AUSTRALIAN COMPETITION & CONSUMER COMMISSION

Country of origin labelling for complementary healthcare products

A guide for business

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Contents

Overview

'Complementary medicines' are therapeutic goods consisting wholly or principally of one or more designated active ingredients. They include a diverse range of products such as:

- vitamins, mineral and nutritional supplements
- herbal and homeopathic medicines
- aromatherapy products.

This guide will assist businesses to understand the application of the Australian Consumer Law (ACL) in relation to country of origin claims and in particular, when businesses can safely make a 'made in' claim about their products.

A country of origin claim can include any words and/or images that state, or imply, where a product's ingredients came from and/or where it has undergone processing. Common claims are 'Made in Australia', 'Product of Australia' and 'Grown in Australia' - or similar claims about goods from other countries.

In contrast to origin labelling requirements for food products, neither the ACL or the *Therapeutic Goods Act 1989* require complementary medicine products to carry country of origin labelling. However, if companies choose to make such claims they must be aware of the laws against false, misleading or deceptive claims.

Note: This guide sets out principles businesses should consider when determining whether to make a particular country of origin claim. Consumers often make purchasing decisions based on the information businesses supply about their products so it is important this information is truthful, clear and accurate.

This document does not constitute legal advice and it is up to individual businesses to decide what claims are most appropriate for their products.

While this guide reflects the ACCC's current views, ultimately the interpretation of the law will be up to the courts. The ACCC always recommends that businesses seek independent legal advice when deciding how to label their products.

The Australian Consumer Law

Under the ACL, businesses are prohibited from making false or misleading representations or engaging in misleading or deceptive conduct about the origin of goods. Whether a representation is false, misleading or deceptive will depend on the particular circumstances of the case and the overall impression created. If a **reasonable conclusion** from the use of particular words or images is that a good originated from a particular country when this is not the case, the business making this claim is likely to breach the ACL.

It's your responsibility to ensure all claims you make about your goods are truthful and accurate. It's not a defence to say that you 'didn't know' the claim was misleading. Failure to substantiate your claim could lead to the ACCC, another ACL regulator, or a third party taking court action against you.

The consequences of breaching the ACL may be significant and could include court-imposed financial penalties of up to $1.1 million per breach.

Making a country of origin claim

In general, businesses are free to make any representation they wish to about their goods provided the representation is **truthful and accurate**. It's up to individual businesses to determine the claims they can make about their products.

In order to give businesses some certainty, the ACL sets out several 'safe harbour' defences which provide a degree of legal protection for businesses that choose to make country of origin claims about their goods. If your claim satisfies a safe harbour, you will have the benefit of a statutory defence against an allegation that the country of origin claim is false, misleading or deceptive under the ACL.[1]

The safe harbours cover representations that goods:

- were **grown in** a particular country, or
- are the **product of** a particular country, or
- were **made or manufactured in**, or otherwise originated in, a particular country.

Each safe harbour has its own criteria that must be met if a business wishes to rely on it. It will be up to individual businesses to provide evidence to show they have met the requirements for a particular safe harbour defence.

The safe harbours only provide a statutory defence against claims that a representation is false or misleading for products sold in Australia. If you make country of origin claims about products that you sell overseas, the laws in the importing countries will apply.

Note: Failure to satisfy the safe harbour criteria for a particular claim doesn't necessarily mean that a business is unable to make such a claim. You may still choose to make that type of origin claim provided an ordinary, reasonable consumer wouldn't consider it to be false, misleading or deceptive.

1 Complying with the safe harbours will provide a statutory defence to an allegation that a business has contravened s. 18, 29(1)(a) or (k) or 151(1)(a) or (k) of the ACL.

The safe harbour defences

From February 2017, the criteria businesses must meet in order to rely on a safe harbour defence with regard to a country of origin claim are as follows:

Making a 'grown in' claim

For the purposes of the ACL, a business can safely make this claim if each of its **significant ingredients** or components were 'grown'[2] in that country and all, or virtually all, of the processes involved in the production or manufacture of the goods occurred there too.

- **Example:** Australian-grown herbs are dried and ground in Australia to create a 'digestion aid'. A business could safely claim the resultant product was 'Grown in Australia'.

Making a 'product of' claim

Similarly to 'grown in', the ACL provides that a business can claim a good is the 'product of' a country if all the **significant ingredients** or components originated there and all, or virtually all, of the processes involved in the production or manufacture of the goods occurred there too.

