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Food Law Bulletin

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In this edition: we look at a New Zealand Court of Appeal case that helps to clarify the meaning of 'health claim' under the Food Standards Code; an update on the Country of Origin Labelling regime in Australia and New Zealand; changes to the laws relating to the importation of food into Australia introduced by new Biosecurity legislation, and new Food & Drug Administration guidelines for nutrition information labelling for food sold in the US.

To bee, or not to bee... Generalised health claims under the Food Standards Code?

In brief: The New Zealand Court of Appeal considered an application by a honey producer seeking a declaration that the labelling of its honey products complied with the requirements for nutrition, health and related claims under the Food Standards Code. The Court of Appeal has clarified that in order for a claim to be a 'health claim' within the meaning of the Code, it must be a claim to an identified health benefit or effect. Associate Lauren John reports.

How does it affect you?

- We previously reported on the new form of standard 1.2.7 and its potential broad reach. The New Zealand Court of Appeal has clarified that a general claim to unidentified benefits (eg, that a product is 'good for you') is not a 'health claim' within the meaning of the Food Standards Code (the ***Code***) and is not prohibited.
- A claim must describe or indicate the relationship between the food or a component of the food to a specific health benefit or effect in order to be caught by the Code. Where such a claim is made it must conform to the requirements for general or high level health claims as set out in standard 1.2.7.
- A trade mark, considered alone, may be a 'health claim'.

The background

Honey New Zealand (International) Limited and Manuka Doctor Limited (***Honey NZ***) are producers and exporters of honey, including manuka honey products under the brands MANUKA DOCTOR and MANUKA PHARM, both registered trade marks.

Section 61(1) of the *Animal Products Act 1999* (NZ) provides that the Director-General of the Ministry for Primary Industries (***MPI***) may issue official assurances in respect of animal products that are to be exported overseas. MPI refused to issue export certificates for the MANUKA DOCTOR and MANUKA PHARM products on the basis that the products' labels breach the Code because they impermissibly claim health effects and therapeutic effects for their manuka honey. Honey NZ sought a declaration that its trade marks are not health claims (or therapeutic claims) as defined in the Code.

The Code

Standard 1.2.7, which sets out the requirements for nutrition, health and related claims, was introduced in June 2013. At that time, businesses could choose to either adopt the new standard or continue to operate under a transitional standard, with the transitional period ending on 18 January 2016. Honey NZ had committed to the new standard and so it was the only standard under consideration.

A 'claim' is defined to mean *'an express or implied statement, representation, design or information in relation to a food or a property of food which is not mandatory in this Code.'* MPI and Honey NZ agreed that the products' labels met this definition.

A 'health claim' is defined to mean *'a claim which states, suggests or implies that a food or a property of food has, or may have, a health effect.'* A 'health effect' is defined to mean an effect on the human body, including an effect on one or more of the following: a biochemical process or outcome; a physiological process or outcome; a functional process or outcome; growth and development; physical performance; mental performance; or a disease, disorder or condition.

The Code distinguishes 'high level health claims' from 'general level health claims'. A 'high level health claim' is a health claim which refers to a serious disease or a biomarker of a serious disease, whereas a 'general level health claim' is simply a health claim that is not a high level health claim.

Standard 1.2.7 provides two routes by which a general level health claim can be made:

- it must be based on, and meet the requirements of, the approved health claims set out in Schedule 4; or
- a food business can self-substantiate a food-health relationship in accordance with the requirements set out in standard 1.2.7.

A high level health claim is permitted where it is based on, and meets the requirements of, a food-health relationship pre-approved by FSANZ as set out in Schedule 4.

Standard 1.2.7 absolutely prohibits 'therapeutic claims', which are claims which refer to the prevention, diagnosis, cure or alleviation of a disease, disorder or condition.

At first instance

MPI asserted that the breach of standard 1.2.7 arose solely by the use of the trade marks MANUKA DOCTOR and MANUKA PHARM, arguing that they are implied health claims. It was not suggested that these alleged health claims satisfied the requirements of standard 1.2.7. Accordingly, if the trade marks were health claims (albeit of a general nature) they were prohibited.

