Ministry for Primary Industries
Manatū Ahu Matua

Guidance Document

Export Exemptions

Regulations made under section 345 of the Food Act 2014

2 September 2025

A guidance document issued by the Ministry for Primary Industries

Te Kāwanatanga o Aotearoa
New Zealand Government

Title

Guidance Document: Export Exemptions

About this document

This guidance document has been prepared to assist operators to meet the requirements for exempting food from compositional and labelling requirements that are covered in the Food (Exemption of Food for Export) Regulations 2025.

Related Requirements

(1) Food (Exemption of Food for Export) Regulations 2025

(2) Medicines (Related Products (Exempted Foods)) Amendment Regulations 2025

(3) Animal Products Notice: Labelling Requirements for Exports of Dairy Based Infant Formula Products and Formulated Supplementary Food for Young Children

Document history

Version Date	Section Changed	Change(s) Description
02 Sept 2025	n/a	New document

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Contents

Page

1 Purpose **3**

2 Background **3**
2.1 New Zealand requirements 3
2.2 Use of export exemptions 3
2.3 New export exemption process 3

3 Definitions used in this guidance **4**

4 Transition period **5**

5 Scope of the section 345 Regulations **6**
5.1 Exemption from specific food standards or regulations only 6
5.2 Human consumption only 7

6 General **8**
6.1 No application required 8
6.2 Free sale certificates and official assurances 8
6.3 Adding exempt food to a risk management programme 9
6.4 Verification 9
6.5 Offences 9

7 Meeting the conditions **10**
7.1 Conditions for all exemptions 10
7.2 Conditions for composition exemptions 11
7.3 Requirements for labelling exemptions 19

8 When things go wrong **23**
8.1 In-market issues 23
8.2 Traceability and recalls 23
8.3 Sending exempt food to a different market than intended 23
8.4 Selling exempt food in New Zealand and Australia 23

1 Purpose

This guidance document has been developed by New Zealand Food Safety (NZFS), a business unit of the Ministry for Primary Industries (MPI) to assist operators that process or package food for export to meet the requirements of the Food (Exemption of Food for Export) Regulations 2025.

2 Background

2.1 New Zealand requirements

All food produced for sale in NZ, including for export, must comply with the composition and labelling requirements of adopted joint food standards and domestic food standards, as well as relevant regulations and notices.

Food that is exported must meet New Zealand's requirements as our food safety systems are the basis on which many countries allow import of our products. However, exported foods may need to be produced to meet the specific compositional and labelling requirements of the importing country.

2.2 Use of export exemptions

MPI provides exemptions that allow food to be made in New Zealand and then exported to countries that have different composition and/or labelling requirements. Prior to September 2025, the exemptions available were composition exemptions issued under section 347 (s 347) of the Food Act, which require application to MPI, and labelling exemptions for dairy and honey exports provided in export labelling exemption Notices.

In June 2024, MPI consulted on options for facilitating export exemptions from New Zealand composition and/or labelling requirements under the Food Act. The purpose was to seek feedback on alternative approaches to better support exporters seeking to comply with different overseas requirements, while managing food safety risks and maintaining our export systems and market access.

2.3 New export exemption process

From 25 September 2025, there is a new pathway for export exemptions, in regulations made under section 345 (s 345) of the Food Act. These exemptions do not require application to MPI. However, the regulations set conditions on the use of these exemptions, and verifiers will be checking that the conditions are being met.

3 Definitions used in this guidance

Adopted joint food standard means the parts of the Australia New Zealand Food Standards Code (Food Standards Code) that have been adopted by New Zealand, as defined in Food Act 2014

Animal Products Act means Animal Products Act 1999

AP E-cert means Animal Products Electronic Certification, which is an electronic system that the Director-General requires operators and exporters to use to obtain an official assurance in the form of an export certificate

Exempt food means a food (including a dietary supplement) that has been produced for export under an s 345 exemption

Food Act means Food Act 2014

FCP means food control plan

Medicines Act means Medicines Act 1981

NP means national programme

Official Assurance means a statement from one competent authority (Government agency) to another, normally about a product, shipment, or process. It is a government to government guarantee that certain commitments have been met

OMAR means Overseas Market Access Requirements. OMARs outline the requirements that exporters need to meet to access markets in different countries. To request access to OMARs, go to this webpage.

Operator means the owner or other person in control of a food business that processes or packages food for export

RCS means regulated control scheme

RMP means risk management programme

Risk-based measure means a food control plan, national programme or monitoring programme created under the Food Act 2014

Section 345 (s 345) exemption means an exemption in the Food (Exemption of Food for Export) Regulations 2025. These are made under section 345 of the Food Act. These exemptions do not require approval or registration with MPI in order to use

Section 347 (s 347) exemption means an exemption in notices made under section 347 of the Food Act. These exemptions must be approved by MPI

Section 345 (s 345) Regulations means Food (Exemption of Food for Export) Regulations 2025

4 Transition period

After the s 345 Regulations take effect, there is a 12-month transition period. From **25 September 2025**, operators can:

- use the new s 345 Regulations to exempt their products; and/or
- continue to use any existing s 347 exemptions for a period of 12 months.

When the **transition period finishes,** from 25 September 2026, any s 347 exemptions that are within the scope of the s 345 Regulations will be revoked. Operators must instead use an exemption in the s 345 Regulations.

Section 347 will remain available to use for exemptions outside the scope of the s 345 Regulations. For example: operators that want a composition exemption for a food for export that is not an animal product produced under RMP.

For more information see Guidance Document: Exemptions from Domestic Food Standards under section 347 of the Food Act.