- **Example:** Emu oil, extracted from Australian emus, is refined and bottled in Australia. A business could safely claim the emu oil was 'Produced in Australia'.

Making a 'made in' claim

A 'made in' claim is a representation about the production process undertaken to create a good. You will have the benefit of the ACL's 'made in' safe harbour defence if your product underwent its last substantial transformation in the country named.[3]

A product is substantially transformed if:

- it was 'grown in' or 'produced in'[4] that country, or
- as a result of one or more processes undertaken in that country, the end product is **fundamentally different in identity, nature or essential character** from all of its imported ingredients or components.

Note: 'Manufacture' in relation to complementary medicines has a particular meaning under the Therapeutic Goods Act. It includes processes such as assembling, packaging, labelling or testing goods, or their ingredients. The question of whether a product has been 'manufactured' within the meaning of the Therapeutic Goods Act is a separate and different legal test to whether it has been substantially transformed for the purposes of making a 'made in' or 'manufactured in' claim under the ACL.

2 Please refer to the definition of 'grown' set out in subsection 255(1) of the ACL.
3 From 23 February 2017, the 50 per cent cost of production test is **no longer relevant** for businesses wishing to meet the 'made in' safe harbour criteria.
4 As defined by section 255 of the ACL.

‘Substantial transformation’

A good with imported ingredients or components can claim to have been ‘substantially transformed’ in a country if processing there has resulted in a finished product that’s **fundamentally different** from the imported ingredients that went into it. This will require a close assessment of the effect that the processing in that country has had on the final product compared to the imported ingredients.

The ‘made in’ safe harbour defence will only be available if the end product is fundamentally different in **identity, nature or essential character** from all of its imported ingredients or components.

The ACL doesn’t define what the terms **‘identity’, ‘nature’ or ‘essential character’** mean. If you’re trying to work out if you’ve substantially transformed something, you should consider the ordinary meaning[5] of the terms:

- **Identity:** the condition, character or identifying features of a thing.
- **Nature:** the particular combination of qualities belonging to a thing by birth or constitution, native or inherent character.
- **Essential character:** the necessary or indispensable qualities that distinguish something from others.

A change in form or appearance will not be enough to satisfy the substantial transformation test. Manufacturers should exercise caution when making a ‘made in’ claim unless the processing in the country claimed has clearly resulted in a product that’s fundamentally different from the imported ingredients used to make it.

If a good was ‘grown’ or ‘produced’ in a particular country, it can also **automatically claim** to have been ‘made’ there. In this scenario, it will not be necessary for the product’s supplier or manufacturer to show that the good has been transformed into something fundamentally different in order to make a ‘made in’ claim. In such circumstances, it’s up to individual businesses to decide which claim to use.

- **Example:** Australian-grown eucalyptus leaves are processed in Australia to make a pure oil that is marketed as providing sinus relief and reducing cold symptoms. In this instance, the oil would qualify as ‘Australian Grown’ or ‘Produced in Australia’ as its significant (and only) ingredient is grown in Australia and all processing occurred in Australia. It could also safely claim to be ‘Australian Made’.

Providing additional or alternative information

The amount and type of information you provide to consumers about your goods is important. Origin claims about goods are generally not limited to representations about which country a good was grown, produced or made in. For example, businesses could instead make a claim that reflects the:

- origin of particular ingredients or components eg ‘contains French lavender oil’
- ‘place of origin’ of the goods eg ‘Made in Tasmania’[6]
- ownership of the company eg ‘Australian owned’
- actual processing undertaken in a certain country eg ‘blended in Australia’
- testing undertaken to comply with safety requirements eg ‘Quality tested and certified to Australian standards’.

A business has the option to consider the use of an alternative claim where their product is unlikely to meet the criteria for a particular safe harbour defence. If businesses choose to make alternative claims or provide additional information about the origin of their goods, they must ensure the representations are accurate, truthful and comply with the ACL.

Businesses cannot rely on small print and disclaimers as an excuse for an overall misleading impression.

5 As taken from the Macquarie Dictionary.

6 A business cannot rely on a safe harbour defence in relation to a non-country place of origin claim. If a business wishes to make a place of origin claim, they must be confident that a reasonable consumer wouldn’t consider the claim to be false, misleading or deceptive.

‘Made in’ claims for complementary medicine products

Broadly, ingredients in complementary medicines fall into two categories: ‘actives’ and ‘excipients’. **Actives** are responsible for the physiological or pharmacological actions performed by a therapeutic good. By contrast, **excipients** are not therapeutically active and do not perform a physiological or pharmacological action. Common excipients include fragrances, preservatives, fillers or binders.