Is a specific identified effect required before a claim is a health claim?

MPI argued that general unspecific claims come within the Code and are prohibited, or as an alternative, that a general claim is to be treated as being a claim about all of the specific effects identified in the definition of 'health effects'. MPI asserted that members of the public would see the use of MANUKA DOCTOR and MANUKA PHARM as claiming the products have health effects.

Honey NZ argued that to be a health claim, some specific effect, as set out in the definition of 'health effect' (eg, a claim directed to physical performance), must be claimed. Honey NZ relied upon the manner in which permitted health claims are expressed in the Code in support of its argument. For example, in relation to the food property calcium, a permitted 'specific health effect' for high level health claims is 'enhanced bone mineral density'. Honey NZ argued it was clear that the Code is aimed at controlling claims about identified health benefits, not general vague claims.

While Justice France accepted Honey NZ's interpretation of the Code that any permissible health claim will always require an identified benefit, his Honour said that the regime of authentication and verification of claimed health effects by proper research and testing cannot be circumvented by making an unsubstantiated general claim that a particular food will be 'good for you'. His Honour said that unsubstantiated and insufficiently verified claims about health benefits of food are not permitted:

> *The better interpretation of the scheme is that the only health claims that are permitted are substantiated claims about identified benefits. A general claim about unidentified benefits is a health claim, just not a permitted one.*

Are MANUKA DOCTOR and MANUKA PHARM implied general health claims?

Honey NZ placed emphasis on the fact that MANUKA DOCTOR and MANUKA PHARM are trademarks, and therefore likely to be seen as identifying the source of the products rather than health effects. Honey NZ invoked the example of DR PEPPER (the soft drink), as it argued that no consumer would infer that this mark is making a health claims about its product. MPI argued that this ignored the particular context in which the MANUKA DOCTOR and MANUKA PHARM marks are being used, namely the long claimed association of manuka honey with health advantages and the association of the words DOCTOR and PHARM with health.

Justice France did not consider the fact that MANUKA DOCTOR and MANUKA PHARM are trade marks to be of particular significance. His Honour accepted that the public will approach the product using a reasonable measure of common sense, however, he considered that the use of DOCTOR and PHARM carries the 'clear possibility' they will be seen as suggesting the product is good for you, in part due to the common association of the concepts of DOCTOR and PHARM with health, healing and medicine.

Finally, his Honour said it was doubtful that the trade marks were therapeutic claims, although it was not necessary to decide the matter in light of his earlier findings.

Appeal

Honey NZ appealed the above findings in relation to its MANUKA DOCTOR branded products only.

The Court of Appeal acknowledged that the primary purpose of the Code is consumer protection and said that where claims of health effects are made, they are to be made in accordance with the standards prescribed by the Code. However, the Court of Appeal disagreed with the judge below that it necessarily followed that general claims of unidentified health benefits are prohibited, finding that the Code is aimed at claims of 'specific measureable health effects'. The Court of Appeal referred to FSANZ's Final Assessment Report, which explained that claims which *'do not explicitly or implicitly indicate the presence or absence of a property of the food or claims that do not describe or indicate the relationship between food or a specific component of food and a health effect'* were not intended to be caught by the Code. Further, the Court of Appeal said that the other purposes of the Code, such as avoiding unnecessary restrictions of trade, would not be achieved if the Code were interpreted as applying to general claims of unidentified effects.

The Court of Appeal also disagreed with the judge below that the trade mark MANUKA DOCTOR amounted to an implied general level health claim that the products are 'good for you'. While it was possible some members of the public might associate the word DOCTOR with health, healing and medicine, the Court of Appeal said that it was unlikely that a substantial number of relevant consumers exercising reasonable care would do so. Also, having regard to the product's labelling as a whole, their Honours considered that the use of the words MANUKA DOCTOR conveyed that the producers of the product are specialists in the quality and purity of honey.

