some notices are not required to be gazetted as they are not secondary legislation).

69. New Zealand Food Safety staff carry out the work with limited resources and the time taken to process requests is very much dependent on the nature, complexity, and technical issues of the applications.

What is the level of stakeholder support for this option? Has this option been affected by consultation?

70. There was some recognition of the benefits of the current process in submissions, including that it is a familiar process and already provides many exemptions. However, most submitters reinforced that the current process is resource intensive, costly, restrictive and time consuming for both MPI and food exporters, and creates a competitive disadvantage. At the same time, several submitters supported retaining the status quo as a 'back stop' for unforeseen future situations, *in addition to* making new regulations under section 345.

MPI comment

71. Based on the feedback from public consultation, we do not recommend maintaining the status quo as the *only pathway* for all those requiring an export exemption from composition and/or labelling requirements. MPI's intention is that section 347 in the Food Act will be retained if new regulations under section 345 are introduced but would only be used for exemption applications that do not fall within the scope of a section 345 exemption.

Overview of proposed regulatory options (Options Two, Three and Four)

72. Regulations made under section 345 could:

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- allow exemptions for all foods for export, or for classes or categories of foods, from the requirement to meet New Zealand food standard requirements for labelling and/or composition; and
- set conditions exporters would be required to meet. These could seek to reduce the likelihood and consequences of a rare event (a food safety incident or market failure with reputational or trade impacts on New Zealand) occurring while not over-burdening industry with compliance costs. The proposed conditions are discussed in more detail below.

73. The intent of introducing regulations is to enable food exports to be exempt from certain New Zealand food standard requirements (relating to composition and/or labelling) provided the operator or exporter meets certain conditions. It would enable assessment of compliance with the conditions to be managed primarily by the operator or exporter rather than MPI, removing the need to request exemptions on a case-by-case basis.

Option Two – *An exemption in regulations for all food exports from New Zealand standards relating to composition and labelling, with conditions*

Key features of this option

74. This exemption in regulations proposed to cover all exported foods to any countries (other than Australia[20]) that do not meet New Zealand composition and/or labelling requirements, subject to conditions.

75. The proposed conditions (outlined in the box below) aim to ensure that the following key outcomes are met by exporters or operators where their products do not meet New Zealand standards for composition and/or labelling:

- The safety and suitability of food for intended consumers is maintained.
- The integrity of New Zealand's export systems to support market access for our food products is maintained.

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What is the level of stakeholder support for this option? Has this option been affected by consultation?

76. A majority of submitters opposed Option Two due to concerns that the proposed conditions could result in increased regulatory complexity for operators, and were likely to restrict innovation, create trade barriers, cause potential interpretation issues, and create enforcement challenges and financial barriers. In particular, these submitters were concerned about the application of conditions to labelling exemptions increasing costs for operators. This was an unintended consequence of Option Two, because there is current a general exemption in place for labelling of export dairy products (which in effect includes an exemption for health claims).

[20] The products exported under this framework are not eligible for sale in New Zealand or Australia. The systems exporters/operators have in place will also need to cover product disposal if required, should an in-market issue arise that prevents their sale overseas to ensure the product is not then shipped to and sold in the domestic or Australian markets.

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MPI comment

77. Based on the feedback from public consultation, we do not recommend progressing this option as proposed. We agree with submitters that the proposed application of conditions to a labelling exemption would create additional regulatory burden compared with the status quo. However, we do not support the view that there should be no conditions included in regulations, which we address later in this paper.

Option 3 - An exemption in regulations for all food exports, with a differentiated approach for labelling versus composition

Key features of this option

78. This exemption in regulations also proposed to cover all exported foods to any countries (other than Australia) that do not meet New Zealand composition and/or labelling requirements.

79. However, this option proposed a general exemption from labelling requirements for exported food (with no conditions attached), whereas certain conditions could be applied to exemptions from composition requirements, where health claims are made, and/or where government assurances are required. The general labelling exemption was proposed on the basis that labelling standards are, for the most part, low-risk and non-contentious. Although some labelling requirements relate to food safety, most are informational. This would, in part, reflect the approach MPI has taken to date with the animal products notice on exemptions from labelling standards for dairy products for export.[21] However, the labelling exemption in regulations was proposed to apply to all food and beverage sectors, where required, not just the dairy sector alone.

80. On the other hand, this option proposed that certain conditions could be applied to exemptions from composition requirements, where health claims are made, and/or where government assurances are required. These conditions could be similar to those provided in Option Two (Table 3).

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What is the level of stakeholder support for this option? Has this option been affected by consultation?

81. A majority of submitters opposed Option Three, on the basis that this option could remove the ability to make health claims from the current general labelling exemption for dairy exports, which they said would be costly and severely limit export dairy trade. This was seen as a "backwards step". Submitters were also concerned that this option assumed all importing countries have requirements, which may not always be the case. Consequently, as with Option Two, submitters felt this option would reduce exports, restrict product innovation, create trade barriers, create potential interpretation issues, enforcement challenges and impose financial burden on MPI and industry.

MPI comment

82. Based on feedback from submitters, we do not recommend progressing this option as proposed. As with Option Two, we agree that the proposed exclusion of health claims

[21] Animal Products (Exemption from Labelling Standards for Dairy Product and Dairy Material Intended for Export) Notice 2006

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from a general labelling exemption would be a backwards step from the current general labelling exemption that is in place for dairy exports. We also recognise that not all importing countries have clearly expressed or explicit requirements in regulations (including relating to composition and labelling). However, as with Option Two, we do not support the view that there should be no conditions included in regulations, which we address later in this paper.

Option 4 - An exemption in regulations for all food exports, with a differentiated approach for different classes of product (e.g. dairy) or market

Key features of this option

83. This exemption in regulations also proposed to cover all exported foods to any countries (other than Australia) that do not meet New Zealand composition and/or labelling requirements.

84. It proposed that different conditions could be applied to exemptions depending on the class of food product and/or the destination market. These conditions would be applied based on either market sensitivities that may be associated with a specific export market, or the food safety and suitability risks associated with certain foods.

85. This option noted that other classes of foods might be granted a general exemption from composition and/or labelling requirements (with minimal or no conditions) if they are low-risk or non-contentious in terms of safety and suitability. It also proposed to encompass a general exemption from New Zealand labelling requirements.

