Australian Government
Department of Industry, Innovation and Science

Eligibility for origin claims in the Complementary Medicines Sector

Consultation Regulation Impact Statement for the Legislative & Governance Forum on Consumer Affairs

Department of Industry, Innovation and Science

3 October 2019

https://consult.industry.gov.au/cool-taskforce/clarifying-eligibility-for-origin-claims

Contents

UPLOADING SUBMISSIONS

Please Upload Submissions via Department of Industry, Innovation and Science Consultation Hub

Website	https://consult.industry.gov.au/cool-taskforce/clarifying-eligibility-for-origin-claims
Mail	Department of Industry, Innovation and Science Trade Facilitation PO Box 2013 Canberra ACT 2601
Phone	02 6213 7116
Enquiries	tradefacilitation@industry.gov.au
Closing	**5pm (AEDT) Wednesday 30 October 2019.**

The principles outlined in this paper have not received Government approval and are not yet law. As a consequence, this paper is merely a guide as to how the principles might operate.

The department may conduct meetings with key stakeholders to discuss the matters outlined in this paper.

GLOSSARY OF TERMS

Term	Description
ACL	Australian Consumer Law
CAF	Consumer Affairs Forum (COAG)
RIS	Regulation Impact Statement
C-RIS	Consultation Regulation Impact Statement
AMAG	Australian Made, Australian Grown
AMCL	Australian Made Campaign Limited
TGA	Therapeutic Goods Administration
CMA	Complementary Medicines Australia
ACCC	Australian Competition and Consumer Commission
CoOL	Country of Origin Labelling
ARTG	Australian Register of Therapeutic Goods
GMP	Good Manufacturing Practices (TGA)
VMS	Vitamins, minerals and supplements
ASMI	Australian Self-Medicated Industry

1. Introduction

In February 2017, in response to consumer concerns about confusing food labelling, amendments were made to Country of Origin Labelling (CoOL) laws requiring that food products are labelled with origin information. The reforms also changed the basis for gaining access to the premium Australian Made, Australian Grown (AMAG) logo for an origin claim. These reforms were set out in changes to the Australian Consumer Law (ACL) agreed with states and territories, and are now in force.

To include the AMAG logo in a food origin label, the amended ACL requires that the product accords with the AMAG Code of Practice (the Rules) that govern use of the logo. The key test of this Code is the product be *substantially transformed* in Australia. To provide certainty to food producers the ACL introduced 'safe harbour defences' (under subsection of the 255(2)), which describes products and process which would satisfy the Code and be eligible to use the logo.

The CoOL reform process concentrated almost exclusively on food however the changes to the substantial transformation test applies to all products across the economy. The expectation at the time of the reforms was that very few products would be affected by this new test.

The law changes have created problems. Consumers of complementary medicines have less access to country of origin labelling then before the changes to the substantial transformation test. This has occurred because a number of products complementary medicines no longer meet the substantial transformation test, meaning they cannot use the AMAG logo. It is worth noting that one of the key benefits associated with the original CoOL reforms was that the AMAG logo would speed up a consumer's assessment of the country of origin of products. Law changes denying use of the logo have had the reverse effect for complementary medicines.

A related problem identified by the Complementary Medicines sector (the Sector) is the likely reduction in investment, loss of jobs and lost sales due to the AMAG logo being less available for the Sector's products. From earlier research conducted by the Department of Industry, Innovation and Science (DIIS), it is known that origin labelling is valued by consumers. Consequently, if consumers are denied access to the AMAG logo on complementary medicines, it is possible that consumer purchasing behaviour, affecting gross sales will be affected

Unlike food products, complementary medicines are not required by law to apply origin labelling. The Sector believes the substantial transformation test is not an appropriate measure of the transformation imported raw materials go through to become complementary medicines manufactured in Australia. Some product lines do not meet the test, despite being well established Australian manufactured products and regulated in accordance with the Therapeutic Goods Administration's (TGA) Good Manufacturing Practice (GMP). The Sector believes the negative effects of the CoOL reforms on origin labelling for complementary medicines are inadvertent but significant damage to brands and sales is occurring, particularly in growing export markets.

The Complementary Medicines Taskforce was established in December 2018 to examine industry's concerns. The taskforce, managed by DIIS conducted consumer and industry surveys, and consulted directly with the industry's peak bodies – Complementary Medicines Australia and Australian Self Medication Industry. Producers of complementary medicines (and brand owners) were also consulted. The taskforce also engaged with consumers and consumer advocates with knowledge of the sector.

The Complementary Medicines Taskforce submitted its report to government in February 2019. Subsequently the Minister for Industry, Science and Technology, the Hon Karen Andrews MP, announced on 5 April 2019 that the Australian Government will support continued access to the AMAG logo for Australian complementary medicines manufactured in Australia in production facilities regulated by the TGA.

This RIS process is designed to put options forward in consideration of the issues faced by consumers and the Sector. The C-RIS is guided by COAG requirements and designed to assist the Legislative and Governance Forum on Consumer Affairs (also known as the Consumer Affairs Forum or CAF) in formatting a policy. CAF consists of all Commonwealth, State, Territory and New Zealand Ministers responsible for fair trading and consumer protection laws. Following consultation through this C-RIS, a Decision RIS identifying the preferred policy option with the greatest net benefits will be used to inform the CAF decision making process.

Complex links exist between the CoOL changes, their genesis, the importance of the complementary medicines industry, the role of the AMAG logo as a mark of country of origin and the role that TGA regulation could play in establishing country of origin. Each of these areas will be explored below and lead to a discussion on the extent of the problem, and options to address the problem.

2. Consultation process

The Australian Government recognises that implementation of CoOL reforms for the Sector requires CAF's agreement through the national consumer policy framework operates as a joint initiative between the Commonwealth and each state and territory. In this regard implementation of CoOL changes through the ACL requires the agreement of the Commonwealth, states and territories.

Accordingly, state and territory governments will be consulted on the proposals contained in this C-RIS, consistent with the requirements in the Intergovernmental Agreement for the ACL.

Public consultations also form a key step in examining the options explored in this C-RIS. The objective of the consultation process is to gather additional evidence and data to inform the decision by CAF.

Public insight gained through the Complementary Medicines sector, consumers and others is crucial to ensure that the final agreement through the Decision RIS is comprehensive and accurate. Once the consultation process has been concluded, a Decision RIS will be published to share the analysis and results of the consultation process and how that has been used to inform a preferred policy option.

All submissions to the consultation process will be published on the DIIS Consultation Hub, unless contributors have indicated that they would like all or part of their submission to remain in confidence.

Specific questions may arise from this C-RIS which may not have been considered at the time of drafting. We may undertake further consultation with key stakeholders if necessary.

Both this C-RIS and the Decision RIS will be published on the Office of Best Practice Regulation (OBPR) website.

Key Stakeholders

Key stakeholders include:

- consumers and their representatives
- complementary medicines businesses, including their supply chain and industry representatives
- other business or users of the AMAG logo, or with an interest in the AMAG logo
- state and territory governments and agencies
- Commonwealth agencies

Request for feedback and comments

We welcomes submissions on the content of this C-RIS.

The consultation process will run for a period of four weeks. If you would like to make a written submission, please provide it before **5pm (AEDT) Wednesday 30 October 2019**.

The earlier that you provide a submission, the more time DIIS has to consider your views.

Questions outlined in this C-RIS provide guidance as to the kind of information being sought through this consultation. There is no obligation to answer any or all of the questions, and there is no limit to the length of submissions.

All information (including name and contact details) contained in submissions will be made available to the public on the DIIS website, unless you indicate that you would like all or part of your submission to remain confidential. Automatically generated confidentiality statements in emails do not suffice for this purpose. Respondents who would like part of their submissions to remain confidential should provide this information marked as such in a separate document.

A request made under the Freedom of Information Act 1982 (Commonwealth) for a submission marked ‘confidential’ to be made available will be determined in accordance with that Act.

Providing a submission

There are a few options providing your response to their C-RIS. You may use one or more of these options:

- upload a formal written submission
- answer C-RIS questions via an online survey
- make a general comment.

Formal written submissions should be uploaded using the consultation page of the DIIS website. For accessibility reasons, please upload responses in a Word or RTF format. An additional PDF version may also be submitted.

