Australian User Guide
Mandatory Iodine Fortification

Implementing the Requirements
of
Mandatory Fortification with Iodised Salt under
Standard 2.1.1 - Cereals and Cereal Products

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Background

Food Standards Australia New Zealand (FSANZ) has developed a mandatory iodine fortification Standard to help address the re-emergence of iodine deficiency in Australia and New Zealand. This Standard requires the replacement of non-iodised salt with iodised salt in all bread when salt is added, except organic bread. The commencement dates for this Standard are 27 September 2009 in New Zealand and 9 October 2009 for Australia. The difference in dates is due to FSANZ deferring its consideration of the Standard for Australia while Health Ministers re-evaluated the evidence on the prevalence and severity of iodine deficiency in Australia.

Because iodine deficiency in New Zealand was recognised as needing intervention, FSANZ developed a Standard for New Zealand while Australian Health Ministers were conducting their re-evaluation. When FSANZ received confirmation that iodine deficiency was prevalent and severe enough to warrant intervention in Australia, the New Zealand-only Standard was amended to become a joint Standard.

The commencement dates for the mandatory use of iodised salt generally aligns with the mandatory folic acid fortification Standards and provides industry with time to prepare for mandatory iodine fortification.

This User Guide, unlike the Standard itself, is not legally binding. If in any doubt about interpreting the Standard, FSANZ recommends that you seek independent legal advice.

In addition to the food standards requirements, it is also necessary to comply with other Australian legislation, including the *Trades Practices Act 1974*¹, the *Imported Food Control Act 1992*², and State, Territory Food Acts³.

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¹ [www.comlaw.gov.au](http://www.comlaw.gov.au)
Purpose of the Guide

FSANZ has developed this User Guide, in consultation with government and industry representatives, to help manufacturers, retailers and food enforcement officers interpret and apply the mandatory iodine fortification requirement under Standard 2.1.1 - Cereals and Cereal Products of the *Australia New Zealand Food Standards Code* (the Code).

This User Guide applies to Australia only. The New Zealand guide to implementing the requirements for iodine and folic acid can be found on the New Zealand Food Safety Authority website: [www.nzfsa.govt.nz](http://www.nzfsa.govt.nz).

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Part 1  Mandatory iodine fortification

1.1 What is the mandatory iodine fortification Standard?

Standard 2.1.1 - Cereals and Cereal Products requires that iodised salt be used for making bread where salt would otherwise be used. However, this requirement does not apply to:

- bread represented as organic
- the addition of salt to the surface of bread (e.g. rock salt)
- the addition of other ingredients containing salt during the making of bread.

It should be noted that Standard 2.1.1 does not mandate the use of salt for bread making but rather requires the use of iodised salt where salt is used for bread making. Iodised salt is defined in Standard 2.10.2 - Salt and Salt Products as:

\[
\text{a mixture of salt and -}\]

\[
(a)\quad \text{potassium iodide or potassium iodate; or} \\
(b)\quad \text{sodium iodide or sodium iodate.}
\]

Standard 2.10.2 requires the salt iodisation level to be in the range of 25 - 65 milligrams of iodine per kilogram of salt. The target level of iodine in iodised salt for bread manufacture is the mid-point of the iodisation range i.e. 45 milligrams of iodine per kilogram of salt. The permitted forms, listed in Standard 1.1.1 - Preliminary Provisions, are sodium and potassium salts of iodide and iodate. In practice, potassium iodate is the form currently used in Australia for the iodisation of salt.

The mandatory iodine fortification Standard is effective from 9 October 2009 in Australia. Prior to this date, manufacturers may use iodised salt for making bread, by virtue of the current voluntary permissions (See Section 2.7).

1.2 Where can I find a copy of the mandatory iodine fortification Standard?

All Standards and subsequent amendments are available from the FSANZ website (www.foodstandards.gov.au).
Standard 2.1.1 and Standard 2.10.2 can be found in Chapter 2 - Food Product Standards. Hard copies of the Code and User Guides can be purchased from Anstat Pty Ltd, phone 61 3 9278 1144 or on-line http://anzfa.anstat.com.au.

Part 2  Responsibilities of industry

Two specific industry sectors are affected by mandatory iodine fortification: salt suppliers and manufacturers of bread and bread products.