What is the level of stakeholder support for this option? Has this option been affected by consultation?

86. While there was some support from submitters for this option, overall a majority opposed it on the basis that it would be complex/costly to administer, decrease exports, not be equitable, and would require adjustment of conditions over time.

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MPI comment

87. Based on feedback from submitters, we do not recommend progressing this option as proposed. We agree that this option is likely to be complex to administer and maintain, and therefore costly to implement and may not be perceived as an equitable approach.

Industry-Proposed Option Five

Key features of this option

88. Two dairy industry representative bodies and one food wholesaling and retailing industry representative body proposed an alternative option they referred to as “Option Five”. The key features of proposed Option Five were:

    a) continuing the existing general exemption without conditions or exclusions for labelling (in some cases, extended to all foods and not just the dairy industry);

    b) establishing a new general exemption under section 345, without conditions or exclusions contained within primary or secondary legislation, for compositional requirements;

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c) utilising the regulatory framework for operators of RMPs/Food Control Plans/National Programmes to self-assess product compliance with the relevant importing country requirements (including OMARs) where they exist.

89. Two of these industry bodies also proposed a single additional condition be required on a self assessment of importing country requirements:

- A condition that verification must occur within a certain time period of first use, or with a set frequency, to manage risks where food businesses currently have low frequency of verification (since any issue may not be identified until the next scheduled verification, which could be an 18+ month frequency).

90. Half of those supporting 'Option Five' also suggested that the current section 347 exemption application process be retained as a "backstop" for exceptional circumstances and future unknowns where required.

What is the level of stakeholder support for this option? Has this option been affected by consultation?

91. 45 percent of submitters supported this proposed alternative option or described a similar option.

92. The submitters who supported Option Five felt it:

- provides greater recognition that the responsibility for meeting importing country regulatory requirements sits with RMP operators (or operators of other risk-based measures);
- provides greater recognition of third countries' jurisdiction for regulating products for sale within their domestic markets;
- recognises the effectiveness of the APA risk management framework in managing dairy export product safety and suitability;
- ensures RMP holders export safe and suitable food and MPI would retain oversight through verifier reports and system monitoring;
- enables innovation and maximises dairy processors' access to export markets, allowing dairy manufacturers to operate on a level playing field with competitors in export markets.

93. Several of these submitters commented that having conditions in guidance rather than regulations would ensure New Zealand retains a more agile regulatory system better able to respond to new emerging market situations.

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MPI comment

94. The below table summarises our response to the key areas of feedback from submitters, that informed the proposed Option Five.

Key submitter feedback	MPI response
Existing labelling exemptions for dairy should be maintained, and extended	We agree. This existing exemption could be incorporated into the new export exemption

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The existing general labelling exemption for dairy[22] (that in effect includes an exemption from health claim requirements under the Food Standards Code) should be continued, without conditions or exclusions. Some submitters thought this should be extended to other foods.	regulations (rather than retaining the current notice), without conditions or exclusions. This existing labelling exemption could also be extended beyond dairy alone, to include all foods for export.[23]
Existing risk management programmes provide the regulatory framework for export exemptions The existing regulatory framework for Risk Management Programme (RMP) operators (in particular) should provide the primary basis for operators to self-assess and manage product compliance with the relevant importing country requirements, where they exist. This includes compliance with the relevant Overseas Market Access Requirements (OMARs).	We agree. Operators manufacturing s 345 exemptions should have an existing Risk-Based Measure. Businesses could manage their compliance with any conditions in regulations under section 345 as part of their risk-based measure.
There should be no conditions or exclusions within the proposed regulations	We do not agree that there should be no conditions within the proposed regulations relating to product composition. The proposed conditions (**Appendix One** refers) seek to mitigate food safety and suitability risks, and potential flow-on reputational and trade impacts. Section 345 provides that an exemption may be subject to any conditions specified in the regulations. Before regulations are made, the Minister must be satisfied of considerations set out in section 346. These include that the Minister has considered overseas market requirements. It is likely that many operators will already be meeting many of the proposed conditions under their RMP. The intention is to make these requirements explicit in the regulations.

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[22] https://www.mpi.govt.nz/dmsdocument/1000-Animal-Products-Exemption-from-Labelling-Standards-for-Dairy-Product-and-Dairy-Material-Intended-for-Export-Notice-2006

[23] It is intended that the current *Animal Products Notice: Labelling Requirements for Exports of Dairy Based Infant Formula Products and Formulated Supplementary Food for Young Children* will remain in place: https://www.mpi.govt.nz/dmsdocument/1000-Animal-Products-Exemption-from-Labelling-Standards-for-Dairy-Product-and-Dairy-Material-Intended-for-Export-Notice-2006 and the *Animal Products Notice: Honey and Honey Based Products – Food Standards Exemption* https://www.mpi.govt.nz/dmsdocument/10817-Animal-Products-Notice-Honey-and-Honey-Based-Products-Food-Standards-Exemption

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Any conditions should be in guidance not regulations, to ensure New Zealand retains a more agile regulatory system	It is not possible to include conditions in guidance because section 345 requires conditions to be set in regulations. Having guidance only 'conditions' would make them unenforceable
Importing country regulatory silence Where the importing country requirements are unclear or silent, operators should not be required to revert to New Zealand law. Regulatory silence does not amount to an in-market prohibition and silence by the competent authority may sometimes be intentional. MPI should not be a proxy standard setter for export markets, and requiring companies to revert to New Zealand law when the importing country is silent on a requirement is regulatory overreach. Evidence of like products for sale or claims being made in-market demonstrates 'tacit approval' or acceptance by the competent authority.	Partially agree. We have adjusted our view and consider that, in this situation, the default should not be New Zealand law. Instead (as one large dairy processing business suggested) operators could self-assess the safety of their product(s) for export under exemption and document some supporting evidence as part of their risk-based measure to demonstrate: a) how they meet relevant international Codex standards for composition or another country's standards that are accepted by the destination market; or b) safety assessments[24] for each compositional change considering the intended consumer. We consider the presence of a product in-market does not necessarily mean that the product complies with the country's regulatory requirements, or that the competent authority accepts it. s9(2)(b)(ii) s9(2)(d)
Retaining section 347 Section 347 should be retained as a 'backstop' so exemptions can still be obtained for circumstances that fall outside the scope of the proposed section 345 regulations.	The section 347 pathway will be retained for any exemptions that fall outside the scope of the proposed section 345 regulations.