3. Background

The complementary medicines industry

Definition

Complementary medicines are therapeutic goods, consisting wholly or principally of one or more designated active ingredients. The term complementary medicines is commonly understood to cover a diverse range of products with intended therapeutic benefits including:

- vitamins, minerals and supplements (VMS)
- herbal, homeopathic and traditional medicines
- sports supplements
- aromatherapy products
- weight loss products

In Australia, the complementary medicine manufacturing industry produces products designed to improve health and wellbeing, including sleep and stress relief, maintaining immune and digestive system health, support nutritional needs and various other indications. This includes general health products including pills, oils, tablets and powdered mixes containing vitamins, herbs, minerals and specialty supplements such as:

- multi-vitamins and single vitamins
- dietary supplements comprised of herbal and traditional ingredients (e.g. echinacea, ginseng, primrose oil, olive leaf extract, spirulina and ginkgo biloba)
- non-herbal supplements (e.g. fish oils and omega fatty acids, calcium, glucosamine, probiotics, proteins and other mineral supplements)

Sales of vitamins, minerals, and supplements

Retail sales of complementary medicine products in Australia have grown strongly over the last five years, but the growth is expected to be more stable over the next five years as per tables 1 and 2 below.

Table 1: Sales of Vitamins and Supplements in Australia (AUD Million)

Year	2013	2014	2015	2016	2017	2018
Sales	1,928.3	1,983.6	2,521.4	2,683.2	2,818.2	2,937.8

Source: Euromonitor, Consumer Health in Australia 2019

Table 2: Sales of Vitamins and Supplements Australian - forecast (AUD Million)

Year	2019	2020	2021	2022	2023
Forecast	2,989.8	3,041.0	3,090.8	3,131.5	3,165.6

Source: Euromonitor, Consumer Health in Australia 2019

Domestic markets

In 2018, the high growth rate of the Sector in recent years, steadied as Australian consumer demand levelled out for vitamins and dietary supplements. In 2018 Blackmores, Swisse and Sanofi-Aventis Australia were market leaders, with very little separating the three players in terms of vitamin sales. Together, these three companies account for well over half of total sales of vitamins in Australia and they are among the leading trend-setters, regularly launching new products that conform to emerging consumer trends. Their products are popular with local and foreign consumers alike for their high quality, innovative features and market positioning.

Alongside Blackmores and Swisse, several major brands dominate the market including Berocca, Bioglan, Nature's Own, Cenovis, Ostelin, MICROgenics, Bio-Organics and Recoverlyte. Key contract manufacturers include Vitex and Lipa Pharmaceuticals. While many of the brands owned by Sanofi use the AMAG logo, it should be noted that both Blackmores and Swisse do not currently use the AMAG logo in their product labelling or branding.

Domestic sales channels

Sales of complementary medicines to Australian consumers occurs through two sales channels – store based and non-store based which includes home shopping, internet retailing and direct selling. As indicated in Table 3 below, Australian consumers primarily gain access to complementary medicines through in-store sales.

Table 3: Distribution of vitamins and dietary supplements by percentage of sales value

Channel	% of total sales
Store-based retailing	81.4
Non-store retailing (including home shopping, internet retailing and direct selling)	18.6

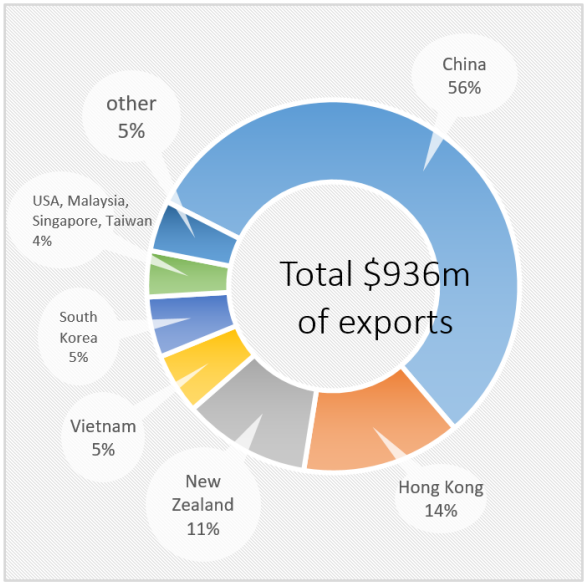
Source: Euromonitor, Consumer Health in Australia 2019

In both distribution channels, discount players such as Chemist Warehouse are attracting increasing numbers of consumers with highly discounted prices on a very wide range of products across the Sector. The rise of discount pharmacies has provided consumers with a high level of competition allowing consumers to access their preferred products at a discount price, consequently increasing sales for the Sector. Also, with online retailing benefiting from the recent entry of online retail giant Amazon, internet retailing is likely to remain the most dynamic retail channel for complementary medicines into the future.

International markets

In 2018, Australia exported $936 million of complementary medicine products according to the current definition of export commodities developed by Austrade and CMA. Of this, $714 million were vitamins. Figure 1, below provides a more detailed country specific break up of exports.

Figure 1. Proportion of international complementary medicine exports by country.



Growth in VMS exports in 2018 continued to be driven by demand from Chinese consumers. This chart identifies the importance of China and Hong Kong to Australia's VMS exports. These two markets combined receive 70% of the value of Australia's exports in this Sector. The industry has also said that trade with New Zealand is driven by the end user in China.

The $936 million export figure likely underestimates the total value of VMS exports for two reasons. First, the statistics produced by Austrade for the CMA do not include all products considered to be VMS (and to a greater extent complementary medicines). One of the main products being fish oils, which are considered an Oil and Fat Manufacturing Industry product according to the Australian Bureau of Statistics (ABS) classification system. As fish oils are classified as one commodity, there is difficulty distinguishing between a food product and a complementary medicine product, or between fish oil in a tank compared to fish oil in a capsule.

The second reason is due to Daigou[1] trade. From research provided to the CMA, this accounts for roughly 20% of Australian domestic sales but those sales are not captured in official export figures. Based on this, Daigou vitamin 'exports' could be worth an additional $130 million; and VMS 'exports' in total could be worth an additional $500 million.

Australia is reliant on imports of raw ingredients for the production of complementary medicine products. Initial findings suggest that Australian firms may add significant value to the outgoing products. For example, in relation to vitamins, analysis by the Office of the Chief Economist shows the Australian vitamins industry adds about 63% ($11 per kilogram) of value to vitamins it exports.

Overview of Australian complementary medicines manufacturing

All states host complementary medicine production facilities however no production facilities are located in the Northern Territory or the Australian Capital Territory. Facilities are concentrated in Queensland, Victoria and New South Wales. The TGA is responsible for licencing manufacturing sites that are involved in the supply chain of listed medicines in Australia.

With the manufacturing industry facing strong completion with its Asia-Pacific rivals, operators have been positioning themselves as world-class drug manufacturers backed by R&D capabilities.[2] The Sector supports advanced manufacturing in Australia; Vitex and Swisse are members of the Advanced Manufacturing Growth Centre designed to transform Australian manufacturing to be globally competitive and generate demand for jobs. The sector also engages in local R&D activities in Australia.

As production activities are gradually being outsourced to developing countries offering cheap labour, more Australian manufacturers are recognising the need to compete on value rather than cost. Most commonly, this involves contributing innovative products, components or services within global supply chains. - Advanced Manufacturing Growth Centre

Australia's regulatory framework has been a point of differentiation in overseas markets and Sanofi has advised that it invested in manufacturing facilities in Australia because of this benefit.

[1] Daigou is an emerging form of cross-border exporting in which an individual or a syndicated group of exporters outside China purchases commodities for customers in China. (https://en.wikipedia.org/wiki/Daigou).
[2] http://clients1.ibisworld.com.au/reports/au/industry/industryoutlook.aspx?entid=188

TGA data indicates there are 148 licenced Australian manufacturing locations in the Sector in Australia performing one or more of the following steps:

- Manufacture of dosage form
- Labelling & packaging
- Testing Microbial
- Testing chemical & physical
- Release for supply

The TGA notes that there is also a regulated non-mandatory sixth step – Secondary packaging.

Complementary medicines production is heavily reliant on imported ingredients. Generally, the ingredients fall into two main categories – actives and excipients. Actives are ingredients 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 addition to actives and excipients imported in bulk, finished or partially finished products either in retail-ready packaging or in bulk form are also imported by the Sector.

Analysis undertaken by IBISworld reported 2,800 people are employed in the manufacture of vitamins and supplements. This is in line with the DIIS Office of the Chief Economist estimates based on ABS data that there are about 2,000 people employed in the vitamin manufacturing segment of the complementary medicine Sector.