The bee all and end all

Even though the decision is not binding on Australian courts, it will be highly persuasive particularly in the interests of achieving consistency in the application of the Code between Australia and New Zealand. Food producers should take comfort that vague or generalised 'wellness' claims will not be caught by the Code, however producers are reminded that such claims remain subject to fair trading and consumer protection legislation which prohibits false and misleading statements in relation to goods.

The CoOL change is here

In brief: Partner Andrew Wiseman and Associate Kaelah Ford provide an update on the new Country of Origin Labelling regime which came into effect on 1 July 2016 and the Federal Government's proposed changes to the safe harbour provisions under the Australian Consumer Law.

How does it affect you?

- New country of origin labelling standards have been introduced for 'priority foods' including fruit and vegetables, meat, fish, dairy, eggs and grains.
- Businesses have a 24-month transition period in which to update their labels.
- The Federal Government has released a Bill proposing changes to the safe harbour provisions under the Australian Consumer Law (***ACL***) for country of origin claims.
- If the Bill is passed, businesses will no longer have to satisfy the '50 per cent production cost test' which should simplify the process of determining when 'made in' claims can be made.

Mandatory labels for priority foods

The Information Standard

In our last Food Law Bulletin, we reported on proposed changes to Country of Origin labelling laws. Since then, the Government has released the final version of the Country of Origin Food Labelling Information Standard 2016 under the ACL (the ***Information Standard***), which took effect from 1 July 2016.

The Information Standard requires labels for food products grown, produced or made in Australia to carry:

- a country of origin label with the well-known kangaroo logo; and
- a bar graphic indicating the amount of Australian ingredients present in the product, by ingoing weight.

Products that are only packed in Australia will not carry the kangaroo logo, as the food is not of Australian origin, but will still carry the bar chart. Wholly imported products will not need to carry the kangaroo logo or the bar chart. Some examples of the new labels are set out below:

The new labels will only apply to 'priority foods'. The Information Standard specifies a 'non-priority' list of foods that are exempt from the new labelling requirements such as confectionery, tea, coffee and alcoholic beverages. Any food not included on the non-priority list should be considered a priority food.

There is a 24-month transition period for businesses to update their labels in line with the Information Standard. From 1 July 2018, compliance with the Standard will become mandatory pursuant to section 136 of the ACL, and pecuniary penalties may apply for non-compliance. Section 31 of the Information Standard also requires businesses to keep records supporting proportion claims for 12 months after the sale of the relevant goods, so it continues to be important for businesses to ensure they have adequate material to substantiate all country of origin claims.

Proposed changes to country of origin safe harbour provisions

The Competition and Consumer Amendment (Country of Origin) Bill 2016 is designed to complement the Information Standard by introducing changes to some of the 'safe harbour' provisions businesses can rely on to justify their country of origin claims.[1] The Bill, introduced earlier this year, was not passed by both Houses before the dissolution of Parliament, and will now be a matter for consideration by the incoming Federal Government.

Businesses will not be found to have made false or misleading claims about country of origin if they meet certain criteria set out in section 255 of the ACL. The most significant changes proposed to these provisions are set out below.

Abolition of production test for 'made in' claims

Under section 255(1), a representation as to the country of origin of goods (for 'made in' claims) will not be false or misleading or deceptive where it is shown that:

(a) the goods have been substantially transformed in that country; and

(b) 50 per cent or more of the total cost of producing or manufacturing the goods as worked out under section 256 is attributable to production or manufacturing processes that occurred in that country.

1. Changes will also be made to the Commerce (Imports) Regulations 1940 to align the labelling requirements for imported food with the Information Standard and revised safe harbour provisions.

The Bill proposes the removal of the 50 per cent production test in (b) above, which is widely considered to be impractical and burdensome for business. As such, businesses will only be required to show that the goods were substantially transformed in the relevant country to justify a 'made-in' claim.