The following Notices will remain in place for the transition period, and will be revoked or amended on 25 September 2026:

- Animal Products (Export Requirements - Dairy Products) Notice 2005
- Animal Products Notice: Animal Products - Food Standards Code - Labelling Exemption 2017
- Animal Products Notice: Honey and Honey Based Products - Food Standards Exemption 2015
- Animal Products (Exemptions from Labelling Standards for Dairy Product and Dairy Material Intended for Export) Notice 2006
- Animal Products Notice: Contaminant Specifications 60b Exemption

Product that uses an existing exemption and has finished being processed or packaged before 25 September 2026, is not then required to comply with the requirements of the s 345 Regulations.

5 Scope of the section 345 Regulations

5.1 Exemption from specific food standards or regulations only

The Food (Exemption of Food for Export) Regulations 2025 exempt:

Composition Exemptions

- A food that is an animal product and has been processed or packaged for export under an RMP from:
  - the compositional requirements of the Food Standards Code excluding tutin limits in standard 1.4.1–3); and
  - the compositional requirements of the New Zealand Food (Supplemented Food) Standard; and
- A dietary supplement that is an animal product and has been processed or packaged for export under an RMP from:
  - Regulations 3, 12 to 17, and 20 of the Dietary Supplements Regulations 1985

(See 7.2.2 Scope of Composition Exemption for further details.)

Labelling Exemptions

- Any food (excluding dietary supplements, non-dairy-based infant formula products, non-dairy-based formulated supplementary foods for young children and wine) that has been processed or packaged for export under a risk-based measure, RMP or RCS from:
  - the labelling requirements of the Food Standards Code excluding
    standard 1.2.3–3 (Mandatory warning statement–royal jelly);
    standard 1.2.7–8 (Claims not to be therapeutic in nature);
    standard 2.9.5–4 (Claims must not be therapeutic in nature); and
  - the labelling requirements of the New Zealand Food (Supplemented Food) Standard.
- Any dietary supplement that has been processed or packaged for export under a risk-based measure, RMP or RCS from:
  - Regulations 4 to 9, and 18 and 19 of the Dietary Supplements Regulations 1985.

General

In order to be exempt from the above food standards, certain conditions must be met. See 7 Meeting the Conditions for more details.

If a food for export will not comply with New Zealand's composition food standards, but is not covered by the s 345 Regulations for example, a food that is not an animal product), then the operator must apply for an s 347 exemption or use an existing exemption in a notice (such as the Food Notice: Food for Export – Exemptions from Domestic Compositional Requirements).

An s 345 exemption does not exempt a food or dietary supplement from having to meet the importing country's requirements.

5.2 Human consumption only

An s 345 exemption can only be used for a food that will be eaten by humans. This includes trade samples that will be eaten.

An s 345 exemption does not apply to:

- products for animal consumption;
- products that are not eaten (such as topical application);
- hides, skins and wool; and
- samples for scientific or analytical purposes.

6 General

6.1 No application required

If the food that will be exported is within the scope of the Food (Exemption of Food for Export) Regulations 2025, the operator does not need to apply for an s 345 exemption. Instead, the operator must ensure they comply with the conditions in the regulations.

See 5 Scope of a Section 345 Exemption for more details.

6.2 Free sale certificates and official assurances

6.2.1 Free sale certificates and free sale statements

Free sale certificates and free sale statements can only be issued for foods produced under a risk-based measure, RMP or RCS that complies with domestic requirements.

A free sale certificate or free sale statement cannot be provided for foods that are manufactured under exemption, as these foods no longer comply with domestic requirements and are not able to be sold in New Zealand.

Free sale certificates are separate to the official assurances (for example, the NZ811 template for product registration) that can be issued under the Animal Products Act.

6.2.2 Official assurances

To support consignment exports and product registrations, operators can still receive official assurances for exempt food produced under an RMP.

Operators are required to keep verifiable product eligibility information that MPI can rely on to issue an official assurance.

Operators should check for any country specific requirements or restrictions in the OMAR for the destination market, as these apply regardless of an s 345 exemption. All attestations on the export certificate must be met for an official assurance to be issued.

Operators must indicate on the transfer document in AP E-cert that the product has been produced under an s 345 exemption by completing a Transfer Control Statement (TCS).

A TCS must clearly identify any exemption, that is, if the exemption relates to composition, labelling or both.

For composition exemptions:

- The country eligibility box can only include countries that the product is eligible for.
- The ZZ code must not be used.
- Where extended eligibility is possible (subject to further processing), the country eligibility box may include multiple countries as long as the TCS specifies the markets that the composition exemption applies to, as well as extended eligibility condition(s) beyond the exemption restriction.

For labelling exemptions:

- The country eligibility box can only include countries that the product is eligible for.
- Where extended eligibility is possible (subject to labelling), the country eligibility box may include multiple countries as long as the TCS specifies the markets that the labelling exemption applies to, as well as extended eligibility condition(s) beyond the exemption restriction.

6.3 Adding exempt food to a risk management programme

Adding production or packaging of an exempt food to an existing RMP will generally be a minor amendment.

An operator's RMP must contain procedures that demonstrate how they control risk factors (including risks to human health, wholesomeness and risks due to false or misleading labelling). The operator needs to have documented procedures that show how they control these risks for exempt foods.

Operators that have been manufacturing food for export under an s 347 exemption may already have appropriate documented procedures in place.

Including these procedures to an existing RMP is a minor amendment.

An operator will still need to consider if the changes they make to produce exempt food are a significant amendment, for example: installation of a new process with different critical control points (CCPs); use of a new ingredient that introduces different hazards into the process; addition of a new line etc.

See the Risk Management Programme Manual for more information on determination of minor and significant amendments.

Note: for new RMPs, the processes and procedures relating to an s 345 exemption will be included in the evaluation process.

6.4 Verification

Verifiers will check that operators have the procedures and records that show they are meeting the exemption conditions during routine scheduled verifications. There will be no change to verification frequencies.

6.5 Offences

Offences under both the Food Act and the Animal Products Act may still apply to exempt food.