In addition to the manufacturing of the products, there are a number of people employed along the supply chain to bring the products to market. The industry's peak body, CMA, on the basis of research conducted by Remplan in 2016, reports that the Australian complementary medicines industry is estimated to directly employ people in 13,200 jobs across the product supply chain. This 13,200 would include the 2,000 involved in manufacturing.

Therapeutic Goods Administration – Good manufacturing practice

In Australia, complementary medicines are regulated as therapeutic goods under the *Therapeutic Goods Act 1989* by the TGA. The TGA provides a national system of regulatory controls relating to the quality, safety, efficacy, performance and timely availability of therapeutic goods used in Australia or exported from Australia. All medicines, including complementary medicines, must be entered in the Australian Register of Therapeutic Goods (ARTG) in order to be legally imported, exported, manufactured or supplied to consumers.

TGA's Good Manufacturing Practice (GMP) ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use. Quality Control is that part of Good Manufacturing Practice which is concerned with sampling, specifications and testing, and with the organisation, documentation and release procedures which ensure that the necessary and relevant tests are actually carried out and that materials are not released for use, nor products released for sale or supply, until their quality has been judged to be satisfactory.

Therapeutic Goods Administration – Good Manufacturing Practice

There are two paths manufacturers receive TGA GMP approval - TGA GMP certification and TGA GMP clearance. The main difference between the two is GMP certification requires a physical on-site inspection by the TGA while a GMP clearance is provided on the basis of an on-site inspection of the *overseas* manufacturing facility by an accepted comparable overseas regulator and a TGA desk-top review of documentation.

There are no differences between the domestic and overseas inspection procedures.

GMP requirements for Australian complementary medicines

In Australia, the *Therapeutic Goods Act 1989* requires, with certain exceptions, that manufacturers of medicines (a type of therapeutic goods) hold a licence. It is an offence, carrying heavy penalties, to manufacture medicines for human use without a licence unless the manufacturer or goods are exempt from this requirement.

Only Australian manufacturing sites can obtain a manufacturing licence. If any of the manufacturing steps are performed in Australia, each nominated manufacturer of that manufacturing step is required to obtain a TGA manufacturing 'licence'. A TGA licence is required regardless of whether the medicine ingredients are sourced internationally or locally.

To obtain a licence, an Australian manufacturer must demonstrate compliance with the relevant code of GMP. This is usually, but not always, done through an on-site inspection.

Overseas manufacturers can instead obtain GMP certification following a successful on-site inspection by the TGA.

GMP certification applications are required to be submitted by the Australian sponsor[3] or an agent acting on the Australian sponsor's behalf. On successful close out of an on-site inspection, the Australian sponsor is issued a 'GMP Clearance' for the purposes of registration or listing.

[3] A sponsor is a person or company who does one or more of the following: exports therapeutic goods from Australia; imports therapeutic goods into Australia; manufactures therapeutic goods for supply in Australia or elsewhere; arranges for another party to import, export or manufacture therapeutic goods.

Alternatively, sponsors may apply for a GMP clearance via a Desk-Top Assessment (DTA) pathway. This process has two further pathways determined by the agreements and arrangements in place between the TGA and other comparable overseas regulators, provided that the products are also regulated as medicines in the other country.

The two pathways for GMP Clearance are the Mutual Recognition Agreement (MRA) pathway and the Compliance Verification (CV) pathway.

The TGA uses internationally harmonised manufacturing standards to allow manufacturers to operate in an international environment. All manufacturers of medicines, including complementary medicines, are required to comply with the GMP Principles set out in the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) Guide to Good Manufacturing Practice for Medicinal Products.

PIC/S presently comprises 52 Participating Authorities coming from all over the world (Europe, Africa, America, Asia and Australasia). However, not all Participating Authorities require products regulated as 'listed medicines' in Australia to comply with these GMP principles[4].

No batch of product (including validation batches) manufactured prior to licensing or certification can be sold or supplied within Australia, or exported from Australia, unless prior approval has been obtained.

The country of origin reforms

The issue of CoOL on food products has been examined through an independent review of the food labelling law and policy commissioned by Food Safety Australia New Zealand (FSANZ) in 2011, and the House of Representatives inquiry into origin labelling for food in 2014. These investigations found that consumers did not always understand the meaning of country of origin statements. Many felt that these statements did not provide appropriate information. Labelling regulations did not require businesses to provide the proportion of Australian ingredients and only a small proportion of businesses opted to do so.

In 2015, Commonwealth agencies were directed by the Australian Government to explore options for reform. This led to a detailed consultation process which included the commissioning of qualitative and quantitative market research and an industry cost-benefit analysis of impacts on the food sector.

Market research showed the importance of CoOL to the Australian community and revealed that consumers mostly wanted to know the amount of Australian ingredients in the foods they bought. Research also indicated that labels featuring the AMAG logo, a bar chart and a statement indicating the proportion of Australian ingredients best conveyed this information.

[4] For example many products considered as complementary medicines in Australia are considered in other countries as food supplements and regulated according to food regulations

Consumers found terms like ‘Made in’ and ‘Product of’ particularly confusing. Almost 60% of consumers mistakenly believed a ‘Made in Australia’ claim indicated that the product was entirely processed in Australia from Australian ingredients, rather than that it complied with the 50% production cost and substantial transformation tests.

Consumers wanted more information regarding the origin of the products they were eating. As set out in the CoOL Consultation and Decision Regulatory Impact Statements (RIS) that preceded the legislative changes, providing consumers with the origin information they most wanted in relation to food required changes to the ACL. This included mandating clear country of origin labelling for food that indicates where the food was made and, for food claimed to be ‘Australian’, displaying the proportion of Australian ingredients. Consumers also wanted the requirements for making Australian origin claims tightened, particularly where ingredients were imported, but cared little about relative costs of production.

Country of origin labelling reforms primarily aimed at addressing these problems were agreed with states and territories in 2016. These reforms comprised:

- A new mandatory country of origin labelling requirements for food, set out in the *Country of Origin Food Labelling Information Standard 2016*, made under s.134 of the ACL.
- Revised safe harbour defence provisions for country of origin claims for all goods (not just food) under Part 5-3 of the ACL.

The reforms were not intended to influence consumer preferences. Rather, they aimed to ensure businesses provided consumers with the information they needed to make informed purchasing decisions.

The impact on non-food sectors of the changes to the substantial transformation test was only briefly explored under the CoOL reform process. The vast majority of consumer and business engagement under the CoOL C-RIS process focussed on labelling changes, and then mostly on the food sector. The benefits and costs of the broader CoOL changes were not well established for non-food sectors or consumers of non-food products.

Country of origin labelling legislation

The ACL provides automatic defences (safe harbours) that can be relied on in the event of court action claiming that a business’ country of origin claims about a good are false, misleading or deceptive. To qualify for the safe harbour in relation to a ‘made in’ claim, the ingredients, to manufacture a product, need to have been ‘substantially transformed’ in Australia.

The *Competition and Consumer Amendment (Country of Origin) Act 2017* came into force on 22 February 2017. The Act revised the safe harbour defences for origin claims on all products (food and non-food) sold in Australia, by removing the 50% production cost test previously included in the safe harbour defence for most country of origin claims.

The Act also clarified and tightened the definition of 'substantial transformation' which is now the only requirement under the safe harbour defence for claims that goods are made in a particular country.

The previous definition of substantial transformation was:

Goods are substantially transformed in a country if they undergo a fundamental change in ***form, appearance or nature*** *such that goods existing after the change are new and different goods from those existing before the change.*

The current definition of substantial transformation is:

Goods are substantially transformed in a country if … as a result of one or more processes undertaken in that country, the goods are ***fundamentally different in identity, nature or essential character*** *from all of their ingredients or components that were imported into that country.*

The change to the definition of 'substantial transformation' made it clearer that substantial transformation requires the final manufactured product to be fundamentally different from its imported inputs in identity, nature or essential character. These changes were made to better reflect consumer expectations about what constitutes 'made in' and also to better align with the position that international trading partners have adopted.

A product claimed to be 'Australian Made' can still meet this safe harbour defence even if it contains entirely imported inputs or components, provided the product underwent its last substantial transformation in Australia.

What is an origin claim?

The ACCC provides guidance to consumers and business in regard to country of origin claims. An extract of this information is provided below. Further information can be obtained via https://www.accc.gov.au.