2.1 What are the responsibilities for the salt industry?

It is currently the responsibility of the salt industry to ensure that the level of salt iodisation is within the prescribed range of 25-65 milligram of iodine per kilogram of salt as required by Standard 2.10.2. Iodised salt products need to be clearly distinguished from non-iodised salt products.

Some salt processing businesses may however need to upgrade their plant by installing a dry mixing system to enable increased production of iodised salt. In addition, where salt products are certified as organic, some businesses may need a separate processing area to ensure there is no cross contamination.

2.2 What are the responsibilities for the bread manufacturing industry?

It is the responsibility of the bread manufacturing industry to ensure non-iodised salt is replaced with iodised salt when making bread and bread products, as outlined in Part 2.3 of this Guide. When purchasing salt, iodised salt needs to be specified.

All labelled products containing iodised salt will be required to list ‘iodised salt’ in the statement of ingredients, if a statement of ingredients is required for that product (refer to Part 2.8 of this Guide or Standard 1.2.4 - Labelling of Ingredients).
2.3 What foods are required to contain iodised salt?

The mandatory iodine fortification Standard requires non-iodised salt to be replaced with iodised salt when making bread.

Bread is defined in Standard 2.1.1 as:\(^4\):

> the product made by baking a yeast-leavened dough prepared from one or more cereal flours or meals and water.

This definition encompasses yeast-leavened bread made from all cereal flours, not solely wheat flour e.g. rye flour. Chemically aerated non-yeast leavened dough, such as damper and soda breads, are exempt from this definition of bread and therefore do not require the use of iodised salt. It is intended that only bread dough be required to contain iodised salt in place of non-iodised salt. Salt added to the surface of bread, or to other ingredients added to bread will not have to be iodised.

If the following products are made from bread dough which contains yeast and salt, there is a requirement that the salt, where used, is iodised:

- bread loaves, buns and rolls including plain white, white high fibre
- wholemeal and multigrain
- flat breads (e.g. pita bread, naan bread)
- focaccia and pide (Turkish bread)
- bagels (white, wholemeal, sweet)
- topped breads, buns and rolls (e.g. cheese and bacon rolls)
- baked English-style muffins (white, white high fibre, multigrain, wholemeal and fruit)
- sweet buns
- fruit breads and rolls.

\(^4\) Changes to the definition of bread for mandatory fortification are currently being considered under Proposal P1008 - Code Maintenance VIII. These changes will further clarify the definition of bread for the purposes of mandatory fortification. It is intended this amendment be included in the Code by 27 September 2009.
Other specialty breads, such as gluten free bread, that meet the definition of bread will be required to be made using iodised salt. Specialty breads that do not meet the definition of bread can still use iodised salt by virtue of the voluntary permissions under Standard 2.10.2.

Note: Iodised salt may also be used in the manufacture of other foods such as pizza bases, crumpets, pikelets, croissants and doughnuts. While the voluntary addition of iodised salt is permitted under Standard 2.10.2, suppliers of these products must adhere to labelling requirements (refer to Parts 2.7 and 2.8 of the User Guide for further information).

2.4 Will frozen dough be required to contain iodised salt?

Bakers, supermarkets and other food outlets in Australia, who purchase frozen dough and intend baking the frozen dough for sale as bread, will need to ensure the salt in the frozen dough is iodised.

Frozen dough made for export products should comply with the specifications of the country of destination.

2.5 Will breadcrumbs be required to contain iodised salt?

It is not a requirement for purpose-made crumbing to contain iodised salt (e.g. for fish, chicken etc.). By virtue of the voluntary permissions, manufacturers could choose to use iodised salt if they wished; however suppliers must adhere to labelling requirements. If breadcrumbs are made from returned bread, the salt present in the bread would be iodised and the breadcrumbs would therefore need to be labelled accordingly (refer to Part 2.11 of this Guide or Standard 1.2.4 - Labelling of Ingredients).

Breadcrumb made for export products should comply with the specifications of the country of destination.
2.6 Will bread mixes for domestic use be required to contain iodised salt?

It is not intended that bread mixes for retail sale for making bread at home will be required to replace salt with iodised salt. Bread mixes for retail sale do not meet the definition of bread, as they are not sold and consumed as ‘bread’ but as ingredients for making bread.