7 Meeting the conditions

7.1 Conditions for all exemptions

7.1.1 Supply information to the exporter of exempt food

[Relates to s 345 Regulation 6)]

The operator who processes or packages an exempt food must have documented procedures to ensure that any exporter of the exempt food knows that the food is exempt and what exemptions under the s 345 Regulations apply to the exempt food.

Additionally, documentation must be provided with the exempt food that states that:

- It must not be sold for human consumption in Australia or New Zealand; and
- It must not be reprocessed as a product suitable for sale in any country other than the one intended for export unless it is reprocessed under an s 345 exemption in relation to the compositional requirements of the new market.

See also 8.3 Sending Exempt Food to a Different Market than Intended and 8.4 Selling Exempt Food in New Zealand and Australia.

7.1.2 Exempt food must be safe and suitable

[Relates to s 345 Regulation 7)]

Exempt food must be safe and suitable (see Section 12 and Section 14 of the Food Act).

Exempt food that is an animal product must be fit for its intended purpose (see Section 5 of the Animal Products Act).

Exempt food must be produced in accordance with the requirements of the approved risk-based measure, RMP or RCS.

For composition exemptions only, see also 7.2.4 Code of Ethics for International Trade in Food.

7.1.3 Medicines Act and Regulations apply to exempt food

[Relates to s 345 Regulations 8 and 11(3)]

Exempt food has not been exempted from the requirements of the Medicines Act or regulations made under that Act. However, the Medicines (Related Products (Exempted Foods)) Regulations 2003 means that a food exempt from labelling requirements under the s 345 Regulations is not considered a “related product” for the purposes of the Medicines Act.

An s 345 exemption can apply unless the food or dietary supplement meets the threshold of a medicine. For example: if an exempt food contains a vitamin or mineral at a level that is permitted by an importing country, but which exceeds the level specified in New Zealand food standards and which would make that food a medicine in New Zealand, the food or dietary supplement for export must meet the requirements of the Medicines Act.

Under the s 345 Regulations, an exempt food is not permitted to make a therapeutic claim and is not exempt from meeting:

- Standard 1.2.3–3 (Mandatory warning statement–royal jelly)
- Standard 1.2.7–8 (Claims not to be therapeutic in nature)

- Standard 2.9.5–4 (Claims must not be therapeutic in nature)

See also 7.3.4 Health Claims and 7.3.5 Therapeutic Claims.

7.2 Conditions for composition exemptions

7.2.1 Foods that may be exempted from composition requirements

Food and dietary supplements that are animal products and are processed or packaged under an RMP may be exempt.

This includes:

- multi-ingredient foods that contain animal products and are made under an RMP; and
- dairy-based infant formula, follow-on formula and formulated supplementary food for young children.

7.2.2 Scope of composition exemption

A compositional requirement is a requirement for the composition of a food or dietary supplement to include, exclude, or limit specified content or attributes. It may apply to anything contained in food, added to food, or intended to be contained in or added to food.

Only certain compositional content or attributes may be exempted under an s 345 exemption.

In Scope

An s 345 exemption for composition may cover any of the following:

- ingredients;
- food additives;
- processing aids;
- substances used for a nutritive purpose (e.g. vitamins, minerals and nutritive substances)
- chemical contaminants and natural toxicants;
- prohibited and restricted plants and fungi; and
- microbiological organisms.

An s 345 exemption for composition may also cover new foods, see Part 1.5 *Foods requiring pre-market clearance* of the Food Standards Code:

- Standard 1.5.1 Novel foods
- Standard 1.5.2 Food produced using gene technology
- Standard 1.5.3 Irradiation of food
- Standard 1.5.4 Cell-cultured foods

Out of scope

An s 345 exemption for composition does not apply to:

- residues of agricultural compounds in food (refer to Schedule 1 of the Food Act Notice: Maximum Levels for Agricultural Compounds); and
- tutin levels in honey (refer to Section 1.4.1–3 and Schedule 19–7 of the Food Standards Code).

See 7.2.3 Composition Requirements that still apply to Exempt Food for further information.

7.2.3 Composition requirements that still apply to exempt food

For all exempt foods, operators must meet Schedule 1 of the Food Act Notice: Maximum Levels for Agricultural Compounds.

Operators must meet the requirements of any other Notice that applies to the exempt food, including:

- APN: Production, Supply and Processing
- APN: Manufacture of Dairy Based Infant Formula Products and Formulated Supplementary Foods for Young Children

Honey must meet the Tutin requirements:

- Section 1.4.1–3 (see also Schedule 19–7) of the Food Standards Code in relation to tutin; and
- Food Standard: Tutin in Honey.

An s 345 exemption does not exempt a food or dietary supplement from having to meet the importing country's compositional requirements.

See also 7.2.2 Scope of Composition Exemption, 7.1.2 Exempt Food must be Safe and Suitable and 7.1.3 Medicines Act and Regulations apply to Exempt Food.

7.2.4 Code of ethics for international trade in food

[Relates to s 345 Regulations 9(4)(c) and 10(3)(c)]

Operators are required to have documented procedures to ensure consistency with Article 4 of the Codex Code of Ethics for International Trade in Food.

To meet this requirement, operators should:

(1) Have documented procedures describing the robust separation and control systems (and the records to support these) that are in place to ensure that exempt food is only exported to countries covered by the operator's exemption documentation; and

(2) Have documented procedures describing how the operator will ensure that unsafe or unsuitable food is not exported as exempt food. This includes food that is:

- hazardous, poisonous, harmful or otherwise injurious to health; or
- not wholesome or contains a filthy, putrid, rotten, decomposed or other substance or foreign matter which renders it unfit for human consumption; or
- is adulterated; or
- is labelled or presented in a manner that is false, misleading or deceptive; or
- is prepared, processed, packaged, stored, transported or marketed under unsanitary conditions; or
- has an expiration date, where applicable, which does not leave sufficient time for distribution in the importing country.