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[24] Further work will be undertaken to determine what would be accepted with respect to safety assessments.

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What option is likely to best address the problem, meet the policy objectives, and deliver the highest net benefits?

Recommended approach

95. The recommended approach is a hybrid of the options proposed in the discussion document, including aspects of "Option Five". The recommended policy approach better aligns with the objective of facilitating trade and enabling product innovation to the extent possible, while ensuring food exports are safe and suitable for intended use. This aims to better support the Government's objectives to double the value of New Zealand exports in 10 years and reduce regulatory burden for businesses.

96. Based on submitter support for an alternative food export exemptions pathway, we recommend introducing new regulations under section 345 of the Food Act for export exemptions from composition and labelling requirements. This would provide the ability for certain food and beverage exporters to utilise a new streamlined exemption pathway and reduce the need to apply for individual exemptions under section 347.

97. We recommend adopting a staged approach to introducing exemptions in regulations. Under Stage One, we propose that new exemptions in regulations would be limited, initially, to:

a) an exemption from the composition requirements of any adopted joint food standards and domestic food standards[25] for all animal products for export produced in accordance with a Risk Management Programme (RMP), subject to conditions;

b) an exemption from the labelling requirements of any adopted joint food standards or domestic food standards for infant formula for export, with conditions or exceptions reflecting those currently applied to infant formula under the *Animal Products Notice: Labelling Requirements for Exports of Dairy Based Infant Formula Products and Formulated Supplementary Food for Young Children*.[26] This includes particular labelling requirements relating to nutrition and health claims;

c) subject to Dietary Supplements Regulations (DSR) being made under section 383 of the Food Act[27], an exemption from the labelling requirements of the DSR, except therapeutic claims, for all dietary supplements (with no conditions) and from the composition requirements of DSR for all dietary supplements regulated as animal products produced with an RMP and subject to the conditions proposed for exempted animal products; and

d) an exemption from the labelling requirements (including health claims) of any adopted joint food standards or domestic food standards for all other foods for export (not including wine), with no conditions.

98. For the proposed composition exemption, businesses would need to manage their compliance with any conditions in regulations under section 345 and this would be verified. As is currently the case for dairy products (excluding infant formula, unless permitted by the importing country), the proposed general labelling exemption would

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[25] These exemptions apply to food intended for export to a destination other than Australia.

[26] Animal Products Notice: Labelling Requirements for Exports of Dairy Based Infant Formula Products and Formulated Supplementary Food for Young Children: https://www.mpi.govt.nz/dmsdocument/43741-Animal-Products-Notice-Labelling-Requirements-for-Exports-of-Dairy-Based-Infant-Formula-Products-and-Formulated-Supplementary-Food-for-Young-Children

[27] This would occur following the proposed lift and shift of the Dietary Supplements Regulations 1985 to the Food Act under the Therapeutic Products Act Repeal Bill.

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include an exemption from domestic health claim requirements. Where there are no conditions or exclusions, labelling would not be required to be checked by verifiers.

99. Under Stage Two, the proposed composition exemption under section 345 could be extended to include other, non-animal product foods. This is expected to require changes to the Food Act and its regulations, to introduce export controls, provide for official certification, and support exemptions for food exports under the Food Act. Some submitters supported a staged approach. We will prepare subsequent Regulatory Impact Statements for these future decisions.

Table One: Proposed staged approach

Phasing	Labelling	Composition
Stage One – by June 2025	An exemption for infant formula for export - with conditions that reflect those that are currently applied to infant formula under the current labelling export requirements notice for infant formula. An exemption for all other food for export, including dietary supplements except for therapeutic claims (and not including wine) – without conditions.	An exemption for animal products for export produced in accordance with an RMP, including dietary supplements regulated as animal products – with conditions.
Stage Two – timeframe to be developed	Labelling exemption continues.	Apply new regulations under section 345 to other food products in addition to animal products – with conditions.

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Proposed conditions

100. An exemption may be subject to any conditions specified in the regulations. In summary, the main proposed conditions for the **composition** exemption would require operators to document:

- relevant New Zealand composition standards (adopted joint food standards or domestic standards) not being complied with;
- importing country requirements, or express written approval from the importing country, for the product's composition that are to be complied with,
- the systems and procedures operators have in place to meet these requirements; and
- where the importing country is silent/unclear on composition requirements, records of:
  a) how the operator meets relevant Codex standards or another country's standards accepted by the importing country; OR
  b) safety assessments for compositional changes considering the intended consumer and directions for use of the product.

101. Additionally, the **labelling exemption for infant formula** products would have conditions that reflect those that are currently applied to infant formula products under

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the current labelling export requirements notice for infant formula products.[28]

102. The proposed conditions seek to mitigate food safety and suitability risks, and potential flow-on reputational and trade impacts. These have been adjusted in response to submitter feedback and to better align the policy approach with the objectives. Some operators exporting under section 347 exemptions are likely to be meeting many of the proposed conditions under their Risk-Based Measure. The intention is to make these conditions explicit in the regulations, and for these to be verified (refer to section three on implementation of verification).

Rationale for proposed approach

103. The animal products industry is already well regulated for exports and is the primary user of the existing export exemption system. This industry has a long history of engaging with the current exemption process and with overseas markets.

104. A specific objective of the APA is to facilitate the entry of animal material and products into overseas markets by providing the controls and mechanisms needed to give and safeguard official assurances for entry into those markets. This is not the case for the Food Act. The primary objectives of the Food Act do not focus on the facilitation of exports and the Food Act does not make special provision for export controls and mechanisms to give and safeguard official assurances.

105. A staged approach enables regulations to be put in place relatively quickly for animal product operators, noting the dairy industry is our largest export earner with revenue currently sitting at around $24 billion. It also addresses concerns raised by the dairy industry about the current exemption process and their desire for a more streamlined and trade-facilitating approach. This approach utilises existing export protections provided in the APA, including the ability to issue official assurances. It also enables the pathway to be tested before expanding the composition exemption to other foods.