Definition of 'substantially transformed'

The Bill also proposes changing the definition of 'substantially transformed', to focus on the ingredients or components the goods are made from.

- Current definition: where the goods *'undergo a fundamental change in that country in form, appearance or nature such that the goods existing after the change are new and different goods from those existing before the change'.*
- New definition: where the goods are *'fundamentally different in identity, nature or essential character from all of their ingredients or components that were imported'.*

The Explanatory Memorandum gives the example of Brazilian cacao imported into Belgium, which is then converted to chocolate using Belgian butter and sugar. It is moulded into truffles before export to Australia. If this product were labelled as 'Made in Belgium' it would meet this safe harbour defence, as the chocolate is 'fundamentally different in identity' from the raw cacao ingredient imported from Brazil.

Beware of generic descriptions that could mislead

It is important to remember that the obligation not to mislead or deceive consumers about country of origin extends beyond direct claims such as 'Made in Australia'. Generic claims about location could potentially create a false impression that a product is made or grown in a particular country.

A recent New Zealand High Court decision illustrates this point. In that case, the Commerce Commission (the New Zealand equivalent of the ACCC) alleged that the company, New Zealand Nutritionals, had contravened the *Fair Trading Act 1986* by labelling and marketing its goat's milk dietary supplements as:

- *'New Zealand made'*; and
- *'100% NZ made and proud of it'.*

While the end products (tablets and powder) were manufactured in New Zealand, the majority of the ingredients, including the goat's milk powder, were imported from Spain. The High Court agreed with the Commission that the representations were misleading.

Under the Information Standard, it is likely an analogous goat's milk product in Australia (if classed as a priority food) would be labelled as *'Made in Australia from X% Australian ingredients'*. If a 'made in' claim could not be substantiated under the substantial transformation test, then a *'Packed in Australia, Made in Spain'* label may apply.

Conclusion

Businesses have until 1 July 2018 to transition to the new labelling Standard for priority foods, but are being encouraged to voluntarily adopt the labels now. The Australian Government has published a Style Guide and Country of Origin Labelling Tool to assist with developing compliant labels, which are available online.

While the Bill amending the safe harbour provisions has not yet been passed, it serves as a timely reminder of the importance of ensuring your business has adequate information systems in place to support its country of origin claims. The ACCC continues to have the power to issue substantiation notices, and serious penalties apply for false or misleading representations.

Food imports and the Biosecurity Act: What's changed

In brief: Law Graduate Lev Gutkin reports on recent changes to the law relating to the importation of food into Australia, introduced by the commencement of the *Biosecurity Act 2015* (Cth).

How does it affect you?

- When an import permit is required, it is now vital that it is obtained prior to the goods entering Australia.
- A larger class of goods may now be imported into Australia without a permit being obtained.
- Quarantine Approved Premises and Compliance Agreements are being replaced with a single, streamlined, Approved Arrangements system.
- Those seeking an Approved Arrangement or import permit will need to satisfy a 'fit and proper person' test, and the background of the applicant's 'Associates' may be taken into account.

The background

Australia's geographic isolation has allowed its agricultural industry to be free of many of the pests that plague other nations. Rules ensuring pests are not inadvertently introduced into the Australian ecosystem were put in place through the *Quarantine Act 1908* (Cth). The replacement of the Quarantine Act with the *Biosecurity Act 2015* (Cth), which took force on 16 June 2016, has made the applicable rules clearer and more flexible in application.

The new legislative regime includes two notable changes relating to the importation of goods into Australia: import permits will no longer be required for a wider class of goods if stipulated conditions are met, and the granting of Quarantine Approved Premises and Compliance Agreements is being replaced by a single, more streamlined process of Approved Arrangements.