If operators use existing documentation that is part of their RMP to meet this requirement, they should clearly indicate this.

See also 7.1.2 Exempt Food must be Safe and Suitable.

7.2.5 Records the operator must hold for composition exemptions

[Relates to s 345 Regulations (9)(4)(a), (9)(9), 10(3)(a) and (10)(8)]

The operator must have a record of which standard or section in the Food Standards Code, clause in the New Zealand Food (Supplemented Food) Standard or regulation in the Dietary Supplement Regulations they are exempting the product from.

Correct identification of the type of food a product is, is necessary to determine what the product is being exempted from. The following links may help operators determine whether the product is:

- a supplemented food – Guidance: Supplemented Food Standard User Guide;
- a formulated supplemented food – FSC Standard 2.9.3 - Formulated meal replacements and formulated supplementary foods; or
- a dietary supplement – Guidance: Supplemented Food Standard User Guide and Categorisation of Products.

Records must be held for 4 years, or the shelf life of the exempt food, whichever is longer.

In addition to 7.2.4 and the above record keeping requirements, there is a hierarchy of options for specific records that operators must keep.

Depending on whether the product is a food or dietary supplement, and what aspect of New Zealand compositional requirements (e.g. additive, microbiological limit) the product does not meet, the options available, and the order they may be used in are:

- Option 1:
  - Option 1A – Corresponding requirement in importing country; or
  - Option 1B – Written approval from a competent authority in the importing country;
- if Option 1 is not available, then Option 2 – Applicable Codex standards;
- if Options 1 and 2 are not available, then Option 3:
  - Option 3A – Scientific evaluation from a national/international/supranational agency; or
  - Option 3B – Scientific evaluation by a suitably qualified person.

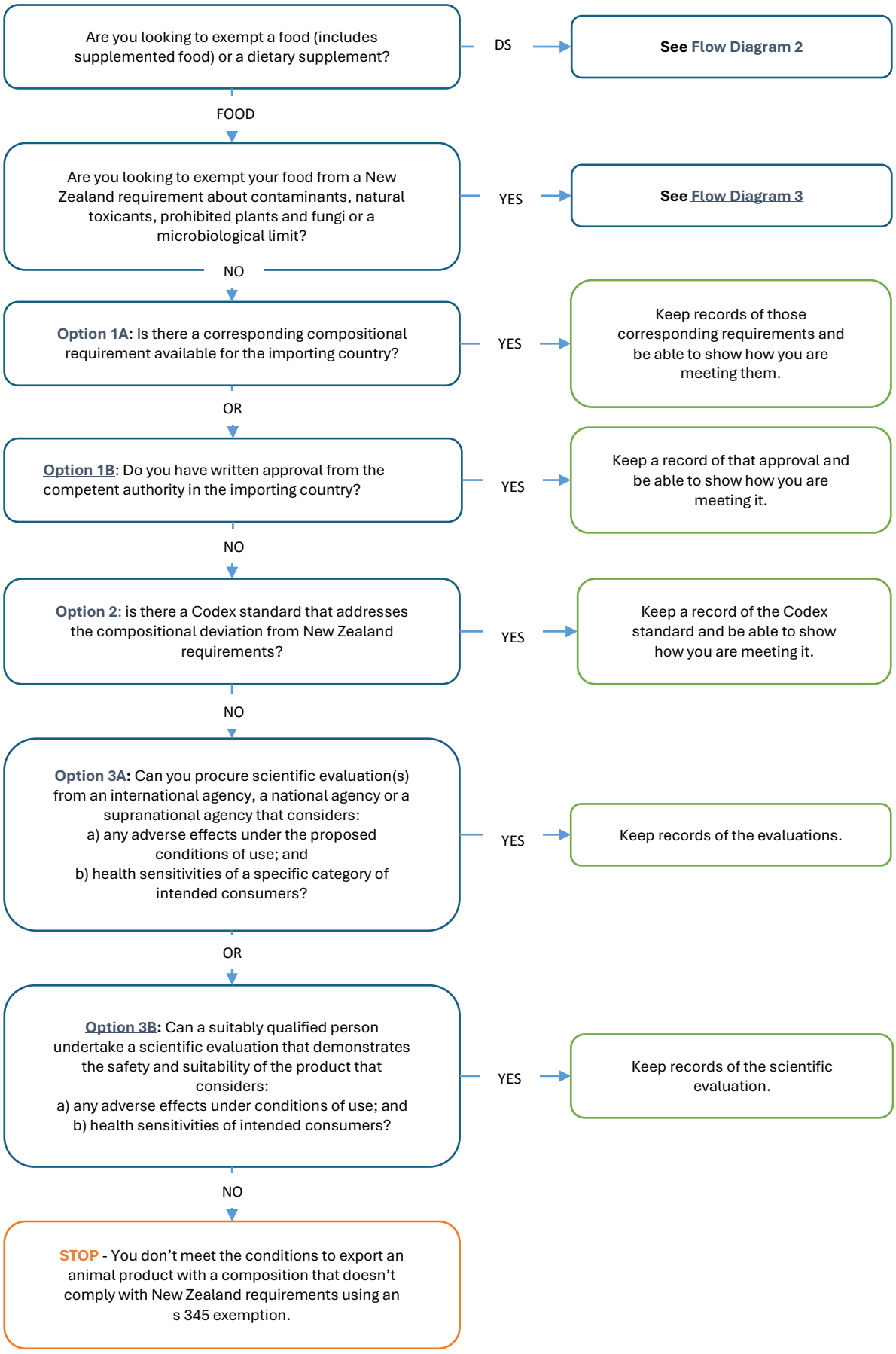
The following flow diagrams can help operators determine which options apply to their product:

Flow Diagram 1 – Exemption from **Food** Compositional Requirements **other than** Contaminants, Natural Toxicants, Prohibited Plants and Fungi or a Microbiological Limit

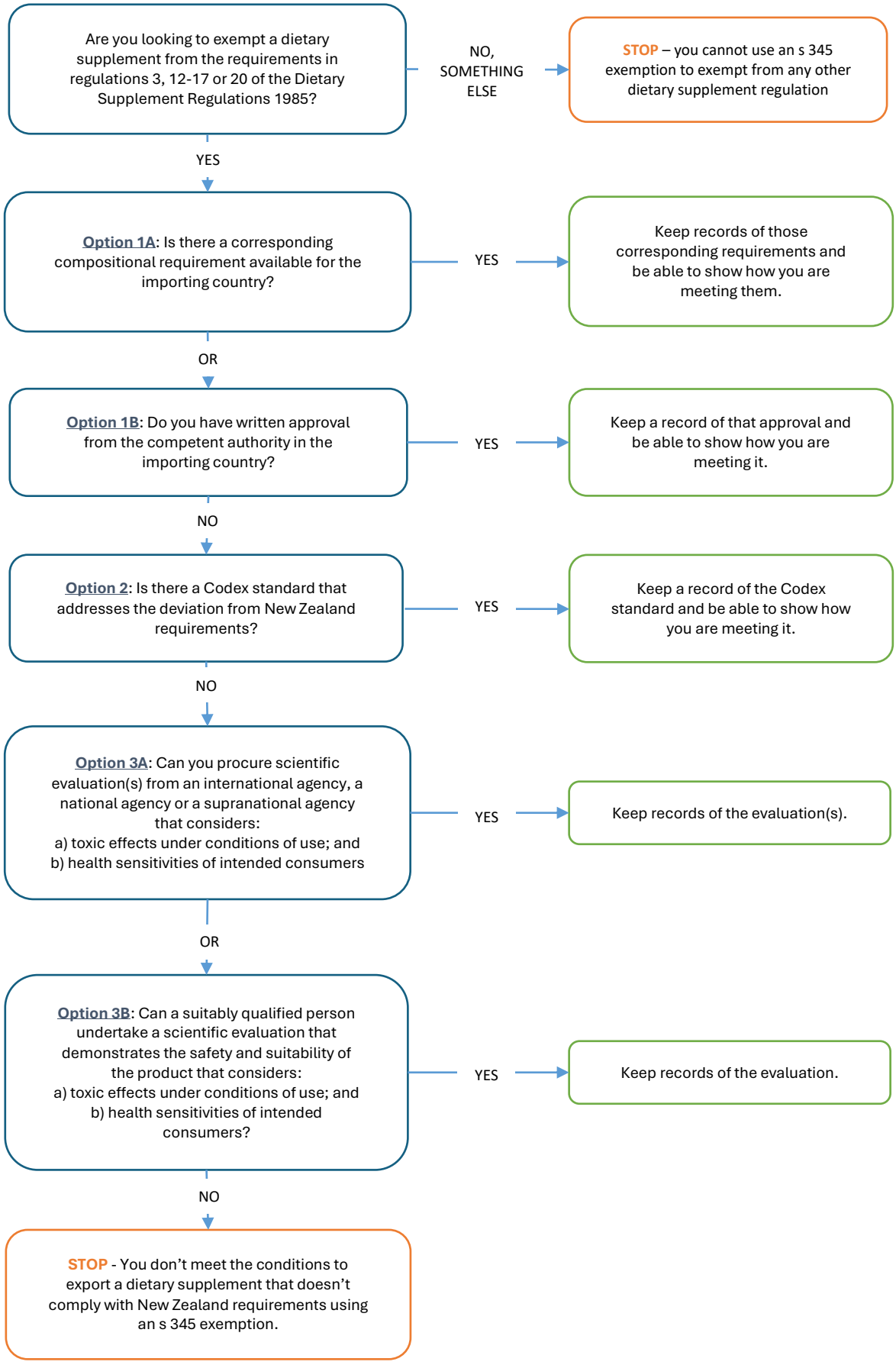
Flow Diagram 2 – Exemption from **Dietary Supplement** Regulations Concerning Composition

Flow Diagram 3 – Exemption from **Food** Composition Requirements Concerning Contaminants, Natural Toxicants, Prohibited Plants and Fungi or a Microbiological Limit