Trade-off of a staged approach

106. The key trade off of a staged approach is that initially, the section 345 compositional exemption would only apply to animal products and not other foods. Exporters of other foods may see this as inequitable. s9(2)(g)(i) [redacted]. A staged approach allows this issue to be addressed without delaying implementation of an improved pathway for animal products. The key changes to the Food Act that would be required before an exemption in regulations for composition could be extended to include the wider food and beverage sector are explained further in the implementation section.

Dietary supplements

107. Exporters of dietary supplements products will have access to case-by-case exemptions under section 347, as well as the proposed section 345 exemptions. This is subject to a proposed 'lift and shift' of the Dietary Supplements Regulations 1985

[28] Animal Products Notice: Labelling Requirements for Exports of Dairy Based Infant Formula Products and Formulated Supplementary Food for Young Children: https://www.mpi.govt.nz/dmsdocument/43741-Animal-Products-Notice-Labelling-Requirements-for-Exports-of-Dairy-Based-Infant-Formula-Products-and-Formulated-Supplementary-Food-for-Young-Children

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(DSR) to the Food Act (anticipated to be completed in December 2024) as part of the Therapeutic Products Act Repeal Bill. If the DSR are made under section 383 of the Food Act, it is proposed that the export exemptions available to dietary supplements under section 345 would be:

- an exemption from the labelling requirements of the DSR, except for therapeutic claims, for all dietary supplements (with no conditions); and
- and exemption from the compositional requirements for the DSR (with conditions) for dietary supplements regulated as animal products produced with an RMP.

108. Dietary supplements may still be subject to controls under the Medicines Act 1981 and amendments to that Act are outside the scope of proposals being considered in the RIS.

109. Further work is underway to determine the regulatory approach for targeted improvements to the DSR. This includes developing exemptions from composition requirements for export-only dietary supplements that are not regulated as animal products.

Future use of section 347

110. The current section 347 application-based exemption pathway would be retained for those exemptions that fall outside the scope of section 345 regulations. For example, non-animal products seeking an exemption from the compositional requirements of adopted joint food standards or domestic standards. There may be opportunities to improve the current operational process so that exemption requests can be processed more efficiently. For example, through the investment of additional staff resource or the use of process mapping software to better understand parts of the current system and any process constraints affecting each step.

111. MPI does not anticipate accepting section 347 application requests for exemptions that are within scope of the proposed section 345 exemptions. Operators would be expected to utilise the new pathway and meet any conditions set in regulations in order to do so.

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Risks, dependencies and mitigations

112. The removal of MPI's current export exemption assessment and approval role from this streamlined exemption pathway does carry some risk. s9(2)(d) [redacted] To help manage this risk, conditions are proposed as outlined above. These conditions will reduce risk while delivering the flexibility and efficiency that a streamlined process provides.

113. The proposals recognise the right of importing countries to set requirements that are suitable for their citizens. Importing country requirements may be more permissive than New Zealand's requirements. Some countries also have limited resources to enforce compliance and have no capacity to put in place regulations. Therefore, 'silence' in regulations does not necessarily mean the country accepts a more permissive approach, s9(2)(g)(i) [redacted]. Any issues arising with New Zealand exported food in overseas markets could be a commercial risk for food businesses and a reputational risk for New Zealand and MPI as the competent authority.

114. In the intervening period between stage one and two, other food and beverage product manufacturers can continue to apply for composition exemptions under section 347. Requests for section 347 exemptions have historically been less common from the

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non-dairy sector. However MPI has seen a recent increase in these which could be due to multiple factors including an increase in innovative products from the 'other processed foods' sector as well as increased awareness of the exemption pathway possibly due to public consultation on this proposal. Section 347 exemption applications would continue to have cost and resource impacts for MPI teams (and/or MedSafe) involved in assessing these. The current process is provided and paid for through Crown funding, at no cost to food exporters. MPI's ability to continue to provide this service and manage any increase in demand and cost would depend on implementation of some operational process improvements and approval of a cost recovery mechanism.

115. Many submitters supported some form of export statement system needing to be developed where countries require this for market access. MPI does not issue official assurances that are incorrect, misleading, relate to products or operations that are non-compliant with New Zealand law, or that have not been supported by appropriate levels of records and verification.[29] Free sale certificates are a form of assurance – and similarly must be truthful, cannot be false or misleading and should not be issued for product materially different to what the other party understands it to be. s9(2)(d) [redacted] .

116. One of the proposed conditions ((7)(b) of Appendix One) would allow operators who utilise the compositional exemption under section 345 to provide a safety assessment where the importing country is silent or unclear. This condition was amended following consultation because submitters strongly opposed the requirement that, where the importing country requirements for composition or labelling are unclear or silent, operators/exporters would need to meet New Zealand law. s9(2)(d) [redacted] Limiting the compositional exemption to RMP operators does mitigate some of this risk however MPI has not had sufficient time to determine what would constitute a 'safety assessment' and the potential impacts this could have on verification. s9(2)(g)(i) [redacted]

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Assessment of the preferred option against the status quo

117. The table below provides an assessment of the preferred option described above against maintaining the status quo.

Key:	
++	much better than doing nothing/the status quo/counterfactual
+	better than doing nothing/the status quo/counterfactual
0	about the same as doing nothing/the status quo/counterfactual
-	worse than doing nothing/the status quo/counterfactual
- -	much worse than doing nothing/the status quo/counterfactual

[29] MPI Official Assurance Principles: https://www.mpi.govt.nz/dmsdocument/53412/direct