In Australia, complementary medicines are commonly processed using actives and excipients imported from other countries. To gain the benefit of the ‘made in’ safe harbour, a business will need to show that the end good after processing in Australia is fundamentally different in **identity, nature or essential character** from all of its imported ingredients.

In this guide we consider:

- dry blending
- encapsulation
- tabletting
- herbal extractions
- essential oils
- semi-solid formulations

It’s important to remember that this guidance is general in nature. The question of whether a specific product has been substantially transformed will depend on the individual product.

Note: The process of developing these products may involve significant effort dedicated to research, testing and quality assurance. While such steps may be important to the development of these products, these processes of themselves will not be determinative in relation to whether a fundamentally different end product has been created.

Dry blending

Many complementary medicine powders are single active products that have been blended with excipients (eg flavours, colourings or flow agents).

The ACCC considers that a business would likely have the benefit of the 'made in' safe harbour defence if an Australian-grown or produced active is processed and subsequently blended in Australia with imported excipients. In this instance, the therapeutic character of the product derives from the Australian active. In our view, the blending of the imported excipients with the Australian active would produce a therapeutic good that is fundamentally different in identity, nature or essential character from its imported ingredients. By contrast, blending Australian excipients with an imported active is, in the ACCC's view, unlikely to constitute a substantial transformation because the end product retains the identity, nature and essential character of the imported active.

In addition, the dry blending of primarily or wholly imported ingredients (both actives and excipients) is unlikely to satisfy the substantial transformation test. In the ACCC's view, while blending in these circumstances may result in an end product that's somewhat different to its individual imported ingredients, it is unlikely to create a fundamentally different end product.

- **Example:** Imported Vitamin C powder is blended with several other minor imported vitamins, fillers and flow agent and packaged in Australia. The powder is sold as a 'Vitamin C complex' powder.

  In this instance, an otherwise edible and consumable Vitamin C product has been mixed and presented in a slightly enhanced form. In our view, this processing in Australia would not be sufficient to meet the substantial transformation test as the end product is not fundamentally different from the imported ingredients.

Encapsulation

Encapsulation refers to the process of converting a starting material into a standardised finished dose capsule form. The starting materials may be formed into soft or hard capsules. Capsules often contain single active ingredients such as fish oil, bee propolis, herb and plant extracts.

In the ACCC's view, encapsulating imported actives is unlikely to constitute a substantial transformation. While encapsulation results in a change to the form and appearance of the imported active, in our view it doesn't result in a fundamental change to its **identity, nature or essential character** when compared to the imported ingredient.

The addition of bulking oils and other excipients such as Vitamin E (added to prevent oxidisation) during processing is also unlikely to result in a substantial transformation. In our view, the finished product is not fundamentally different and will have retained the identity, nature and essential character of the imported active(s).

Note: Although the encapsulation of imported actives is unlikely to meet the safe harbour criteria for making a 'made in' claim, businesses can choose to instead highlight the actual processing that has occurred in Australia. For example, a business could label their product as 'Encapsulated in Australia' as long as this was truthful and accurate.

- **Example:** A business imports 10 strains of bacteria into Australia; each of which claim to support healthy bowel movements and a healthy immune system. They are encapsulated into an imported hard capsule casing to form a 'probiotic capsule'. It's our view that this is **unlikely to constitute a substantial transformation** as the end product will not be fundamentally different in identity, nature or essential character to its imported ingredients. Combining the actives has simply packaged them in a more convenient form so consumers can take one capsule instead of 10.

- **Example:** A business imports krill oil into Australia and processes it into soft capsules. In the ACCC's view, the krill oil soft capsule isn't fundamentally different in identity, nature or essential character to the imported krill oil material used to create it. The end product retains the clearly established identity and traditional use of krill oil. While its delivery method and portion size has changed, its fundamental properties have not.

  While the additional process of forming the capsule shell in Australia from imported gelatine may change the shape and appearance of the imported gelatine, the capsule filling (ie the imported active) has not been substantially transformed when compared to the imported oil.

  The criteria for the 'made in' safe harbour defence requires the end product to be fundamentally different in identity, nature or essential character to **all** of the imported ingredients.

  As the krill oil is consumable as a liquid, the real point of difference between the end product and its imported ingredients is that the capsule packages the oil in a more convenient or desirable form for consumers to take.