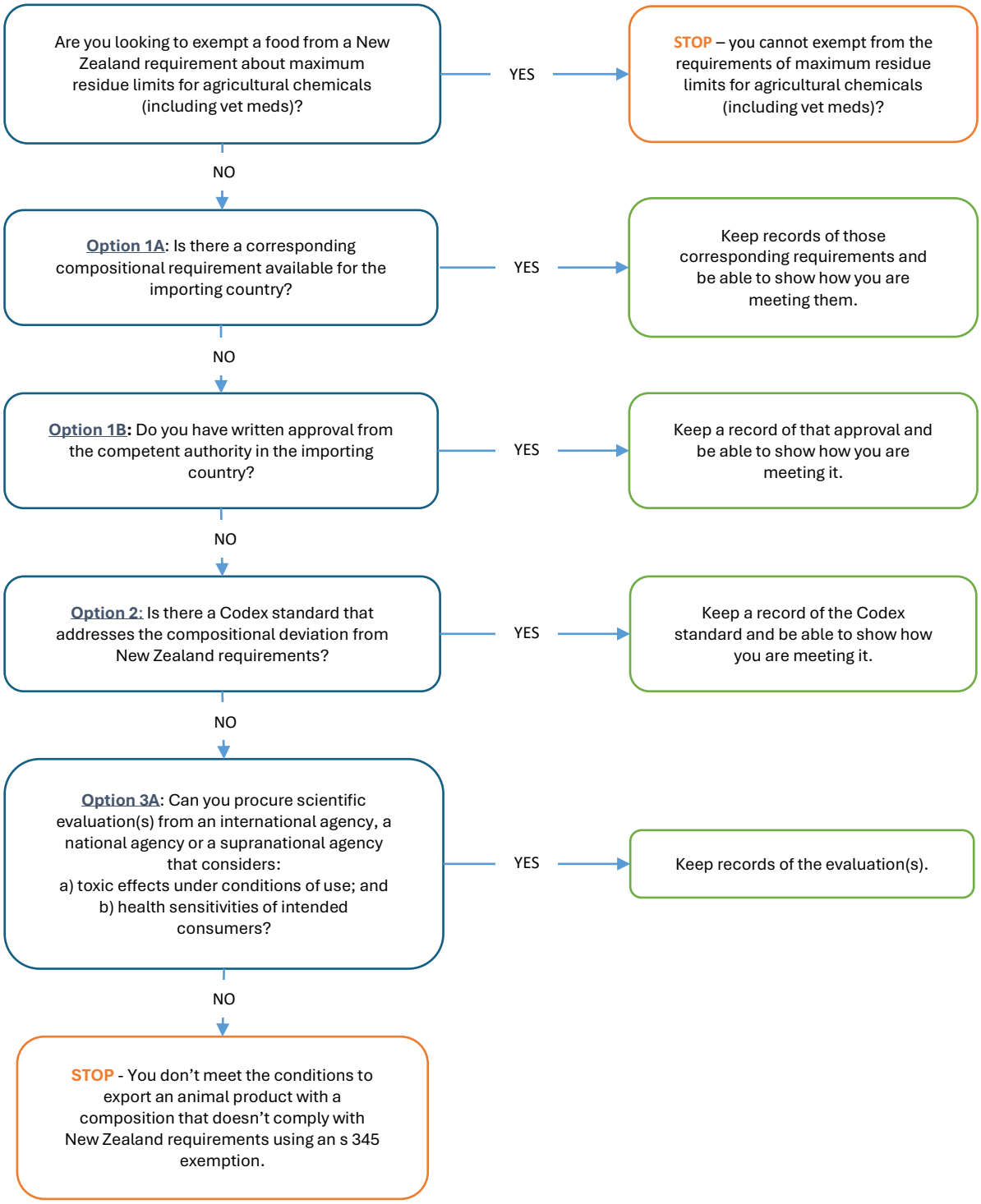
Flow Diagram 1 – Exemption from FOOD composition requirements *other than* contaminants, natural toxicants, prohibited plants and fungi or a microbiological limit



Flow Diagram 2 – Exemption from DIETARY SUPPLEMENT regulations concerning composition



Flow Diagram 3 – Exemption from FOOD composition requirements *concerning* contaminants, natural toxicants, prohibited plants and fungi or a microbiological limit



7.2.6 Option 1A – Corresponding requirement in importing country

[Relates to s 345 Regulations 9(4)(b)(i) and 10(3)(b)(i)]

Option 1A is to meet the corresponding compositional requirements in the importing country. Most countries publish their requirements online. An operator can also work with the importer in the importing country to find out what the requirements are.

The operator:

- must keep a copy of the actual requirements (product standard, food standard, other relevant specifications) as issued by the relevant government authority of the importing country; and
- should keep an English translation of the requirements; and
- should highlight or refer to the specific area in the requirements document(s) that indicates that the compositional attribute that is being exempted, and its limits, are acceptable to the importing country.

  If only the reference number/clause of the requirements that applies to the exempt product is recorded, the operator should be able to show their verifier the actual importing country requirement if requested.

In addition to 7.2.4 and 7.2.5, the operator must have documented procedures to show how they are meeting the corresponding compositional requirements. If operators use existing documentation that is part of their RMP to meet this requirement, they should clearly indicate this.

7.2.7 Option 1B – Written approval from a competent authority in the importing country

[Relates to s 345 Regulations 9(4)(b)(ii) and 10(3)(b)(ii)]

Option 1B is an alternative to Option 1A (meeting the importing country's corresponding compositional requirements). This option is to gain written approval from the competent authority in the importing country. Some countries have a process where operators can apply to have a particular product or the specific ingredient in the food approved for import.

The written approval should have the appropriate letterhead of the competent authority in the importing country or a country stamp. Electronic versions of approvals are acceptable.

The operator must keep a copy of the written approval and be able to clearly identify to which product it applies.

In addition to Keep records7.2.4 and 7.2.5, the operator must have documented procedures to show how they are meeting the compositional attribute and its limits, as per the written approval. If operators use existing documentation that is part of their RMP to meet this requirement, they should clearly indicate this.

7.2.8 Option 2 – Applicable Codex standards

[Relates to s 345 Regulations 9(5) and 10(4)]

If Option 1A (meeting the importing country's corresponding compositional requirements) or Option 1B (written approval) are not available (e.g. if the importing country requirements are silent or unclear on the compositional attribute), the operator can refer to a corresponding compositional requirement in a published Codex Alimentarius (Codex) international food standard.

A list of all published Codex international food standards can be found here: https://www.fao.org/fao-who-codexalimentarius/codex-texts/list-standards/en/

The operator:

- should keep a copy of the Codex standard; and
- must highlight or refer to the specific area in the Codex standard that indicates the compositional attribute that is being exempted, and its limits.

In addition to _Keep_records7.2.4 and 7.2.5, the operator must have documented procedures to show how they are meeting the corresponding compositional requirements. If operators use existing documentation that is part of their RMP to meet this requirement, they should clearly indicate this.