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	Option One – [*Status Quo*]	Preferred Option
Criterion 1: Facilitates food export trade and product innovation	0	**++** Removes the requirement to apply for case-by-case exemptions for all animal products (composition) and other food products (labelling only) Dietary supplements will have access to exemptions for labelling and composition (with conditions for the latter). Conditions applied to the labelling exemption for infant formula align with those already applied in the current export requirements notice (no change). Conditions applied to the composition exemption are likely to already be met by most operators who are already exporting under section 347 exemption.
Criterion 2: Manages risks to food safety and suitability	0	**0** If adequately managed by the exporter, this is an improvement of the status quo as risk management is appropriately assigned to the operator (rather than MPI). s9(2)(d) [redacted] .
Criterion 3: Manages risks to NZ trade and reputation	0	**-** The proposed conditions for the compositional exemption seek to align management of these risks with the current approach for section 347 exemptions. s9(2)(d) [redacted]
Criterion 4: Cost effectiveness	0	**+** Costs to verifiers will increase to incorporate any new verification requirements (checking operators meet the conditions) Costs will be reduced for MPI as food exporters utilise the new pathway (reduced s 347 applications) Opportunity costs should increase for industry due to the more permissive approach.
Criterion 5: Equality considerations	0	**0** Non-animal product operators will not initially have access to compositional exemptions under s 345, which they may see as unfair, but they will still have access to the current pathway which is in line with the status quo for them. Animal product operators will not need to apply to MPI for exemptions under s 347 (can self-assess eligibility to export under s 345 exemption instead) which aligns with international approaches.
Overall assessment	0	**+2**

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What are the marginal costs and benefits of the option?

Affected groups *(identify)*	**Comment** *nature of cost or benefit (eg, ongoing, one-off), evidence and assumption (eg, compliance rates), risks.*	**Impact** *$m present value where appropriate, for monetised impacts; high, medium or low for non-monetised impacts.*	**Evidence Certainty** *High, medium, or low, and explain reasoning in comment column.*
Additional costs of the preferred option compared to taking no action			
Regulated groups	Businesses currently utilising exemptions will likely already be meeting some or all of the proposed conditions. Those not currently utilising exemptions will likely have some initial system and procedure set-up costs to meet the section 345 conditions.	Low	Low/Medium
Regulators	Costs associated with developing guidance for operators and verifiers, and amending notices. Costs for verifiers to incorporate any new requirements into the verification process – and to understand these/ upskill/train staff.	Initially medium impact for both MPI and verifiers associated with implementation but low once implemented.	Low
Others (eg, wider govt, consumers, etc.)	No	No	Low
Total monetised costs		$N/A	Low
Non-monetised costs		Low/Medium	Low
Additional benefits of the preferred option compared to taking no action			
Regulated groups	Time/cost for businesses to prepare current exemption application if the country/product exemption hasn't already been gazetted. Evidence certainty is low to medium as anecdotal/self-reported and mostly qualitative data has been provided to MPI through the consultation process.	Medium-High	Medium
Regulators	Time/resources currently to assess 347 applications,	Medium	Medium

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	particularly from AP businesses.		
Others (eg, wider govt, consumers, etc.)	No	No	Low
Total monetised benefits		$N/A	Low
Non-monetised benefits		Low/Medium	Low

Time and resource savings

118. The key benefit of the preferred approach for both operators and the regulator (MPI and verifiers) is the time-cost saving associated with the current section 347 application process. The introduction of the proposed section 345 regulations should result in a reduction of operators needing to use the section 347 exemption pathway – reducing the number of case-by-case applications that MPI assesses under section 347. Feedback from submissions on the impacts of the current section 347 application process included that it is resource intensive, time consuming and therefore costly for food exporters. Submitters said this creates a competitive disadvantage and can delay product launch/registration and hinder speed to market. The proposed section 345 regulations will allow operators to self-assess their eligibility to export under the exemption – reducing the need for (and associated time & cost of) applying to MPI. Cost savings may initially be greater for the animal products sector than the wider food & beverage sector until stage two can be implemented.

119. There should be a net reduction in time/resource costs to MPI as operators begin to utilise the preferred section 345 pathway instead of the status quo. Additionally, if that pathway can be cost-recovered in future, this will improve costs to the regulator (noting cost recovery is not part of this proposal – but may be implemented in the future).

Time and resource costs

120. Although the preferred pathway will remove the need to apply to MPI for an exemption, there will still be some time/resource costs to operators associated with self-assessing their eligibility for exemption and meeting any of the proposed conditions (**Appendix One**) associated with the exemption. This time/resource cost will differ depending on the type of exemption (labelling or compositional) and the type of operator. For example, animal products operators utilising a proposed section 345 exemption for a compositional requirement will have more conditions to meet (therefore more time and resource requirements) than an animal products operator wishing to utilise a section 345 labelling exemption. MPI understand most RMP operators who have previously applied for section 347 exemptions are likely to already have the systems and processes in place to be able to meet most of the proposed section 345 conditions. Regardless of the operator or exemption type, there should be a net decreased resource/time cost for all these operators because they no longer have to undertake the section 347 application process – and in some cases (such as labelling exemptions for non-infant formula products) do not need to meet any conditions.

Implementation costs

121. The main cost of the preferred pathway to MPI will be the costs associated with implementing the new regulations. Namely, the time and resource required to:

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- amend or revoke notices, guidance and possibly regulations (to align these / remove any repetition with the proposed section 345 regulations); and
- develop new guidance for operators and verifiers on the new section 345 regulations.

Verification costs

122. The preferred option will add to the verification requirements of RMP operators seeking a compositional exemption for an animal products – to ensure the proposed conditions associated with the section 345 exemption are being met. However as above, it is anticipated that operators currently utilising exemptions are likely to already have the systems and processes in place to meet most of these conditions. Therefore, any added costs related to verification requirements on the operator are expected to be low. Those not currently utilising exemptions, particularly, those who have not applied for a section 347 exemption before, will likely have some initial system and procedure set-up costs.

123. Verifiers themselves will be the only stakeholder with a cost and no benefit related to this proposal. This cost will largely be time and resource based – to understand and implement any new verification requirements associated with the preferred pathway (namely – verifying that operators are meeting the proposed conditions if operating under a section 347 exemption).

124. MPI will have initial resource costs associated with setting up guidance and training for verifiers.

Minor and significant amendments to RMPs

125. Operators utilising the section 345 exemption pathway will not be *required* to amend their RMP in order to meet the proposed conditions, but could choose to do so. If operators choose to amend their RMP to meet the conditions, MPI anticipate that, in most cases, this will be a minor amendment and therefore not require evaluation. This is explained in more detail in Section Three below.

126. Notifiable minor amendments need to be registered with MPI. Currently, the MPI service fee to process these costs business between $77.63 and $155.25. The actual cost depends on the type of amendment being made. MPI's standard processing time of completed application forms is 20 working days.