Country of origin claims are representations about where a product's ingredients or components came from and/or where it has undergone processing. Country of origin claims can be made using words and/or pictures. Common country of origin claims are that a product was 'made', 'produced' or 'grown' in a certain country.

The ACL doesn't require non-food products to carry country of origin labelling, although other laws may do so. Businesses can however, choose to make country of origin claims about these goods.

All businesses, whether they are legally required or choose to display country of origin labelling, are prohibited from making false or misleading representations or engaging in misleading or deceptive conduct about the origin of goods (both food and non-food).

If a reasonable conclusion from the use of particular words or images is that a good was grown, made or produced in a particular country when that is in fact not the case, there is a risk of breaching the ACL.

To help businesses that wish to make country of origin claims regarding their goods, the ACL provides defences ('safe harbours') for certain claims. The defences relate to claims a product that is one of the following:

1. was 'Made in' a particular country
2. is the 'Product of' or 'Produce of' a particular country
3. was 'Grown in' a particular country
4. carries a text and graphic country of origin label (referred to as a 'mark') under an Information Standard relating to country of origin labelling

If a business is able to meet one of the 'safe harbours', then the relevant claim is automatically deemed not to be false, misleading or deceptive.

'Made in' claims

These claims are about production process rather than content. A product with a 'Made in Australia' label will not necessarily contain Australian ingredients or components. To establish the safe harbour defence the goods must have been substantially transformed in the country of origin being claimed.

A product is 'substantially transformed' in a country if it was either:

it was 'grown' or 'produced' in that country

as a result of one or more processes in that country, the end product is fundamentally different in identity, nature or essential character from all of its imported ingredients or components

It will not be sufficient for the purposes of the ACL for a product to be somewhat different from its imported parts. Mere changes to the form or appearance of imported goods will not satisfy the substantial transformation test.

'Product of' claims

Traders who wish to alert consumers that their good is the 'Product of' or 'Produce of' a country can establish a safe harbour defence by demonstrating that each significant component or ingredient of the goods originated in the country, and all, or virtually all, of the production processes took place in the country.

When determining whether something is a significant ingredient or component, businesses should consider the importance of the ingredient or component to the nature or function of the product. An ingredient or component does not have to be a certain percentage to be 'significant'.

Source: https://www.accc.gov.au/publications/advertising-selling/advertising-and-selling-guide/marketing-claims-that-require-extra-care-premium-and-credence-claims/country-and-place-of-origin-claims

The complementary medicines sector and the substantial transformation test

In considering the issues outlined in this C-RIS, it is useful to gain perspective on what products or processes within the complementary medicines manufacturing industry do or do not already meet the requirements for substantial transformation, and are therefore eligible to apply for use of the AMAG logo.

The ACCC provides useful guidance in this regard. The following information is sourced from the ACCC's guidance document for industry titled 'Country of origin labelling for complementary healthcare products: A guide for business, March 2018'. This document is available via the ACCC website at https://www.accc.gov.au

Encapsulation

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).

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

Herbal extraction

These products are created by extracting an herb's medicinal profile (i.e. the active) out of the raw or dried materials using a solution of alcohol and water or glycerine 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 (the ACCC) 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 (i.e. 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.

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.

The ACCC's guidance to the Sector has been adopted by AMCL to assist them to decide which products can carry the AMAG logo. A Federal Court case[5] involving a test of the AMCL's interpretation of the substantial transformation test was recently concluded. AMCL, using the ACCC's guidance had withdrawn access to the AMAG logo for imported fish oil being encapsulated in Australia. The Federal court ruled that encapsulation in Australia of imported fish oil (from Chile) and Vitamin D (from China) did not qualify for the 'Made in Australia' logo as mere encapsulation did not represent 'substantial transformation' of a product as required under the Australian Consumer Law.

[5] http://www.judgments.fedcourt.gov.au/judgments/Judgments/fca/single/2018/2018fca1936

The food sector and the substantial transformation test

To further consider issues in this paper a useful perspective is also provided by the ACCC's guidance on food products and processes that are, or are not, likely to meet the requirements of the substantial transformation test. Food products are a useful comparison to complementary medicine products in that a large proportion of these products are ingested by consumers. As such, consumer understanding and expectations of origin claims and labelling are likely to be similar across these two sectors. Table 4, below is an indication of the ACCC's view on what may or may not meet substantial transformation in the food sector.

Table 4 Country of Origin Food Labelling: A guide for business current as at March 2019.

Processing	**Substantially transformed?**
Roasting, grinding and blending imported whole spices to make a curry paste	Yes
Blending imported dried herbs to make herbal tea	No
Roasting an imported nut	No
Roasting a green coffee bean to make coffee for drinking	Yes
Chopping up imported fruit to make a fruit salad	No
Chopping up imported apples and combining it with other ingredients to make an apple pie	Yes
Slicing/dicing/grating imported fruits and vegetables, meats or cheeses	No
Mixing imported meat with sauces, spices and vegetables to make a ready-to-bake meatloaf	Yes
Adding a marinade to imported chicken meat	No
Forming imported mince into patties	No
Curing and drying imported pork to make bacon	Yes
Smoking imported bacon to add flavour	No
Mixing imported ingredients together and using the mixture to bake a cake	Yes
Dry blending imported rice and imported herbs to make a spiced rice mix	No
Adding a chocolate coating to an imported biscuit	No
Baking a frozen raw imported pie	Yes
Browning or finishing off par-baked imported bread	No
Juicing imported fresh fruit and vegetables to make a juice	Yes
Reconstituting an imported fruit liquid concentrate to make a juice	No
Mixing imported prawns and squid, seasoning and processing them to make a mixed seafood snack	Yes
Crumbing an imported prawn	No
Cooking imported dried pasta, rice or legumes	Yes

Source: https://www.accc.gov.au/publications/country-of-origin-food-labelling

The Australian Made, Australian Grown Logo

The ‘Australian Made, Australian Grown’ (AMAG) logo, the triangular logo encasing a kangaroo, is a registered certification trade mark developed in 1986 by the Australian Government primarily as a consumer information tool – through which Australian businesses could assure Australians and other consumers that their products were genuinely Australian because they met certain rules.

The logo provides information to consumers in Australia and overseas that goods using the logo have met particular requirements under ACL to be able to display the logo. It is the most recognised and trusted country of origin symbol in Australia, enjoying a 99.6% recognition level amongst Australian consumers and is considered a very strong marker that the product that carries it is of Australian origin.[6]

Following the 2017 CoOL reforms, the Commonwealth assumed responsibility for use of the AMAG logo on food products sold in Australia under the terms of the *Country of Origin Food Labelling Information Standard 2016.* [7] The Australian Made Campaign Limited (AMCL) retains responsibility for licensing use of the AMAG logo on all other products sold in Australia and overseas, and on Australian food products sold internationally.

Australian Made Campaign Limited (AMCL)

AMCL is a not-for-profit public company established in 1999 by the Australian Chamber of Commerce & Industry and the network of state and territory chambers of commerce, with the cooperation of the Australian Government. The primary function of AMCL is the administration of the AMAG logo. AMCL regulates use of the logo by issuing 12-month renewable licences which allow businesses to use the logo.8 Over 2,700 companies are currently licensed to use the AMAG logo on more than 16,000 products.

[6] Roy Morgan Research, 2017
[7] The Food Information Standard is available at https://www.legislation.gov.au/Details/F2017C00920
[8] AMCL 2019. Website About Australian Made

History and use of the Australian Made, Australian Grown logo

Use of the logo, officially called the Australian Made, Australian Grown Certified Trademark, is governed by the Australian Made Code of Practice.

The code of practice aims to:

- Provide information to licensees of the 'Australian Made, Australian Grown' logo on their rights and obligations to ensure the consistent, correct usage of the 'Australian Made, Australian Grown' logo.
- Build consumer confidence that goods promoted in association with the 'Australian Made, Australian Grown' logo comply with established legislative consumer information and country of origin labelling standards, promote the benefits of buying Australian goods.
- Raise the domestic and international profile of goods that are produced in Australia.

As the then owner of the logo, the Commonwealth licensed its use to AMCL in 1999. In 2002, the Commonwealth transferred ownership of the logo to AMCL via a Deed of Assignment and Management, which set out strict conditions under which AMCL may administer the logo. In 2007, the logo coverage was expanded and it became the 'Australian Made, Australian Grown' (AMAG) logo.