Tablet manufacture

Tablet manufacture is a multi-step procedure that involves three key stages: the blending (wet or dry), granulation and compression of actives and excipients (including binders and disintegrants) into tablet forms.

In the ACCC's current view, a substantial transformation is likely to occur in Australia where imported actives and imported excipients undergo the full tableting process to transform raw bulk materials into a tablet here. We consider that this processing of actives and excipients together results in a finished product (a tablet) that possesses a fundamentally different identity or essential character to the individual imported ingredients it comprises.

- **Example:** A number of actives are individually imported into Australia in bulk. They are combined with imported excipients (notably a binder), granulated, lubricated and then compressed into tablet form to make a multivitamin. In our view, the combination of these processes creates an end product that **is fundamentally different in identity, nature or essential character** from the imported raw materials (actives and excipients) that went into its production.

Of course, this will depend on the nature and extent of the production processes and the particular product in question. For instance, the ACCC is aware that ingredients are sometimes brought into Australia in the form of 'granulations'. A granulation is a compressible powder made up of granules, with each granule containing a mix of the ingredients of the formula.

The ACCC considers that the step of compressing imported granules into a tablet is unlikely to satisfy the 'made in' safe harbour defence. In the ACCC's view, the compression of the imported granules alters the physical form of the granules, but is unlikely to create a fundamentally different end product for the purposes of the substantial transformation test.

- **Example:** Glucosamine granules are imported and compressed into a tablet. While the process of compression allows the manufacturer to control the dosage of the active, in our view, the glucosamine tablets are **not fundamentally different in identity, nature or essential character** from the imported glucosamine granules.

Herbal extraction

These products are created by extracting a herb's medicinal profile (ie the active) out of the raw or dried materials using a solution of alcohol and water or glycerin and water. The extraction process allows the actives to be sufficiently concentrated to be therapeutically effective. Herbal extracts may be used in a range of forms including liquids, powders or tablets.

We consider that there is likely to be a substantial transformation where raw imported ingredients are processed in Australia to isolate the herbal active(s). However, herbal extracts purchased overseas and bottled in Australia would not meet the safe harbour criteria for making a 'made in' claim, even if additional ingredients are added during the bottling process.

Essential oils

Essential oils are found in the flowers, seeds, roots and various other parts of plants. They are commonly extracted from the raw material by one of two key methods: distillation or cold pressing.

Similar to herbal extraction, the ACCC considers that the processing of imported raw plant material in Australia to draw out its volatile aromatic compounds (ie the small organic molecules that give the plant material its aroma) is likely to result in a substantial transformation of the raw imported product.

On the other hand, a business that imports essential oils and bottles them in Australia would not meet the test for substantial transformation.

Within the practice of aromatherapy, different essential oils are commonly blended together with the aim of producing certain desired responses in the user. In the ACCC's view, blending imported essential oils would not result in a substantial transformation of those imported ingredients.

- **Example:** Mandarin and neroli essential oils are imported and mixed together in Australia to create a 'stress relief blend'. Individually, these oils are traditionally associated with relaxation and reducing stress and tension. The combination of these imported oils into a single blend would not meet the substantial transformation test. In our view, the end product is not fundamentally different in identity, nature or essential character from the imported individual oils.

Semi-solid formulations

Semi-solid formulations are mostly creams or ointments that, unlike many therapeutic goods, are applied topically rather than ingested.

The processing of raw imported ingredients into a semi-solid preparation that has been chemically and physically modified to penetrate the skin or mucosa by the active may support a 'made in' claim.

However, if a cream or lotion is imported in bulk and combined with other minor ingredients like fragrances, pigments or preservatives, the mixing of the imported ingredients in Australia would not amount to a substantial transformation and a 'made in' Australia claim should not be made.

- **Example:** Imported arnica herb undergoes processing in Australia to extract the active and is then combined with a number of raw local and imported ingredients to form a cream that claims to assist with pain and swelling. In the ACCC's view, the extraction of the herb and its dilution into a topical cream that can safely permeate the skin would likely support a 'Made in Australia' claim.
- **Example:** An aloe vera lotion is imported in bulk into Australia where it is enriched with imported Vitamin A and shea butter. The blending of the imported ingredients into a single product is unlikely to qualify for a 'Made in Australia' claim. In the ACCC's view, the finished lotion is not fundamentally different and **retains the identity, nature and essential character** of the imported aloe vera lotion.