127. Because many RMP operators (from the dairy sector in particular) have already utilised the current exemption framework, MPI anticipate that these operators are likely to already have the systems and processes in place within their current RMP to meet most of the proposed conditions associated with a section 345 compositional exemption. Therefore, MPI do not anticipate that most operators will require significant amendment to their RMP. The MPI service fee to process a significant amendment application costs business between $232.88 and $388.13. Significant amendments to RMPs also require evaluation by a recognised evaluator which will also incur a fee for the operator.

Costs and benefits to the dietary supplements industry

128. A key benefit of the preferred approach would be access to export exemptions for the dietary supplements industry, who currently do not have an export exemption

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pathway.[30] Submitters from the natural health products industry, including dietary supplements, provided feedback that export exemptions should be applied to dietary supplements. For this industry, maintaining the status quo would mean they do not have access to export exemptions. One submission indicated the industry was losing out on an estimated NZD $500 million in export trade per annum by not having access to exemptions.

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[30] Subject to the proposed 'lift and shift' of the Dietary Supplements Regulations 1985 to the Food Act under the Therapeutic Products Act Repeal Bill.

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Section 3: Delivering an option

How will the new arrangements be implemented?

Implementation timeframes

129. We anticipate that the new regulations for 'stage one' would come into force in June 2025.

130. A transition period of 12-months from when the section 345 regulations come into effect is anticipated to enable operators to put in place the systems and procedures required to meet proposed conditions for a compositional exemption. This would also allow time for verifiers to update their procedures in line with MPI guidance.

131. For a period of 12-months, operators would be able to use either existing exemptions in notices (for example compositional exemptions listed under the *Food Notice: Exemptions from Domestic Compositional Requirements No.20 2024)* or the new section 345 regulations.[31] However, it is not anticipated that new applications under section 347, which are in scope of a section 345 exemption, will be assessed during the transition period. This is because operators should only use the existing section 347 exemption pathway if their exemption does not fall within scope of a section 345 exemption.

132. Eventually, the compositional exemption under section 345 could be extended to include other foods and beverages. This second stage requires additional scoping to determine the extent of changes required under the Food Act to provide the necessary export protections to enable these exemptions. A timeframe and analysis will be specified in a subsequent regulatory impact statement for these decisions.

Regulator

133. As the competent authority, MPI will be responsible for implementing the proposed new regulations and for supporting verifiers to make sure the relevant verification requirements (proposed conditions) are being met.

134. To support the new regulations MPI will need to:

- develop guidance to support operator understanding of the conditions to be met when utilising a section 345 compositional exemption;
- develop guidance and training material for verifiers – who will need to verify operator compliance with the proposed conditions;
- review existing notices and make changes necessary to incorporate content into proposed section 345 regulations. This may include revoking or amending some notices; and
- review the ability to provide certificates and official assurances for market access where required, for products exported under exemption.

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[31] Notices impacted by the proposed regulations will need to be amended or revoked on the date at which the proposed section 345 regulations come into effect. For the proposed transition period, operators will be able to meet the requirements of those notices as at one day prior to this.

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Guidance and training

135. Guidance will be developed for operators on meeting the section 345 conditions, and ensuring these are verifiable. This will include the factors to be considered in businesses' safety and suitability assessment when importing country requirements are unclear or silent (e.g. market regulations, product registration, Codex standards, science-based risk assessments). Some submitters who supported Option Five indicated they would like to jointly develop guidance for operators with MPI. We consider this would assist in facilitating transition to the new arrangements.

136. An awareness-raising campaign will be needed to ensure awareness of the new exemption requirements for food operators/exporters.

137. Verifiers will require training and support to develop technical capability to interpret the guidance and verify that the conditions are being met. The intention is to align any new verification of conditions being met with existing verification requirements wherever possible, to limit the impact(s) on industry and verifiers.

Verification

138. MPI recognised verifiers will be required to verify operators' compliance with the proposed conditions in section 345 regulations (see **Appendix One**). Verifiers will need time to get up to speed with any new verification requirements – including training and guidance developed by MPI. The proposed transition period allows for this.

Approvals

139. MPI would need to approve any RMP changes by operators who choose to amend their RMP in order to meet the proposed conditions in section 345 regulations.

Official assurances and other export certification

140. Half of the submitters supported some form of export statement system needing to be developed where countries require this for market access and sought a commitment from MPI to work with industry on this. A workstream will be required to look at impacts for export certification in parallel to developing section 345 regulations.

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Regulated parties

141. Businesses wanting to use the exemption under section 345 would be responsible for managing their compliance with any conditions in regulations, and this would need to be verified. These verification requirements are expected to involve some changes to current requirements in guidance, notice and/or possibly in regulation.

142. Some businesses who are operating under a section 347 exemption will already have many of the systems and procedures in place to support their compliance with the regulations. For other businesses not currently operating under exemption, this may require new systems and procedures to be established, which the proposed transition period allows for.

Verification and potential amendments to RMPs

143. Operators would be required to keep records showing the proposed conditions are being met and make these available for verification, which could be through their RMP. If an operator chooses to meet the conditions through their existing risk-based

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measure, this could result in some operators needing to amend their RMP.[32] Guidance will likely need to be developed to assist operators in understanding this.

Implications for existing Notices

Existing Notice description	Action	Comment
Animal Products (Exemption from Labelling Standards for Dairy Product and Dairy material Intended for Export) Notice[33] Issued originally in 2006, this Notice provides that all dairy product and dairy material intended for export is exempt from the requirements of any food standards issued under Part 2A of the Food Act 1981 concerning food labelling. This includes health claims.	This existing section 60B APA notice will be revoked.	There is no need to keep it because the proposed section 345 regulations will exempt from labelling requirements.
Animal Products Notice: Labelling Requirements for Exports of Dairy Based Infant Formula Products and Formulated Supplementary Food for Young Children[34] This Notice was first issued in 2014. It sets specific minimum labelling requirements for all infant formula and follow-on formula and: • **prohibits health claims** on infant formula intended for infants aged 0 to 6 months, **unless a claim is expressly permitted by the importing country** or market in its laws or executive directives; and • permits nutrition claims on infant formula and nutrition and health claims on follow-on formula (for older infants aged 6 to 12 months) and formulated supplementary foods for young children products where such claims are accepted by the importing country or market, are not misleading and do not	This existing section 60 APA notice will be incorporated into the proposed exemptions regulations under section 345.	The exemption will continue to apply and can be amended if deemed necessary.