7.2.9 Option 3A – Scientific evaluation from a national/international/supranational agency

[Relates to s 345 Regulations 9(7) and 10(6)]

If Option 1A (meeting the importing country's corresponding compositional requirements), Option 1B (written approval) and Option 2 (Codex standard) are not available (e.g. if the importing country requirements are silent or unclear on the compositional attribute), the operator can refer to one or more published scientific evaluations from a national, international or supranational agency responsible for food safety which demonstrates safety and suitability in relation to the compositional attribute that is being exempted.

Some examples of national, international or supranational agencies responsible for food safety where operators can find scientific evaluations include:

- World Health Organization (WHO);
- Joint FAO/WHO Expert Committee on Food Additives (JEFCA) assessment;
- Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA) assessment;
- any assessment undertaken by Food Standards Australia New Zealand (FSANZ);
- any assessment undertaken by the European Food Safety Authority (EFSA);
- any assessment undertaken by Health Canada.

The evaluations must cover, in relation to the compositional attribute that is being exempted:

- any adverse effects under the proposed conditions of use. Adverse effects include any immediate, short-term, or long term adverse effects or cumulative toxic effects; and
- the particular health sensitivities of a specific category of consumers where the exempt food is intended for that category of consumers.

Multiple evaluations may be referred to in order to cover all the above requirements.

In addition to _Keep_records7.2.4 and 7.2.5, the operator must hold copies of these scientific evaluations. The operator should highlight or refer to the specific areas in the scientific evaluations that indicate the compositional attribute that is being exempted, and its limits.

The operator should also have documented procedures to show how they are meeting the compositional attribute and its limits. If operators use existing documentation that is part of their RMP to meet this requirement, they should clearly indicate this.

7.2.10 Option 3B – Scientific evaluation by a suitably qualified person

[Relates to s 345 Regulations 9(8) and 10(7)]

If Option 1A (meeting the importing country's corresponding compositional requirements), Option 1B (written approval) and Option 2 (Codex standard) are not available (e.g. if the importing country requirements are silent or unclear on the compositional attribute), the operator can refer to one or more scientific evaluations undertaken by a suitably qualified person that demonstrates the safety and suitability of the animal product.

A 'suitably qualified person' would have career experience and/or training in nutrition, toxicology, food technology, or health sciences relevant to the exempt food type.

This is not an option for exemptions for food composition requirements that concern contaminants, natural toxicants, prohibited plants and fungi or a microbiological limit.

The evaluations must cover, in relation to the compositional attribute that is being exempted:

- any adverse effects under the proposed conditions of use. Adverse effects include any immediate, short-term, or long term adverse effects or cumulative toxic effects; and
- the particular health sensitivities of a specific category of consumers where the exempt food is intended for that category of consumers.

An assessment should:

- include a description of:
  - the intended consumer;
  - the purpose of the change; and
  - the proposed levels, limits or amounts of the compositional attribute required for the intended purpose; and
- include a safety assessment, covering toxicity studies, metabolism and absorption, quality and stability, allergenicity;
- include a dietary exposure assessment against toxicity threshold or health-based guidance values. Where applicable, this should include nutritional impact on the intended levels in the population of interest; and
- for special purpose foods and/or foods intended for infants, include a description of the target population, in addition to supporting evidence for nutritional safety, tolerance and efficacy specifically for the intended consumer.

Some examples of the information that is required for a scientific assessment to demonstrate safety and suitability can be found in the following frameworks:

- FSANZ Application Handbook;
- US FDA GRAS process;
- EFSA Scientific requirements for novel foods.

Multiple evaluations may be referred to in order to cover all the above requirements.

In addition to _Keep_ records7.2.4 and 7.2.5, the operator must hold copies of these scientific evaluations. The operator should highlight or refer to the specific areas in the scientific evaluations that indicate the compositional attribute that is being exempted, and its limits.

The operator should also have documented procedures to show how they are meeting the compositional attribute and its limits. If operators use existing documentation that is part of their RMP to meet this requirement, they should clearly indicate this.

See also 7.1.2 Food must be Safe and Suitable and 6.5 Offenses.

7.3 Requirements for labelling exemptions

7.3.1 Foods that may be exempted from labelling requirements

All foods may be exempted from labelling requirements if they meet the following:

- they are processed and packaged under a risk-based measure, RMP or RCS; and
- they are processed and packaged for export (excluding export to Australia).

This does not include:

- wine (wine has its own labelling exemption for export, see Wine Act 2003 section 14(2A)); and

- **non-dairy based** infant formula products and formulated supplementary foods for young children. Non-dairy based, in relation to food, means that the predominant protein constituent of the food is not derived or processed from milk extracted from a milking animal such as a cow, goat, or sheep.

7.3.2 Definition of label

Label is defined in Standard 1.2.1–3 of the Food Standards Code and as *any tag, brand, mark or statement in writing or any representation or design or descriptive matter that:*

a) is attached to the food or is a part of or attached to its packaging; or
b) accompanies and is provided to the purchaser with the food; or
c) is displayed in connection with the food when it is sold.

Labelling is defined in Standard 1.2.1–3 of the Food Standards Code as:

d) in relation to a food being sold, labelling means all of the labels for the food together; and
e) a requirement for the labelling of a food for sale to include specified content is a requirement for at least one of the labels to have that content.

Sold covers any type of sale including sale to other businesses, retail, intra-company sale, but excluding cross-border e-commerce (CBEC) to specified markets. See OMARs for details relating to CBEC.

7.3.3 Labelling requirements that still apply

In relation to labelling of food (except for dietary supplements) for export, the following requirements of the Food Standards Code must be met:

- Standard 1.2.3–3 (Mandatory warning statement—royal jelly); and
- Standard 1.2.7–8 (Claims not to be therapeutic in nature); and
- Standard 2.9.5–4 (Claims must not be therapeutic in nature).