A further welcome simplification from the prior law is that the provisions of the Biosecurity Act relating to the importation of goods expressly exclude the operation of any state or territory laws on this topic, providing importers with a simpler and more certain process.[1]

Import Permits

Along with the introduction of the Biosecurity Act, the Quarantine Proclamation 1998 is being replaced by the new Biosecurity (Prohibited and Conditionally Non-prohibited Goods) Determination 2016 (the ***Determination***), which takes effect from the same day as the Biosecurity Act. The Department of Agriculture and Water Resources (the ***Department***) has stated that it intends for the new Determination to impose the same import conditions as previously existed for most goods, so for now, major changes should not be expected. The updated regulatory regime features two general categories of goods:

- Prohibited goods, which must not be imported into Australia; and
- Conditionally non-prohibited goods, which may be imported if certain stipulated requirements are satisfied.

Most conditionally non-prohibited goods will require a permit to be imported into Australia, but the new regime allows for a wider class of goods to be imported permit free than was previously possible. For those goods, importers will now be able to meet specified conditions as an alternative to acquiring a permit. For example, a permit won't be required for the import of fruit, vegetables, leaves or herbs, if they have been adequately treated or processed.[2] Further, some species of fruit, vegetables, leaves or herbs will now be importable without a permit in an unprocessed form.[3]

A list of the new products that will no longer require a permit, when specified conditions are met, is provided by the Department on their website.

The new regime also allows for the Department to seek a security or bond for those seeking to import conditionally non-prohibited goods, or from those seeking an Approved Arrangement (as discussed below).[4] Importers of goods who have had dealings with the Department which have resulted in the Department being financially burdened when managing or responding to the importer's associated biosecurity risks should be conscious that a security may be required from them.

1. Biosecurity Act s172.
2. Specifically, the condition is that:
   The goods:
   (a) have been treated or processed (or both) to ensure that biosecurity risks associated with the goods (including any packaging) have been managed to an acceptable level; and
   (b) are accompanied by evidence that the condition referred to in paragraph (a) has been complied with.
   For more information, refer to the BICON website.
3. Biosecurity (Prohibited and Conditionally Non-prohibited Goods) Determination 2016 (Cth) s29; refer to the BICON website for further details.
4. See Biosecurity Act, ss 175 & 407.

According to the new law, goods from overseas automatically become subject to biosecurity control once they enter Australian territory, which includes the 12 nautical mile area around Australia, Christmas Island, Cocos (Keeling) Islands, and any other prescribed external territory. There was a concern that the new provisions of the Biosecurity Act would now impose import restrictions on fishing activities carried out outside the 12 nautical mile zone but within the exclusive economic zone of Australia. However, the Determination expressly excludes, from the definition of conditionally non-prohibited goods:[5]

> Goods sourced from the ocean, or the ocean floor, within the exclusive economic zone of Australia that have not left the exclusive economic zone of Australia before being brought or imported into Australian territory.

Biscuits, breads, and certain non-dairy cooked cakes are also expressly excluded from the requirement for an import permit or compliance with substantive import conditions.[6] The Australian Biosecurity Import Conditions website (***BICON***) states that importers of cooked versions of these goods will need to provide, on a food product label, 'importer declaration', 'manufacturer's declaration' or invoice, evidence that all fillings and toppings were cooked with the biscuits, bread or cake.

As emphasised by the Department in their Biosecurity Advice 2016-20, importers will need to apply for a permit **prior** to the arrival of goods in Australia. This advice acknowledges that in the past the Department facilitated imports that landed without a permit, allowing importers to subsequently apply for one. Under the new Biosecurity Act, the Department has expressly stated that this will no longer be the case. It further states that, where the biosecurity risk cannot be managed post arrival, 'the goods will be subject to export or destruction'.

The BICON website will remain the gateway used for checking import conditions and for making permit applications.

Approved Arrangements

The new legislative regime consolidates approvals for Quarantine Approved Premises and Compliance Agreements under a single Approved Arrangements system. In order to transition to the new regulatory scheme, operators of Quarantine Approved Premises were required to apply for, and receive, approval to be registered as an Approved Arrangement by 30 June 2016, or have their certification lapse on that date. Holders of existing Compliance Agreements will need to renew their transitional arrangements, or apply for new ones, prior to December 2017. Current approvals for registered export establishments are not affected by the introduction of the Biosecurity Act. However, due a separate legislative development, exporters of livestock should be aware that they will need an Approved Arrangement to export from 1 January 2017.