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[32] Amendments to RMPs can be either minor or significant. Significant amendment to RMPs are required to be registered with MPI under section 25 of the APA. Minor amendments to RMPs do not require registration but most are required to be notified to MPI under section 26 of the APA. RMP changes that constitute a significant amendment are outlined in section 30 of Animal Products Regulations 2021. Both minor (notifiable) and significant amendments require submitting an application for MPI to approve. MPI do not anticipate that most operators who have already used a section 347 exemption will need to make significant amendments to their RMPs in order to meet the proposed conditions.

[33] https://www.mpi.govt.nz/dmsdocument/1000-Animal-Products-Exemption-from-Labelling-Standards-for-Dairy-Product-and-Dairy-Material-Intended-for-Export-Notice-2006

[34] https://www.mpi.govt.nz/dmsdocument/43741-Animal-Products-Notice-Labelling-Requirements-for-Exports-of-Dairy-Based-Infant-Formula-Products-and-Formulated-Supplementary-Food-for-Young-Children

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imply that the product is nutritionally equivalent or superior to breastmilk.		
Food Act Notice: Food for Export – Exemptions from Domestic Compositional Requirements[35] This Notice exempts food for export from certain requirements of New Zealand adopted joint food standards or domestic food standards where the importing country requirements differ. It gazettes individual exemptions granted under section 347.	This Food Act Notice will need to be amended to delete the information that is covered by the section 345 exemption in regulations.	Some content will need to be retained if it is not captured by the section 345 regulations (for example, any non-animal product compositional exemptions).
Animal Products Notice: Honey and Honey Based Products – Food Standards Exemption[36] This Notice exempts these products from requirements in the Food Standards Code where importing country requirements differ.	The labelling exemptions provided in this APA notice will be removed as these exemptions will be covered by the general labelling exemption provided under section 345.	The exemptions provided in this Notice will be covered by the labelling exemption in section 345 regulations. However consideration is still required as to whether any of the record-keeping requirements listed in this Notice need to be kept.
General Export Requirements for Bee Products[37] Sets export requirements for honey bee products. In particular: a) requirements for ensuring that bee products meet market access requirements; and b) requirements for ensuring traceability through the export supply chain; and c) definition for monofloral and multifloral mānuka honey and associated requirements.	This APA notice will need to be kept to ensure current export requirements for mānuka honey are maintained.	If there are any aspects of this Notice that overlap with the proposed section 345 exemptions in regulations, then these sections will be revoked.
Animal Products Notice: Production, Supply and Processing[38] This Notice sets out requirements in relation to the production, supply and processing of	This APA notice will need to be kept but may require amendment to the requirements for verifiers, to include	

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[35] https://www.mpi.govt.nz/dmsdocument/34623-Food-Notice-Food-for-Export-Exemptions-from-Domestic-Compositional-Requirements

[36] https://www.mpi.govt.nz/dmsdocument/10817-Animal-Products-Notice-Honey-and-Honey-Based-Products-Food-Standards-Exemption

[37] https://www.mpi.govt.nz/dmsdocument/26500-Animal-Products-Notice-General-Export-Requirements-for-Bee-Products

[38] https://www.mpi.govt.nz/dmsdocument/50182-Animal-Products-Notice-Production-Supply-and-Processing

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animal material and animal products; and verification; and recognised agencies and persons.	exporters in the scope of verification.	

Regulatory changes required prior to 'stage two' implementation

144. The Food Act requires that all food for sale, including for export, must be safe and suitable and that manufacturers must operate under risk-based measures (Food Control Plans or National Programmes). It also provides for export exemptions under sections 345 and 347.

145. However, the Food Act does not make special provision for export controls and 'exporters' are not regulated under the scope of the Act. The primary objective of the APA is to facilitate food exports by providing controls and mechanisms to give and safeguard official assurances – which is not a primary objective of the Food Act. As such there are limitations to regulating businesses under the Food Act via the section 345 export exemptions regulations in the same way as businesses regulated under the APA. To include other, non-animal product foods in the exemption regulations, enable export controls and export certification would require substantive changes to the Food Act and regulations.

146. s9(2)(f)(iv)

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147. s9(2)(f)(iv)

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How will the new arrangements be monitored, evaluated, and reviewed?

148. Verifiers will be able to identify which businesses are exporting food under an exemption, and the products they are exporting, as they will now be required to identify this in the scope of their operations.

149. MPI, through its business unit New Zealand Food Safety (NZFS), has mechanisms to monitor and review new and existing requirements through monitoring and review of system data including registration, verification, certification and enforcement data.

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NZFS also commissions system audits. These mechanisms will be proactively used to monitor potential risks to food safety and New Zealand's international reputation.

150. NZFS also interview/survey participants from across the system and they have a number of channels for contacting MPI/New Zealand Food Safety through email, phone, web etc.

151. NZFS may look to establish a systems issues log to record and respond to any issues as they arise.

152. As above, the preferred staged approach will initially limit the compositional exemptions to animal products. However, the intention is to later expand this to include other foods. The effectiveness of the composition exemption, including the conditions set in regulation under section 345, can be reviewed for efficiencies before expanding to the wider sector.

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Appendix One – Proposed content for section 345 exemption in regulations

The following broad content is proposed for inclusion in an exemption in regulations under section 345 (noting this is not final drafting). The conditions associated with an exemption from compositional requirements are highlighted by the red box.

(1) A clear definition of animal products for export [trade samples may be out of scope].

(2) An exemption from the labelling requirements of adopted joint food standards or domestic standards for infant formula for export, with conditions or exceptions reflecting those currently applied to infant formula under the *Animal Products Notice: Labelling Requirements for Exports of Dairy Based Infant Formula Products and Formulated Supplementary Food for Young Children*.[39] [This includes particular labelling requirements, including relating to nutrition and health claims, to be included in the regulations].