However, manufacturers may choose to use iodised salt in their bread mixes, by virtue of the voluntary permission for the addition of iodised salt (refer to Parts 2.7 and 2.8 of the User Guide for further information).

2.7 What is the voluntary iodine permission?

As outlined in Standard 2.10.2, the voluntary permission for iodine in iodised salt and reduced salt will be retained at the current range of 25 - 65 mg/kg, to be consistent with the mandatory requirements. This allows food manufacturers to use iodised salt in other products. For example, manufacturers who are required to use iodised salt in their bread production may choose to use iodised salt in other products, such as pancakes, crumpets and other hot plate items. In these instances, manufacturers must adhere to labelling requirements (refer to Part 2.8 of this Guide or Standard 1.2.4).

2.8 What ingredient labelling will be required under the mandatory iodine fortification Standard?

The mandatory iodine fortification Standard affects the labelling requirements of bread and bread products that contain iodised salt. Ingredient labelling requirements are set out in Standard 1.2.4 - Labelling of Ingredients. The requirements for labelling with a statement of ingredients differ depending on whether the food is for retail sale or not, or is for catering purposes.

Food for retail sale

Food for retail sale means food for sale to the public and includes food prior to retail sale which is not intended for further processing, packing or labelling. Suppliers will be required to list ‘iodised salt’ in the statement of ingredients on foods for retail sale that contain iodised salt.
A declaration of iodised salt in the ingredient list will provide consumers with information about whether their choice of bread and bread product contains iodised salt.

In some situations, foods for retail sale are exempt from the requirement to label with an ingredient list. These include:

- unpackaged food
- food made and packaged on the premises from which it is sold
- food packaged in the presence of the purchaser
- food in a small package\(^5\).

For further details, refer to clause 2 of Standard 1.2.4 and clauses 1 and 2 of Standard 1.2.1 - Application of Labelling and Other Information Requirements. For these products, consumer information about the presence of iodised salt may be made available from the food outlet upon request; however this is not a requirement.

**Food not for retail sale**

Food not for retail sale means food not for sale to the public and includes food intended for further processing, packaging or labelling prior to retail sale e.g. frozen dough provided to a supermarket that will be baked by the supermarket prior to retail sale (this does not include for food catering purposes (see below)). These foods are not required to be labelled with a statement of ingredients. However, if requested by the purchaser or relevant authority, the product must be accompanied by enough information for the purchaser to comply with the compositional and labelling requirements of the Code. This information must be provided in writing if requested by the purchaser or relevant authority.

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\(^5\) Small package is defined in Standard 1.2.1 and means a package with a surface area of less than 100 cm\(^2\).
Food for catering purposes

Food for catering purposes includes food supplied to catering establishments, restaurants, canteens, schools, hospitals and institutions where food is prepared or offered for immediate consumption e.g. bread sold to a restaurant. Such food is not required to be labelled with a statement of ingredients. However, a statement of ingredients, amongst other information, must be provided in documentation unless exempt under clause 2 of Standard 1.2.4. Suppliers may choose to provide this information electronically, in written documentation, or by placing it on the label. In addition, if specifically requested by the purchaser or relevant authority, the product must be accompanied by enough information for the purchaser to comply with the compositional and labelling requirements of the Code.

For further details, refer to Standard 1.2.1.

2.9 Will nutrition and health claims be permitted?

Manufacturers can make nutrition claims about iodine; however, they must meet certain compositional requirements and make a declaration of the iodine content in the nutrition information panel (NIP). For further details on nutrition claims refer to Standard 1.2.8 - Nutrition Information Requirements and Standard 1.3.2. - Vitamins and Minerals.

For further details on health claims refer to Standard 1.1A.2 - Transitional Standard - Health Claims. FSANZ is developing a new standard to regulate nutrition, health and related claims under Proposal P293 - Nutrition, Health & Related Claims. FSANZ is considering the conditions for making claims about the presence of vitamins or minerals and associated health impacts under this Proposal. The new standard, when gazetted, may therefore affect the current information on nutrition and health claims.