Immediately prior to the 2016 CoOL reforms, the AMAG logo was owned and managed by AMCL under deeds with the Commonwealth in accordance with the Code of Practice.

On 1 July 2016, the Country of Origin Food Labelling Information Standard 2016 (the Information Standard) came into effect. The Information Standard sets out mandatory country of origin labelling requirements for food products sold in Australia.

A key feature of the new labels is the inclusion of the logo as part of the country of origin label for foods grown, produced or made in Australia. As a consequence of this, the Deed of Management between AMCL and the Australian Government was amended in January 2017.

Under the amended deeds, use of the AMAG logo on food products sold domestically is free of charge to the producer but must be used under the terms of the Information Standard published by the Australian Government. AMCL retains responsibility for licensing use of the logo on other Australian products sold in Australia and overseas, and on Australian food products sold overseas.

The Complementary Medicines sector's use of the AMAG logo

The Complementary Medicines Taskforce was able to access data for just over 90% of domestic sales of the vitamins, minerals and supplements subset of complementary medicines in 2018.9 Of that share of the market at least four in five domestic sales (by value) do not carry the AMAG logo. This figure is derived from retail market share values for companies in the Sector, and whether those companies are registered to use the AMAG logo.

Of the remaining 10% of the market that we do not have information on, we make no assumption on whether the AMAG logo is used on some, none, or all of their products. At a minimum, of the total market (100% of VMS products sold in Australia) at least 73.6% of those products by value, do not carry the AMAG logo.

Wider economy use of the logo

The AMAG logo is used across a wide variety of sectors across the economy. The industrial sector has the greatest usage of the logo at 20%. Beauty, skin care and cosmetics represents 15% of total logo usage with food and beverage (12%) clothing and footwear (eight per cent), pharmaceutical and medical (six per cent) and furniture (five per cent) representing the next largest users of the logo. Around 31% of logo usage falls into the broad 'other consumer' category.10

The complementary medicines sector's response to the CoOL Consultation RIS

The CoOL Decision RIS, released on 3 March 2016, noted the changes to the safe harbour defences were generally supported by all industry sectors. However, the Sector in its submissions during CoOL reform consultation had different views on the need to retain the 50% production cost test.

CMA - July 2015

> *Should the 50% or more of total cost test be removed, industry will require a clear definition of substantial transformation. A greater focus on the processes involved to determine substantial transformation would be of benefit to Australian producers.*

ASMI – February 2016

[9] ibid

[10] Australian Made Campaign Limited 2018 Annual report to the Department of Industry, Innovation and Science.

There should be no change to the definition of 'substantial transformation' and the existing definition (in subsection 255(3) of the ACL) should be retained.

ASMI is concerned that despite this being a profound change to the existing definition, there were no specific questions that addressed this change in the Consultation RIS. Many other respondents may also have missed this profound change.

The complementary medicines sector's proposed regulatory solution

Before considering a regulatory solution to the issues raised by the Sector it is appropriate to examine the proposed solution Complementary Medicines Australia (CMA), one of the Sector's peak bodies, put to the Australian Government.

The proposal put forward by CMA (as published on their website cmaustralia.org.au) notes that:

'The Competition and Consumer Act 2010 , subsection 255(3)(b), provides a mechanism for including in the Regulations examples of particular classes of goods that have undergone certain process that would otherwise have the same result as those described in subsection 2(b), the 'substantially transformed' definition.

Subsection 255(3)(b) of the Act provides that:

'Without limiting subsection (2), the [Competition and Consumer] regulations may include examples (in relation to particular classes of goods or otherwise) of processes or combinations of processes that, for the purposes of that subsection, have the result described in subsection (2)(b).'

Therefore, it is proposed (by CMA) that wording to the following effect be included in the Regulations for the purposes of 255(3)(b):

'In relation to the class of goods that are finished medicinal products, the combination of processes specified for this part are the 'manufacture of dosage form' and 'packaging and labelling', when performed in accordance with prescribed Manufacturing Principles within the Therapeutic Goods Act.'

CMA further state that:

'This mechanism would efficiently and succinctly address the unintended consequences that have arisen due to the amended Australian Consumer Law. That is; the production of medicines, which when manufactured under processes of Good Manufacturing Practice, substantially transforms them into goods that are fundamentally different in identity, nature, or essential character from the raw material components used in their production.'

All complementary medicine products sold in Australia are regulated by the TGA. As noted above, the TGA regulates five mandatory steps and one non-mandatory step in the manufacture of the Sector's products. The TGA does not require the steps to be carried out in Australia. Domestic facilities supplying to the domestic market are *licensed* by the TGA. Overseas facilities supplying to the domestic market and domestic facilities which supply export markets only, are *certified* by the TGA.

Under the sector's request to the Australian Government, it was conceivable that products meeting all of the TGA's mandatory steps could have taken place in certified offshore facilities and carry the AMAG logo. It is unlikely that the expectations of consumers would be met if a product manufactured offshore from no Australian ingredients carried the AMAG logo. In consultations with the Complementary Medicines Taskforce, CMA noted that their intent was to focus on Australian manufacturing, and that they would support refinement of their initial proposal to achieve this target.

As the AMAG logo references Australian manufactured activity, it is reasonable that the logo be associated with activities that involve a transformative action. Reviewing the five mandatory GMP steps and one non-mandatory GMP step closer, shows that only one of those steps is related to the transformation of a product. That step is referred to as the 'Manufacture of dosage form'.

Manufacture of dosage form involves a series of activities that transforms the raw bulk product into the final form the product is taken in by the consumer. The other steps relate to testing of products, bottling and labelling, not the transformation of an ingredient into a further or final stage of production. Therefore of the regulated TGA steps, the 'Manufacture of dosage form' step most closely represents activities that the AMAG logo could be associated with.

It is reasonable to expect that a proposed regulatory solution to address industry concerns would require some or all of the activities that fall under the 'Manufacture of dosage form' step would need to occur in Australia for the logo to remain connected to its intent.

Country of Origin Labelling Complementary Medicines Taskforce

The policy proposals outlined in this C-RIS were informed by stakeholder consultation, including consumer and industry market research, undertaken by the Complementary Medicines Taskforce.

Previous consultation

The Department led the Complementary Medicines Taskforce established in December 2018 and reported to the Australian Government at the end of February 2019. Through the taskforce, we engaged with stakeholders through two separate surveys (one with complementary medicines businesses and stakeholders and the other with consumers).

The complementary medicines industry survey was widely distributed. Members of both complementary medicines peak bodies; CMA and the Australian Self-Medicated Industry (ASMI) received the survey. Austrade notified 40 non-CMA members, who were active in the Sector and had received export market development grants. AMCL notified AMAG logo licensees about the survey. The survey was open from 22 January to 12 February 2019.

The survey sought responses to questions relating to:

- characteristics of businesses
- activities they are involved in
- imported ingredients
- exports
- use of the AMAG logo
- impact of the CoOL changes, including any impact on production methods

The survey received 26 responses, of which 24 were from businesses involved in the manufacturing of complementary medicines. About a quarter of the Sector's businesses responded to the survey.[11]

Consumer research firm Colmar Brunton was commissioned by DIIS to undertake consumer research in January 2019. The objective of the research was to understand consumer purchasing behaviour and preferences for the use of the AMAG logo on a range of complementary medicine products. Information obtained through this work has been reflected in this C-RIS.

The consumer research involved facilitating 12 consumer focus groups and an online consumer survey of 2100 consumers.

Industry consultation

The Complementary Medicines Taskforce surveyed the Sector to gather their views on the 2017 CoOL legislation changes and the affect they have had on the industry.

While all exporting complementary medicine manufacturers who responded to the survey were aware of the changes, one respondent (a raw material supplier) was not aware of the February 2017 changes to CoOL requirements.

Business characteristics

Firms who responded to the survey ranged across the spectrum of turnover levels (Table 5) and employee numbers (Table 6). Most firms that answered the survey had a wholly Australian-based workforce, or very close to it.

[11] The TGA have 142 listed manufacturers. The CMA consider 82 of these to be part of their industry group. CMA represents 70% of all product sales and the entire value chain.