Questions and answers

Is my product eligible to use the 'Australian made, Australian grown' (AMAG) kangaroo logo?

The AMAG logo is a registered trademark overseen by the Australian Made Campaign Limited (AMCL) under a certification scheme. Certification schemes are used to give consumers confidence that a good meets a particular standard.

To use the logo in relation to a therapeutic good, a business must be registered with AMCL and meet the criteria set out in the AMCL Code of Practice. Fees and conditions apply. For more information, including on the process for obtaining a license to use the logo, visit the AMCL website or call 1800 350 520.

Is the number of ingredients in my product relevant to whether it has been substantially transformed?

No. The number of ingredients in a good is generally not relevant to the question of whether those ingredients have been substantially transformed. Substantial transformation is not a 'numbers game'. A product with two ingredients may satisfy the test in a given instance, whilst a product with 12 ingredients may not. The only question relevant to whether substantial transformation has occurred is whether the end product is **fundamentally different in identity, nature or essential character** from all of its imported ingredients.

If I give my product a name that reflects its therapeutic benefits rather than its imported ingredient(s), can I claim to have substantially transformed its identity?

No. The identity of a good is more than just its name. Naming your product isn't a process that changes its **identity, nature or essential character**. For example, encapsulating imported fish oil and selling the resultant product as 'brain health' capsules doesn't mean that you have created a fundamentally different product. It is still a fish oil capsule, just with a different name. Businesses should ensure that the name of their product does not create a false or misleading impression about the product's uses or benefits, otherwise they are likely to breach the ACL.

Can I make a country of origin claim based on where the named ingredient in my product is grown, produced or manufactured?

It depends on the circumstances. In the case of complementary medicines, it will be up to individual businesses to decide how detailed or explicit they want to be. A business could choose to make a claim about the origin of individual ingredients eg 'Made with wild Alaskan salmon oil'. However, businesses should be cautious to ensure that a country of origin claim based on the origin of a single ingredient doesn't create a misleading impression.

- **Example:** A business imports US grown gingko biloba into Korea. It also imports hard capsules from China and excipients (primarily flow agents) from a range of countries. The ingredients are combined to create a hard capsule in Korea which is then imported into Australia for sale to consumers. The manufacturer labels the product as 'Made in USA' as the significant ingredient (the gingko biloba) is from there. In the ACCC's view, this claim is likely to be misleading. It could reasonably lead a consumer to think that all or the majority of processing of the capsules has occurred in the USA when this is not the case.

  If the manufacturer chooses to make a country of origin claim, they should consider making a claim that more clearly reflects what has happened where. For example, 'Encapsulated in Korea' or 'Encapsulated in Korea using US grown gingko biloba'.

As part of manufacturing my product, I blend multiple ingredients from multiple sources. After blending, I can't pick apart, or separate the ingredients. Does this mean I have substantially transformed them?

Not necessarily. In most cases, the mere blending of imported ingredients is unlikely to result in a substantial transformation of those imported ingredients, even if they can't be easily separated. Please refer to the section entitled 'Dry Blending' on page 6 for further information.

Is the location of where I package or label my product relevant to where I have substantially transformed it?

No. The question of substantial transformation is about the effect the processing has on the finished product when compared to the imported ingredients and is unrelated to where the end product is packaged and/or labelled.

What is the ACCC's role in complementary medicines?

The ACCC is an independent Commonwealth statutory body that administers the *Competition and Consumer Act 2010* (CCA), which contains the ACL. The ACCC promotes compliance with these laws and where appropriate, takes action against businesses that breach the law.

The ACCC does not have a specific role in relation to the regulation of therapeutic goods, but may take action against any business if their conduct breaches the ACL or the CCA more broadly.

The Therapeutic Goods Administration is Australia's regulatory authority for therapeutic goods, including complementary medicines. They carry out a range of assessment and monitoring activities to ensure therapeutic goods available in Australia are of an acceptable standard. Please visit their www.tga.gov.au or call 1800 020 653 for further information.

Where can I find more information?

More information about the safe harbour defences and substantial transformation can be found in the ACCC's 'Country of origin and the ACL' guide, which is available at www.accc.gov.au/cool.

If you have a specific enquiry, you can submit an online form at www.accc.gov.au/contact-us or call our Small Business Hotline on 1300 302 021. We note that we are unable to provide legal advice in response to enquiries.

Your industry association may also be able to assist with any enquiries you may have about the changes to the safe harbour defences in the ACL.


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