2.10 What about use of ‘natural’ claims?

The Australian Competition and Consumer Commission (ACCC) considers that ‘natural’ claims imply the product is made up of natural ingredients, i.e. ingredients nature has produced, not man-made or interfered with by man.
Iodised salt is not a natural substance, so ‘all natural’ claims for foods containing iodised salt should not be used, though the product may be labelled as ‘contains natural ingredients’. Care should be taken when labelling a product as ‘contains natural ingredients’ to avoid providing the impression that all the ingredients in the product are natural.

For further details refer to the ACCC ‘Food and Beverage Industry - Food Descriptors Guideline to the Trade Practices Act’6.

2.11 How should food containing breadcrumbs be labelled?

Breadcrumbs made from returned bread will contain iodised salt. Therefore ‘iodised salt’ must be listed on the ingredient list of the breadcrumb package or the package of foods where these breadcrumbs are used as an ingredient.

When breadcrumbs are used as an ingredient of a food, they are classified as a ‘compound ingredient’. Compound ingredients can be declared in the statement of ingredients either:

(a) by declaring the compound ingredient by name and listing its ingredients in brackets; or
(b) by declaring all of the ingredients of the compound ingredient separately as if they were individual ingredients of the final food.

If breadcrumbs (containing iodised salt) are declared as outlined in (a), and the breadcrumbs make up less than 5% of the final food, the individual ingredients of the breadcrumbs do not need to be declared, including iodised salt (note: allergens and certain food additives still need to be declared).

6 www.acc.gov.au
It is a requirement however for foods containing breadcrumbs as a compound ingredient to include breadcrumbs in the list of ingredients on the label of foods for retail sale. For further detail on the labelling of compound ingredients, refer to clause 6 of Standard 1.2.4 and clause 4 of Standard 1.2.3 - Mandatory Warning and Advisory Statements and Declarations.

Part 3  Exemptions to the mandatory iodine fortification Standard

3.1 What are the exemptions?

Bread represented as organic is exempt from the mandatory iodine fortification Standard. This will allow manufacturers of organic bread to follow any existing organic practices and standards in Australia.

This exemption from the mandatory iodine fortification Standard is consistent with the mandatory folic acid fortification Standard exemption for organic bread.

As outlined in Section 1.1 of this User Guide, salt added to the surface of bread (e.g. rock salt), or the addition of other food containing salt during the making of bread, is also exempt from mandatory iodine fortification.

3.2 What is bread represented as organic?

The Australian Trade Practices Act 1974 prohibits traders from misleading consumers as to, amongst other things, the nature, characteristics, and quality of goods. The Act also prohibit traders from making false or misleading representations that goods are of a particular kind, standard, quality or have had a particular history.

Therefore, if a trader wishes to represent their product as ‘organic’, to ensure they do not breach the Trade Practices Act, all of the product’s ingredients must be 100% organic through the entire food chain. To assure consumers that the foods they produce are organic, many organic food producers and manufacturers choose to have their production processes certified as organic.
There are a number of organic certification organisations in Australia. Under Australian fair trading legislation, mandatorily fortified foods with iodine and folic acid may not be labelled as ‘organic’.

3.3 Will bread imported into Australia be exempt?

All bread imported into Australia must comply with the mandatory iodine fortification Standard, with the exception of organic bread. This includes pre-mixes or frozen dough intended to be baked and sold as bread.

3.4 Will bread exported from Australia be exempt?

Bread exported from Australia may contain iodine provided it is permitted in the destination country.

Part 4  Relationship to mandatory folic acid fortification

Food Ministers accepted the mandatory folic acid fortification Standard in June 2007. It takes effect in September 2009. The Standard for Australia requires the addition of folic acid to all wheat flour used for making bread. New Zealand has issued its own food standard under the New Zealand Food Act 1981 that requires the addition of folic acid to bread, rather than to wheat flour for making bread. Flour and bread represented as ‘organic’ are exempt from mandatory fortification.

The commencement date for the mandatory iodine fortification Standard generally aligns with the mandatory folic acid fortification Standards. This provides manufacturers and retailers with the opportunity to make one set of labelling changes instead of two, thereby helping to reduce the costs associated with meeting these mandatory requirements.