(3) An exemption from the labelling requirements of any adopted joint food standards or domestic food standards for all other foods for export (not including wine), with no conditions.

(4) An exemption from the composition requirements of any adopted joint food standards or domestic food standards for all animal products for export produced in accordance with a Risk Management Programme (RMP), subject to conditions (6) through (10).

(5) An exemption from the labelling requirements of the Dietary Supplements Regulations (with no conditions) for all dietary supplements and from the composition requirements of the Dietary Supplements Regulations for all dietary supplements regulated as animal products produced with an RMP, subject to conditions (6) through (10).

(6) An operator exporting animal product in reliance on the exemption in (4) and (5) must keep the following records:

a) A list of relevant standards in the Food Standards Code or New Zealand only standards, or in the Dietary Supplements Regulations (once lifted and shifted) that are not being complied with.

b) A list of importing country requirements for the product's composition, or express written approval from the overseas competent authority for the product including its composition.

c) The documented systems and processes they have in place to meet the composition requirements of the importing country (or the requirements under (7)(a) or (7)(b)) and ensure consistency with Article 4 of the Codex Code of Ethics in International Trade.

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[39] Animal Products Notice: Labelling Requirements for Exports of Dairy Based Infant Formula Products and Formulated Supplementary Food for Young Children: https://www.mpi.govt.nz/dmsdocument/43741-Animal-Products-Notice-Labelling-Requirements-for-Exports-of-Dairy-Based-Infant-Formula-Products-and-Formulated-Supplementary-Food-for-Young-Children

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(7) Where the importing country requirements are silent or unclear, the operator must keep records of:

a) how they meet relevant international Codex standards for composition or another country's standards that are accepted by the destination market; or

b) safety assessments for each compositional change considering the intended consumer and directions for use of the product [examples of what this could comprise will need to be included in guidance].

(8) Records must be kept for 4 years or the shelf life of the product.

(9) Product subject to an exemption in (2), (3), (4) or (5) must not be sold on the New Zealand or Australian market, and should only be sold to the market(s) where they meet the importing country's labelling and composition requirements.

(10) Businesses manufacturing product under an exemption must operate under an independently verified Risk-Based Measure or Risk Management Programme.

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Appendix Two - How do the options compare to the status quo/counterfactual?

The assessment below takes into consideration feedback received during public consultation. As such, our assessment of options has been re-evaluated since the discussion document was released, and also includes the industry-proposed Option Five.

Key:

++	much better than doing nothing/the status quo/counterfactual
+	better than doing nothing/the status quo/counterfactual
0	about the same as doing nothing/the status quo/counterfactual
-	worse than doing nothing/the status quo/counterfactual
- -	much worse than doing nothing/the status quo/counterfactual

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	Option One – [*Status Quo / Counterfactual*]	Option Two – [*An exemption for all food exports, with conditions*]	Option Three - [*An exemption for all food exports, with a differentiated approach for composition (and other) requirements vs labelling*]	Option Four – [*An exemption for all food exports, with a differentiated approach for different classes of product or market*]	Proposed Option Five [*A labelling exemption and a composition exemption with no conditions included in legislation –for RMP operators, possibly extended to other operators*]
Criterion 1: Facilitates food export trade and product innovation	0	- Removes the requirement to apply for case-by-case exemptions but conditions applied to labelling exemption is a	0 Removes the requirement to apply for case-by-case exemptions and a general labelling exemption is maintained (in line with	0 Removes requirement to apply for exemption but some product types and markets will have more conditions than others –	++ Removes requirement to apply for exemptions and no conditions in regulation to be met

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		backwards step from the currently available export labelling exemption notices for dairy and honey*	current notices for export labelling exemptions for dairy and honey) but proposed labelling condition excludes health claims which are currently included in the general dairy labelling exemption notice*	and market-specific conditions could have trade impacts	
Criterion 2: Manages risks to food safety and suitability	0	+ If adequately managed by the exporter then this is an improvement of the status quo as risk management appropriately assigned to the operator (not MPI)	+ If adequately managed by the exporter then this is an improvement of the status quo as risk management appropriately assigned to the operator (not MPI)	+ If adequately managed by the exporter then this is an improvement of the status quo as risk management appropriately assigned to the operator (not MPI)	- - Although risk management is more appropriately assigned to the operator (not MPI), there is some food safety risk in having no conditions in regulations specifying the operator should adequately manage these risks.
Criterion 3: Manages risks to NZ trade and reputation	0	0 The proposed conditions seek to align management of these risks with the current approach for section 347 exemptions.	0 The proposed conditions seek to align management of these risks with the current approach for section 347 exemptions.	0 The proposed conditions seek to align management of these risks with the current approach for section 347 exemptions.	- - No conditions in regulations specifying the operator should have the systems in place to manage these
Criterion 4: Cost effectiveness	0	- Costs will be reduced for MPI and food exporters utilising the new pathway	- Costs will be reduced for MPI and food exporters utilising the new pathway But verification costs may increase for Food Act	- Costs will be reduced for MPI and food exporters utilising the new pathway, But verification costs may increase for Food Act	++ No cost to verification as no conditions attached that would require verification

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		But verification costs may increase for Food Act exporters, and there would be increased costs to dairy operators if the general labelling exemption notice is removed and replaced by conditions in regulation*	exporters, and there would be increased costs to dairy operators if health claims are carved out of the general labelling exemption*	exporters and there are likely to be up-keep costs related to maintaining these regulations to reflect market and product risk changes over time.	Costs will be reduced for MPI and food exporters utilising the new pathway Time-cost reduced to operator as no longer have to apply to MPI for an exemption and no conditions to comply with
Criterion 5: Equality considerations	0	0	0	- Some food products, and certain markets may have more conditions to meet than others, to reflect product or market sensitivities. This may be seen as unfair.	+ If the exemption is applied to all operators
Overall assessment	0	**-1**	0	**-1**	**1**

*The proposed conditions for a labelling exemption in regulations for Option Two, and the potential carve-out of health claims from the proposed general labelling exemption in Option Three were both unintended consquences of the options. Consultation brought to light that both of these proposals would be a backwards step for dairy operators who currently have available to them a general export labelling exemption notice, which in effect includes health claims. The honey sector also have a general export labelling exemption notice.

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