In relation to labelling of dietary supplements for export, the following requirements must be met:

- Dietary Supplements Regulation 10 – Misleading statements;
- Dietary Supplements Regulation 11 – Therapeutic claims; and
- New Zealand (Bee Product Warning Statements - Dietary Supplements) Food Standards 2002

The labelling requirements of Notices and Standards (that apply to the exempt food) must be met, including, but not limited to, the following:

- Animal Products Notice: Production, Supply and Processing Part C3 Labelling, packaging, and repacking;
- Animal Products (Export Requirements - Dairy Products) Notice 2005 (includes multi-ingredient foods that are principally dairy);
- Animal Products (Fish Export Processing Requirements) Notice;
- Animal Products Notice: Labelling Requirements for Exports of Dairy Based Infant Formula Products and Formulated Supplementary Food for Young Children; and
- OMARs.

An s 345 exemption does not exempt a food from having to meet the importing country's labelling requirements.

The Fair Trading Act 1986 still applies to exempt food with respect to false or misleading representations (see section 13).

See also 7.1.2 Exempt Food must be Safe and Suitable, 7.1.3 Medicines Act and Regulations apply to Exempt Food, 7.3.4 Health Claims, 7.3.5 Therapeutic Claims and 8.2 Traceability and Recalls.

7.3.4 Health claims

A health claim makes a link between a product and a health benefit. A claim may state, suggest, or imply that a food or a property of food has, or may have, a health effect. An example is 'calcium is good for strong bones'.

Standard 1.2.7 of the Food Standards Code specifies the requirements for a health claim.

The Animal Products Notice: Labelling Requirements for Exports of Dairy Based Infant Formula Products and Formulated Supplementary Food for Young Children specifies the requirements for a health or nutrition claim for dairy-based infant formula products and formulated supplementary food for young children.

Rules can vary between importing countries and an importing country may call health claims by a different name. An s 345 exemption can be made in relation to health claims, **provided the claim is not 'therapeutic' or 'therapeutic in nature'**. See 7.3.5 Therapeutic Claims.

7.3.5 Therapeutic claims

An s 345 exemption **does not** permit a food (including food for special medical purposes) or dietary supplement for export to make a claim that is 'therapeutic in nature' or 'therapeutic' (depending on the standard or regulation that applies to the product).

Claims include those that may be present on labels, or in any advertising connected with or attached to the product.

There is **no exemption** from the following food standards:

- Standard 1.2.7–8 of the Food Standards Code – claims for food are 'not to be therapeutic in nature':

  A claim must not:

  a) refer to the prevention, diagnosis, cure or alleviation of a disease, disorder or condition; or
  b) compare a food with a good that is:

  i) represented in any way to be for therapeutic use; or
  ii) likely to be taken to be for therapeutic use, whether because of the way in which the good is presented or for any other reason.

- Standard 2.9.5–4 of the Food Standards Code – claims for food for special medical purposes 'must not be therapeutic in nature':

  A claim in relation to food for special medical purposes must not:

  a) refer to the prevention, diagnosis, cure or alleviation of a disease, disorder or condition; or
  b) compare the food with a good that is:

  i) represented in any way to be for therapeutic use; or
  ii) likely to be taken to be for therapeutic use, whether because of the way in which the good is presented or for any other reason.

There is **no exemption** from the following Dietary Supplement Regulation:

- Regulation 11 of the Dietary Supplements Regulations 1985 states:

  Except as permitted by the Medicines Act 1981 and any regulations made under that Act, no dietary supplement or package or container containing a dietary supplement shall be advertised or labelled with a statement relating to any of the following matters:

  a) treating or preventing disease:

b) diagnosing disease or ascertaining the existence, degree, or extent of a physiological condition:
c) altering the shape, structure, size, or weight of the human body:
d) otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating or reducing or postponing, or increasing or accelerating, the operation of that function, or in any other way.

Health claims other than those that are 'therapeutic in nature', or 'therapeutic' can still be made. These types of claims include nutrition claims and health claims that are not therapeutic. See 7.3.4 Health Claims.

8 When things go wrong

8.1 In-market issues

If an operator exports an animal product that is a food and it is found to be non-conforming (non-compliant), the operator must notify the Ministry for Primary Industries (MPI) as soon as possible. This must not be later than 24 hours after the event or after they find out about it.

More information on export non-conformances can be found here: https://www.mpi.govt.nz/export/meeting-nz-standards-for-export/export-non-conformances/

8.2 Traceability and recalls

Traceability and recall requirements in the Food Act and Animal Products Act continue to apply:

- Food Act – Section 133B Tracing and recall
- Animal Products Act – Section 77B Tracing and recall requirements

While exporters will be exempt from the labelling requirements of the Food Standards Code, it is the operator's responsibility to show how they continue to meet the traceability requirements of these Acts.

Under the Food Regulations 2015 and Animal Products Regulations 2021, operators and exporters must notify MPI as soon as practicable (but within 24 hours) of a recall of exported food.

Information on recalls, recall procedures and simulated recalls can be found here: https://www.mpi.govt.nz/food-business/food-recalls/food-recall-documents/

8.3 Sending exempt food to a different market than intended

If the operator is able to reprocess or relabel the product so that it meets the requirements of a new market, they can do this.

If the operator is sending the product as an exempt food to another market, they must ensure that they have completed the appropriate assessment for the exempt food/market combination and meet any conditions and record keeping requirements.

See 7 Meeting the Conditions.

8.4 Selling exempt food in New Zealand and Australia

Exempt food cannot be sold for human consumption in New Zealand or Australia. In order to reprocess exempt food for sale in New Zealand or Australia, the operator is responsible for:

- Ensuring the food meets the composition requirements in the Food Standards Code. This may mean reprocessing the food;
- Ensuring the food meets the labelling requirements in the Food Standards Code. This may mean relabelling the food; and
- If the food is a dairy product, following the requirements in APN: Disposal of Non-conforming Dairy Material or Dairy Product.

The operator must document how they have met all of the above requirements.