For further detail on meeting the Australian mandatory folic acid fortification requirements refer to the Mandatory Folic Acid Fortification User Guide, available on the FSANZ website at www.foodstandards.gov.au. Information on meeting the New Zealand mandatory folic acid and iodine fortification requirements is available on the New Zealand Food Safety Authority website at www.nzfsa.govt.nz.
Part 5  Compliance/enforcement

5.1 How will the mandatory iodine fortification Standard be assessed for compliance?

State, Territory and New Zealand enforcement agencies are responsible for assessing compliance with food standards. These agencies have developed a Compliance and Enforcement Model for Mandatory Fortification (the Model).

The Model is based on manufacturers developing a documented system, such as a quality assurance arrangement or an approved alternative, which is capable of being audited. This system helps demonstrate compliance with mandatory iodine fortification by including monitoring, sampling and analysis protocols. Third party or alternative audit arrangements (such as by enforcement agencies) can be applied to demonstrate the documented system is in place and achieving the stated outcomes. However, the Model does not preclude enforcement agencies from taking samples for analysis should the need arise.

Contact your local enforcement officers or state/territory health department for further advice regarding this issue.

5.2 When will the mandatory iodine fortification Standard commence?

The mandatory iodine fortification Standard is effective from 9 October 2009 in Australia. However, non-iodised salt may be replaced with iodised salt in bread prior to the implementation date by using the existing voluntary permissions, provided labelling requirements are adhered to (refer to Parts 2.7 and 2.8 of this Guide).

5.3 At what point does iodised salt need to meet the mandatory fortification range?

Iodised salt must meet the mandatory fortification range of 25–65 milligrams of iodine per kilogram of salt at the final point of production in the salt refinery. Imported iodised salt must meet the fortification range at the point of import into Australia.
The level of iodine in iodised salt will also need to remain within the specified range over the declared shelf-life of the product. Salt manufacturers should obtain their own information to verify the shelf-life of their product. However, literature sources indicate that iodised salt (iodised with potassium iodate) showed no significant loss of iodine when stored in polyethylene bags for two years. This may not be the case with other forms of iodine.

5.4 How will the level of salt iodisation be assessed for compliance?

The Model recognises that compliance will be monitored by assessing manufacturing records and, if samples are taken, on the basis that a sample should be representative of a lot. To determine how a manufacturer is managing compliance with the Standard, sample results will be considered in conjunction with other information available at the salt refinery.

The minute particles of potassium iodate do not have a natural affinity with the salt crystals. As a result, some separation of potassium iodate is likely to occur during transport and storage. Therefore, as outlined in the compliance and enforcement model, the recommended sampling point for compliance should be at the salt manufacturing facility, as soon as possible after addition and mixing.

5.5 Do bread and other food manufacturers have compliance requirements under the mandatory iodine fortification Standard?

Bread manufacturers need to specify iodised salt when placing orders for salt for use in bread making. In addition, they should specify bread pre-mixes or frozen dough with iodised salt if they are intended to be baked and sold as bread.

Bread and other food manufacturers using iodised salt are required to adhere to the specific labelling requirements (refer to Part 2.8 of this Guide or Standard 1.2.4).
Part 6  Public health monitoring

6.1 Will the mandatory iodine fortification Standard be monitored?

The Ministerial Policy Guidelines for Mandatory Fortification states that:

*Any agreement to require fortification should require that it be monitored and formally reviewed to assess the effectiveness of, and continuing need for, the mandating of fortification.*

6.2 Who is responsible for monitoring?

Monitoring the impacts of mandatory fortification is the responsibility of health and food regulatory agencies at the Commonwealth and State/Territory levels in Australia and New Zealand. The Australian Institute of Health and Welfare (AIHW) has overall responsibility for the monitoring program and reporting on progress. FSANZ will contribute directly to some elements of the monitoring program as part of its on-going work and may also be involved indirectly in other fortification monitoring program activities.

Part 7  Consumer information

Fact sheets on iodine, food sources, benefits, and possible adverse effects of iodine are attached and are available separately from the FSANZ website: www.foodstandards.gov.au.

7.1 What is iodine?

Iodine is a natural element found as a nutrient in our food. Iodised salt, dairy products, seafood, kelp and eggs can all contribute to iodine intakes. Of these, certain seafood and kelp can contain very high levels of iodine.

Iodine-containing supplements and medicines can also contribute to iodine intakes as can drinking water.
7.2 Who needs iodine and why is it important in our diet?