Table 5: Firms by turnover range

	$50k to less than $200k	$200k to less than $2m	$2m to less than to $10m	$10m to less than $50m	$50m to less than $100m	$100m or more
Number of firms	3	1	8	3	3	5

Table 6: Firms by employment range

	1–4 employees	5–19 employees	20–199 employees	200 or more employees
Number of firms	4	6	9	5

Imported ingredients

All but one of the firms surveyed imported raw materials; yet more than half do not import any finished or near finished products. The products imported by complementary medicine manufacturers are largely raw or slightly processed:

- Half of respondents imported 80% or more of their raw material, while four firms imported less than 40% of their raw material.
- Meanwhile, only a fifth of respondents imported less than 40% of their bulk or raw ingredients from overseas.
- For products in a finished or near finished state, 88% of responding firms indicated that less than half of their ingredient imports were in a finished or near finished state. Only one firm imported 80% or more of its ingredients in a finished or near finished state.

When asked about individual products, several respondents explained that their import decision is based on the lack of some products within Australia and is sometimes influenced by seasonal availability. In addition, some products are patented and therefore only available from one country.

This is consistent with feedback from consultation where industry representatives advised the Complementary Medicines Taskforce that Australia does not produce some of the key ingredients required to manufacture complementary medicine products, and they must therefore be imported.

Export sales

The complementary medicine manufacturers' business reliance on exports sales varies considerably:

- A quarter of responding firms reported exporting 80% or more of their total production, while nearly half of respondents exported less than 50% of their output.

As a result, there was considerable variation in firms' revenue from export sales over the 2017-18 financial year. Of the ten firms that provided data in relation to this area:

- four reported earning less than $1 million from export sales
- four reported earning between $1-5 million
- only two firms reported $40 million or more in export revenue

Eight of the top 10 export destinations cited by respondents were located in Asia and the Pacific, with the top export destinations being China, Hong Kong, the United States and Vietnam

Australian origin claims

Two-thirds of survey respondents used Australian origin claims on 90% or more of their product ranges. Only two respondents reported using such claims on less than 30% of their ranges.

Firms that use Australian origin claims said they use them equally for both international and domestic markets. One respondent further noted its business aims to base as much of its supply chain in Australia, including the manufacture of its packaging and labelling.

AMAG logo

Despite the AMAG (Australian Made, Australia Grown) logo being a well-recognised brand, both domestically and internationally, only around half of survey respondents used the logo on their products.

- For the firms that said they do use the logo, they used it on at least 80-100% of their product range.
- For the firms that said they do not use the logo, most said they would wait for the rules to be further refined [in their favour].

A number of firms, including two of the largest who did not complete the survey, noted during consultation that they have been successful in getting their brand recognised as 'Australian made' without the logo, including in the Chinese market. Several firms noted that they would be likely to use the logo in the future, when they expanded to new markets where their brand is not synonymous with being Australian.

Survey results confirm the importance of the Australian origin branding to the complementary medicine manufacturing industry. Firms that responded to the survey considered that Australian origin claims were an important reputational asset in competitive international markets.

Insight gained from survey respondents indicated that:

- The price premium enjoyed by products claiming to be Australian made was said to compensate for the additional costs associated with manufacturing those products in Australia.
- Australia was consistently reported to be a 'highly regarded' and 'trusted' source country for complementary medicines, with Australian products reputed to be of 'superior quality and safety' (particularly due to an assumption of high purity for the ingredients used). Survey respondents further said that this reputation underpins 'consumer confidence' in Australian produced complementary medicines.
- In the domestic market, Australian origin claims were deemed 'less important but still reassuring to local consumers who are interested in where the product is made.'

Respondents noted that the credibility or implied quality of complementary medicines made in Australia was primarily attributable to the TGA's oversight of industry processes. They consistently highlighted that it was the TGA quality control and enforcement system that distinguished Australian products from other competing countries in Asia and North America, where complementary medicines are regulated as foods. The traceable nature of Australia's supply chains was also cited as another pillar of trust for Australian complementary medicines.

The quality and safety implied with goods made in Australia is seen as a significant marketing tool for complementary medicine manufacturers.

- All firms that used the logo believed it to be beneficial to them.
- Only three respondents did not believe the use of the logo increased their international competiveness (although these firms still believed it to be beneficial to their businesses).
- The use of the logo influenced a majority of the firms' business decisions (employment, marketing or investment).
- Only three respondents said their firms did not make business decisions based on the use of the logo.

Some respondents noted those reputational benefits were in part a return on logo licensees' own investment in marketing and establishing the 'Made in Australia' brand both domestically and overseas, including through industry groups.

In terms of the logo's impact on price, views were mixed:

- Whilst almost two thirds of respondents said that using the logo does not affect the price they can charge, most agreed that the logo affects customers' perception of quality and their willingness to buy.
    - Some said the logo is critical for sales in China and that it adds significant value and credentials to their brands.
    - One firm suggested that the logo 'used to be important but has become a commoditised logo and that every company under the sun uses it but because

it is not regulated it has no impact anymore'. Another firm said 'it was a benefit back in the early days but now it's just expected'.

    - While there is limited official research on the Daigou trade, media reports have suggested that Daigou shoppers are able to sell goods at 20-30% higher in overseas market than the Australian RRP. This includes brands that have a strong Australian brand but contain no origin labelling.

- Some respondents explained that including an Australian origin claim on their labelling or packaging affects what they can charge for their complementary medicines. The higher perceived quality allows them to justify premium pricing for authentic Australian products.

Over 70% of responding firms agreed that the availability of the AMAG logo affects the quantity of products they sell. Some explained that it is difficult to provide evidence to this effect since many firms have only ever used the AMAG logo. However, they argued that the loss of the AMAG logo would cause doubt in overseas customer's minds about the quality of products.

Consumer consultation

The Complementary Medicines Taskforce commissioned consumer research to examine consumer preferences for the use of the AMAG logo on a range of complementary medicine products.

The aim of the research was to gather information that provides an accurate, representative and defensible view of the importance of the AMAG logo on purchasing decisions and consumer expectations of the use of the logo on vitamins, minerals and supplements. The specific objectives of the research included understanding:

- The importance of the AMAG logo to the complementary medicines consumer; and
- Consumer preferences for the use of the AMAG logo on an array of complementary medicine products including:
    - when the logo should be used
    - under what circumstances would logo use be an inappropriate designation of 'Made in Australia'

Of the Australian consumers surveyed, 78% either purchase or use complementary medicines. While there was great variety in why some products were purchased over others, the most common consumer purchasing drivers were price (62%) and brand (50%). The research showed that country of origin is not something Australian consumers immediately looked for or noticed when purchasing complementary health products, as reflected by survey and focus group responses. However country of origin ranked fifth on purchasing drives and upon probing during the focus group sessions, most consumers said they would prefer a product that was made in Australia.

The research indicated that brand choice is based predominantly on a perceived faith or trust in that brand. These views are based on the brand's perceived reputation, prominence,

familiarity and perception of quality. Some consumers admitted that they would prefer a known brand that was not made in Australia over an unknown brand that was made domestically if the quality and value for money was perceived to be higher. It was also found that price is a considerable factor or driver in consumers' choice of vitamins, minerals and supplements. Specifically, there was a relationship between increased price and perceived product quality.

The quality of complementary medicines is evaluated on the physiological changes or improvements noticed by consumers. Past experience was also important for some who had trialled and experimented with different brands and products. The strength of the ingredients and the form of product is also considered by many when choosing complementary medicines.

Only 11% of surveyed consumers nominated country of origin (other than Australia) as a deciding factor when purchasing complementary medicine products. Consumers stated that as long as the products are 'Made in' a country perceived to be quality, trustworthy and with rigorous quality control, such as the US, UK and Europe, consumers did not mind where these products were made.

There was a strong theme of perceived quality for domestically manufactured products. The online survey results demonstrated that 65% of Australians expect the quality of onshore manufactured complementary medicines to be better than products made elsewhere, while 22% felt they would be the same. Further to that, 54% of Australians felt that the effectiveness of locally made complementary medicines would be better than those made elsewhere, while 32% felt it would be comparable. This stems from the understanding that products sold in Australia would have undergone strict quality testing.

When consumers were shown the AMAG logo, participants responded positively to this label, trusting it almost immediately. Consumers feel the AMAG logo guarantees them a wholly Australian product – from the sourcing of ingredients through to the manufacture and packaging.

On being made aware that the current AMAG labelling rules contradicted consumers' expectations, some consumers doubted how high Australian standards were when it comes to regulation of complementary medicine products, given some products can be claimed as 'Australian Made' when they contain imported ingredients. Many assumed that the complementary medicine products they purchased that were 'Australian Made' were from local ingredients and were surprised when told this was not necessarily the case.