Holders of Approved Arrangements will be referred to as Biosecurity Industry Participants. To reduce the regulatory burden, all Approved Arrangements obtained prior to 29 June 2022 will be set to expire on 30 June 2022, meaning that renewal will not need to be carried out annually, although annual levies will continue to apply.

The Department's website sets out the requirements that need to be met before approval of an Approved Arrangement can be given.

Fit and proper test

Those seeking an Approved Arrangement, or an import permit, will now need to satisfy a fit and proper person test.[7] Matters that can be taken into account include breaches by the applicant or an 'Associate' of the Quarantine Act, the *Customs Act 1901* (Cth), certain breaches of the Australian Criminal Code or the *Crimes Act 1914* (Cth), or debts owing to the Commonwealth. Consideration can also be given to whether the applicant or their Associates have had an application for an import permit, or Approved Arrangement (or the prior equivalents), rejected, suspended or revoked. Of further relevance is if the applicant is convicted of an offence against, or ordered to pay a pecuniary penalty under, any Australian law.

Applicants should be particularly conscious of the impact the background of their 'Associates' can have. The term Associates may encompass a very large group of people, that goes beyond bodies corporate, including those that are concerned in, or have influence over, a business or undertaking of the applicant, or of 'a corporation of which the first person is an officer or employee, or in which the first person holds shares'.[8] As a result, corporate entities that share directors or employees with other corporations will be deemed Associates.

Conclusion

The Biosecurity Act provides a long overdue clean-up of state and Federal legislation and provides a unitary scheme for the regulation of imports. Many changes should make it easier to comply without significantly disrupting current practices.

5. Biosecurity (Prohibited and Conditionally Non-prohibited Goods) Determination 2016 (Cth) s10 (2) (b).
6. Biosecurity (Prohibited and Conditionally Non-prohibited Goods) Determination 2016 (Cth) s10 (2) (a).
7. See Biosecurity Act s530.
8. Biosecurity Act s11.

The new FDA nutrition information panel guidelines

In brief: Law Graduate Natasha Dixon reports on the new FDA guidelines regarding nutrition information labels for packaged foods sold in the USA.

The new requirements

The new guidelines will apply to packaged foods imported into the United States and will come into force on 26 July 2016. Generally, the requirements regarding the overall look of the nutrition information panel have not been altered, yet there have been some changes to the format and content of the panel. The key changes to be aware of are below.

The background

- Added sugars will now need to be included on the nutrition label, both in grams and as a percentage of the daily value.
- The serving size listed on the label will now be required to be based on the amount of food or beverage that people actually consume, as opposed to what they should be eating. Additionally, packages that are between one to two servings will be required to be labeled as one serving as people are likely to consume the item in one sitting.
- Companies will no longer need to declare the 'daily value' percentage of vitamin A and C, but instead will need to declare the percentage of vitamin D and potassium, as well as calcium and iron. They are also able to voluntarily declare the gram amount of any other vitamins or minerals.
- The font size of the total calorie count, servings per packet and serving size declarations have been increased.
- The daily value percentages listed on the nutrition label for constituents such as sodium, dietary fibre and vitamin D are now to be based on the new 2015-2020 Dietary Guidelines for Americans.
- 'Dual column' labels have been introduced for certain products that are larger than a single serve, yet could be consumed in one or multiple sittings. For these products, companies will need to provide two columns on the nutrition label to indicate the amount of calories and nutrients on both a 'per serving' and 'per package' basis.

Compliance dates

The final requirements of the new guidelines will come into force on 26 July 2016. Companies selling food in the US market will have until 26 July 2018 to comply with the guidelines, yet companies with less than $10 million in annual food sales will have until 26 July 2019 to comply.

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