We all need iodine. It is essential for the production of thyroid hormones and thyroid health throughout life. Thyroid hormones regulate body temperature and metabolic rate in adults and children. These hormones are also very important for the normal development of the brain and nervous system before birth, in babies and young children. It is therefore particularly important that pregnant women, breast-feeding mothers and young children get enough iodine. For more information, see the Fact Sheet ‘Mandatory Iodine Fortification’, available on the FSANZ website: www.foodstandards.gov.au

7.3 What is mandatory iodine fortification?

Mandatory fortification is the compulsory addition of certain vitamins and minerals to foods in response to a significant public health need. The mandatory iodine fortification Standard requires that iodised salt be used for making bread, where salt would otherwise be used. This will mean most bread in Australia and New Zealand will contain iodised salt.

However, bread represented as organic, salt added to the surface of bread and the addition of other ingredients containing salt during the making of bread, are exempt from mandatory iodine fortification.

Mandatory fortification is estimated to increase iodine intakes of adults by 30-70 micrograms (approximately three slices of bread) or the equivalent of a large glass of milk (300 mL).

7.4 Why mandatory iodine fortification?

Historically, people living in Tasmania, the Australian Capital Territory, New South Wales, Victoria and New Zealand have had low iodine intakes, and goitre was common. This was due to the low iodine content of foods grown in iodine deficient soils in these regions. In the past various initiatives, such as iodine supplements given to school children, the unintentional contamination of milk with iodine from iodine-containing cleaning agents, and the widespread use of iodised salt, helped provide extra iodine.
Between 1960 and 1980, it was thought that iodine deficiency was no longer a problem. However, mild iodine deficiency has re-emerged over the last 10-15 years. The use of iodised salt in bread has been used successfully in countries overseas and a recent project in Tasmania where iodised salt was voluntarily added to bread has shown an improvement in the iodine status of the Tasmanian population.

7.5 Why was bread chosen for fortification?
FSANZ chose bread as the appropriate food vehicle for fortification because it is eaten regularly by a large proportion of the population including women of child-bearing age and young children across all socio-economic sub-groups.

7.6 What choice do consumers have who want to avoid iodine?
Bread represented as organic will be exempt from mandatory iodine fortification. This will provide some choice for consumers who do not wish to eat bread with added iodised salt.

Manufacturers may choose to use iodised salt in manufacturing other foods such as crumpets, pikelets and croissants by virtue of the voluntary permissions that exist. If you wish to avoid foods with iodised salt, it will be important for you to check the ingredients list of food labels.

Iodine sensitive consumers who wish to reduce the level of iodine in their diets could choose no added salt bread. Bread with lower levels of salt as indicated in the nutrition information panel, will contain on average lower levels of iodine. Consumers wanting more information on the level of iodine in specific bread products should contact the relevant bread manufacturer or supplier.

7.7 Are there any adverse health effects?
The risk of adverse health consequences from mandatory iodine fortification is small across all groups.
FSANZ estimates mandatory iodine fortification will increase iodine intakes by approximately the same amount as drinking a large glass of milk (300ml). This increase in iodine is modest and therefore unlikely to cause harm even in the majority of iodine sensitive individuals. Further information is provided in the Fact Sheet ‘Iodine Sensitivities and Mandatory Iodine Fortification’ available on the FSANZ website: www.foodstandards.gov.au

Part 8  Where can I get more information?

For information about the Code, contact FSANZ at info@foodstandards.gov.au.

Additional User Guides are available on the FSANZ website:
www.foodstandards.gov.au

• Overview of Food Labelling
• Legibility Requirements for Food Labels
• Information Requirements for Foods Exempt from Bearing a Label
• Ingredient Labelling
• Nutrition Information Labelling
• Mandatory Folic Acid Fortification.

FSANZ can provide assistance with navigating the Code. However FSANZ does not provide approval of labels, or food compliance of any type. FSANZ is limited to providing information about the Code only and does not provide legal advice on or interpretation of the Code.

Enforcement of mandatory iodine fortification will be the responsibility of State and Territory enforcement agencies in Australia and the New Zealand Food Safety Authority. Contact your local enforcement officers or State/Territory health department for further advice regarding this issue.

The onus is upon suppliers, including food companies, to ensure compliance with relevant food legislation. You may wish to engage a food compliance consultant or your own legal counsel for further advice.