It should be noted that an 'Australian Made' claim is not linked to Australian sourced ingredients under the current legislative regime. Even before the new substantial transformation test came into force in February 2017, both the previous substantial transformation test and the 50% production cost test allowed products consisting entirely of imported ingredients to qualify for an Australian origin claim if that product met those tests. Understandably, this is a level of detail that may not be apparent to most consumers who have not studied the ACL.

Whilst certain foods now require mandatory labelling of the proportion of imported ingredients, non-food products do not. Overall, most agreed that the country of origin

terminology, despite being simple, created confusion as consumers identify three key elements in the overarching process – sourced ingredients, manufacture and packaging.

When prompted to consider CoOL on vitamins, minerals and supplements, consumers indicated that they would like to see CoOL apply to vitamins, minerals and supplements as seen below.

Observations from the consumer research commissioned by DIIS suggests that surveyed consumers, if considering origin claims, would prefer greater clarity regarding the proportion of ingredients that are from Australia when purchasing complementary medicine products.

4. Statement of the problem

The problem created by the CoOL reforms to the substantial transformation test effects two broad categories – consumer's and the Sector.

The consumer problem

Prior to February 2017 when the definition of substantial transformation changed, consumers could regularly see the AMAG logo used specifically on many complementary medicines manufactured in Australia. Even though the ingredients of complementary medicines were often imported, the manufacturing of the product consumed was undertaken in TGA regulated facilities and a number of products claimed Australian Made status and sought use of the logo.

Through a law change, those same products ceased to be able to claim Australian Made status under the safe harbour defences and so lost access to the logo even though nothing may have changed in the production process, or where the products were manufactured. This has resulted in changed country of origin labelling information for consumers who, through the CoOL law changes, now receive different product labelling information compared to the origin claims allowed under the superseded substantial transformation test. As noted earlier, even if origin labelling of complementary medicines may not be the primary reason to purchase a product, origin labelling is seen still by many consumers as an important consideration when purchasing.

The change to the CoOL laws inadvertently created a contradiction in regards to the Sector where a product is deemed to be manufactured in Australia under one Australian law (regulated by the TGA), but not Australian Made under the ACL's safe harbour defences. Consumers may perceive an inconsistency where a product was manufactured in Australia but not 'made in Australia'.

The Sector's problem

As has been noted earlier, the Sector has expressed concerns to the Australian Government that changes to CoOL laws mean that many of its products will no longer meet the revised requirements of the substantial transformation test that came into effect in 2017. Products that no longer meet this test cannot access the AMAG logo.

This may undermine a product's ability to compete in some export markets, or cause manufacturers (or brand owners) to move production off-shore, putting Australian manufacturing and jobs at risk.

The Sector had reason to believe the CoOL changes would not affect their ability to make origin claims. The CoOL Decision RIS recognised that some non-food stakeholders were concerned that a revised definition of substantial transformation might be too strict. However, given the generally supportive response to the proposed changes to the safe harbour defences, the RIS concluded that there would be a likelihood that non-food firms would continue to meet the revised safe harbour defences if they met the defences in place prior to the law change:

> *Overall, it is expected that food and non-food businesses that currently make these claims will be able to continue to make the claim. (CoOL Decision RIS)*
>
> *For non-food products, the removal of the 50% production cost test will not be replaced with other information. However, given that business stakeholders support its removal and it is expected that businesses already using the claim will be able to continue to do so, it is unlikely that this amendments will be a concern to consumers. (CoOL Decision RIS)*

That said, in the cost analysis, there was some recognition that this might not always be the case:

> *Some of any benefit accrued through the removal of the 50% production cost test could be countered by the clarification of 'substantial transformation'. While such clarification will mean some businesses will be able to make claims about where their products are made more easily, others might need to reconsider their current claims. The extent to which clarification of 'substantial transformation' would mean businesses would have greater or lesser ability to make 'Made in' claims could not be quantified. (CoOL Decision RIS)*

The Sector argues that it has been unfairly disadvantaged by the changes driven by labelling of food products.

For the Sector, the key changes to the law introduced in 2017 were the changes to the country of origin safe harbour defences – particularly the change in the definition of substantial transformation. As the Sector relies almost exclusively on imported raw ingredients, these ingredients must be substantially transformed in Australian for an 'Australian Made' claim to be protected by the safe harbour defences. Removal of the 50% production cost test had minimal impact, given it applied only if the substantial transformation test was also met.

Following enactment of the new CoOL laws, the Sector has pointed to a number of perceived anomalies in the guidance provided by the ACCC to various sectors as to what constitutes substantial transformation of an imported ingredient. The Sector claims the regulatory processes they are required to follow under the TGA's GMP means many of the imported raw ingredients (for instance bulk imported vitamin powders) are more 'transformed' than the transformation of products of other sectors that use imported ingredients/materials to gain access to the AMAG logo. CMA submitted these claims to the Complementary Medicines Taskforce, as well as businesses within the Sector, and have also expressed these view directly to representatives of the Australian Government.

Anomalies of AMAG logo use; Food products versus complementary medicine products as identify the by the Complementary Medicines Sector

The sector raises a number of anomalies where certain foods can gain the Australian made logo, whereas many complementary healthcare products are restricted form using the logo. Examples the sector cites as anomalies includes:

- Combining imported soap noodles with pigments and fragrances to create bars of Soap
- Cooking imported dried pasta, rice or legumes
- Baking a frozen raw imported pie

Each of the above examples can use the AMAG logo, whereas a complementary medicine consisting of imported raw materials that then goes through domestic processes cannot claim use of the logo such as:

- Dispensing
- Blending
- Compression
- Film coating
- Testing and packaging

Of note is that food carrying the AMAG logo is required to disclose the proportion of Australian ingredients via a visual bar, whereas, if an eligible complementary medicines product does carry the logo, there is no requirement to disclose the proportion of Australian ingredients

The Sector's desire for further consideration of the rules around substantial transformation was supported by comparisons to products in other sectors. For example, consumers' views and expectations of labelling and claims on food products often aligns with their expectations on complementary medicine products. This is primarily because so many products within the complementary medicines sector are ingested by the consumer to obtain a perceived health benefit.

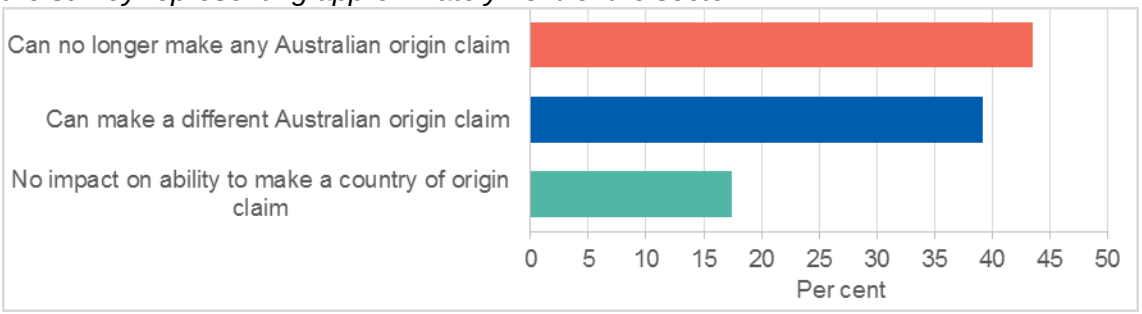
Impact on the Sector from current laws

The Sector reported to the Complementary Medicines Taskforce that the current definition of substantial transformation has resulted in the loss of the AMAG logo for some products and will have a detrimental effect on the industry's export success. Potential detrimental impacts claimed by the sector include a reduction in investment in Australian operations, offshoring of manufacturing and loss of Australian jobs and specialist skills.

Based on the responses received to the industry survey undertaken by the Complementary Medicines Taskforce, the following impacts of the changes (Figure 2) was identified:

- More than a third of respondents reported they can no longer make any Australian origin claim on their products.
- Another third responded that they can no longer make the same claim but can make a different Australian origin claim.
- Only four respondents reported no impact from the legislative change on their ability to make a country of origin claim.

Figure 2. Impact of country of origin labelling law on Vitamins, Minerals and/or Supplements manufacturing firms' ability to make country of origin claims – based on 100% of returns to the survey representing approximately 25% of the sector



Respondents also noted the full impact from the legislative changes on their businesses were yet to be determined.

The main impacts consistently reported by respondents at the time of the survey related to:

- Physical changes to their labelling and packaging. This included removing all Australian claims or replacing the logo with a bar chart or statement. Several respondents noted the packaging redesign itself had a high financial cost and resulted in significant waste.
- Consumer confusion. Several complementary medicine manufacturers and distributors reported having to explain the changes in response to questions from customers, who tended to assume the products were no longer made in Australia. Respondents attributed this to a perception that Australia's new 'made in' definition was different to that applied in other countries.

While only one respondent reported having experienced a reduction in sales, most other respondents anticipated reduced sales in the short to medium term. They noted that an inability to use Australian origin claims suppressed their main competitive advantage in overseas markets.

The removal of an Australian origin claim was seen as a major reputational risk. One respondent wrote that 'taking it away from use in our products will have a greater affect as it will be seen by our customers that we have either lost government endorsement or that the products are no longer 'Made in Australia'.'

- One respondent said the logo is highly regarded within the Chinese market and that ‘customers question then refuse to purchase our products because we are no longer able to use the AMAG logo’. One firm stated that the change to the logo ‘will damage the market and industry extremely badly’.
- Another claimed that there will be a loss of employees in science and innovation as manufacturers move offshore to reduce costs to make a level playing field.
- One firm said they will be out of business without use of the logo and urged decision makers to consider the effect of these changes on the industry’s ability to export and earn foreign exchange for Australia.

Almost three quarters of businesses that responded to the industry survey through the Complementary Medicines Taskforce claimed that the changes to country of origin laws had not influenced their production methods or how they source ingredients because of the limited or seasonal availability of required ingredients. (Figure 2).

- Most respondents reported that they have to source some raw materials overseas because the ingredients they used were either not available in Australia, or not available in the required quantity, quality, or time of year.
- Some respondents noted that adapting to the new requirements by sourcing only ‘Australian made’ ingredients may reduce the quality of their products, as they currently source the best quality, most appropriate ingredients to fit specific formulations.
- Some businesses reported that certain products and ingredients are patented and therefore only available from a particular country.

While no company had relocated activities offshore, seven respondents (just over a quarter of the sample) said they had either started to consider offshore manufacturing options or were planning to do so in the near future. Of these, one respondent reported having made the decision to offshore a segment of their range affected by the new legislation.

Offshoring production was attributed to the loss of the business’ competitive advantage against cost-cutting overseas competitors. A majority of respondents highlighted that it was the marketing benefits of Australian origin claims (and the associated price premium for labelled products) that justified the added costs of locating their complementary medicine manufacturing and packaging processes in Australia.

5. Policy objective

This C-RIS identifies a number of concerns for consumers and Australian manufacturers and brand owners of complementary medicines. Acting on these concerns, the Australian Government policy objectives are to:

- Provide greater certainty for consumers and business about ‘Australian Made’ claims regarding complementary medicines manufactured in Australia.
- Ensure that consumer interests remain protected and that adequate information about country of origin claims is available to inform purchasing decisions.

Whilst some consumers may equate the country of origin of a product with a level of product quality country of origin labelling is not intended to be used as a proxy for any quality indicator.

This C-RIS’s policy objective and the following options do not promote country of origin labelling as an indicator of the quality, safety or efficacy of a complementary medicine.

Extending the reach of country of origin labelling to other non-food sectors is outside the scope of this C-RIS process.

6. Policy options and impact analysis

Summary

The options presented in this C-RIS include making no changes to origin labelling on complementary medicines; industry led branding; and creating regulations allowing AMAG logo use when TGA processes have taken place in Australia.

The Options

Options	Description
Option 1	Status quo
Option 2	Industry-led regulated branding
Option 3a	Complementary medicines manufactured in Australia are eligible to use the AMAG logo
Option 3b	As per Option 3; plus a statement on the packaging listing that the ingredients are imported
Option 3c	As per Option 3; plus a visual representation of the proportion of ingredients that are imported.

Broadly, there are 4 key groups that could be effected by each option. These are:

- consumers of complementary medicines
- consumers more broadly (and those that use the AMAG logo as an indicator of country of origin)
- the complementary medicines sector
- and broader industry (especially users of the AMAG logo) not in the complementary medicines sector

The options below, do not necessarily create a conflict between all groups. Each option presents benefits to one or more groups and detriments to others. For instance, creating access to the AMAG logo for Australian manufactured complementary medicines regulated by TGA would benefit the Sector (through sales) and consumers of complementary medicines (though greater origin labelling), however non-sector users of the logo and other consumers may be negatively impacted.

Following stakeholder consultation on the options identified in this C-RIS, a Decision RIS for CAF consideration will identify the option/s which is/are likely to have with the highest net benefits. An overview of each options and their pros and cons is presented in Table 7, below.

Table 7: Pros and cons of options presented in this Consultation RIS

Options	Description	Pros	Cons
Option 1: Status quo	Australian Manufactured Complementary Medicines will remain bound by the ACL substantial transformation test	• maintains the policy settings achieved through the Country of Origin Labelling (CoOL) reforms • maintain a consistent approach for users of the AMAG logo across all sectors of the economy as to what constitutes substantial transformation of manufactured products with imported ingredients • does not competitively disadvantage businesses that already meet the substantial transformation test • unlikely to affect consumer confidence in the AMAG logo due to different standards of use for one sector	• Consumers potentially confused by one government regulator classifying the products as manufactured in Australia, while the ACL does not allow the safe harbour defence 'Made in' claim • Maintains loss of AMAG logo for many complementary medicines • Without the AMAG logo, manufacturers may choose to move production facilities offshore and/or reduce investment in Australian facilities leading to job losses or lower job outcomes
Option 2: Industry-led self-regulated NEW branding	Sector-led development and promotion of an alternative industry certification trade mark or quality branding system	All pros as per Option 1 and in addition: • Industry can define use of the logo, as allowed though appropriate regulators • Symbol use will likely be voluntary • An industry controlled symbol where the industry can use in specific marketing campaigns	All cons as per Option 1 and in addition: • Time and cost take for the sector to develop a new trade mark or other symbol including the development of use rules • Time and cost associated with convincing the sector as a whole to support a new symbol • Cost of changing label to incorporate the new symbol • The risk that the market is already crowded with industry specific symbols and that a new symbol for this Sector would have little meaning • Costs and time associated with gaining market recognition of the new symbol
Option 3a: AMAG logo access is linked to Australian manufacturing	Businesses can voluntarily access the AMAG logo for a product if, as a minimum, the last TGA agreed activity within the TGA	• Complementary medicines manufactured in Australia would have access to the AMAG logo • Consumers would have greater access to origin labelling allowing informed choices • Consumers would benefit from unification of laws - recognising products manufactured in Australia as being 'Australian Made'	• Creates a dual qualification for the AMAG logo (substantial transformation test, or complementary medicine product specific qualification process) • Two methods to meet the requirements of claiming 'Australian Made' under the safe harbour defences may lead to some consumers being confused as to the meaning of the AMAG logo leading to possible loss in consumer confidence in the logo

Options	Description	Pros	Cons
practices	manufacture of 'manufacturer of dosage form' step occurs in a TGA licenced or certified manufacturing facility located in Australia	• Certainty for manufacturers to claim 'Australian Made', where currently such a claim relies on interpretation of law with minimal case law to support those interpretations • Evidence of manufacture easily established as records are kept in accordance with the regulator's requirements. • For complementary medicines, this option fulfils the initial expectations of the CoOL reforms, which held that origin claims would not be affected by the change in the substantial transformation test	• Possible loss of competitive advantage to firms that already met or have incurred costs to meet the substantial transformation test
Option 3b: Option 3a plus a statement of origin of the key ingredient(s)	As per Option 3a but includes a statement with the AMAG logo acknowledging the product consists of imported ingredients	All pros as per Option 3a and in addition: • Consumers benefit from knowing if any ingredients are imported	• Manufactures may not want to provide information on the label that ingredients are imported • More information on the label may be a cost to manufacturers and complicate information for consumers
Option 3c: Option 3a plus visual representation of imported ingredients	As per Option 3a but visually identifies ingredients as being imported – such as the bar chart used on food products.	All pros as per Option 3a and in addition: • Consumers would benefit from an easily identifiable visual representation of the proportion of imported ingredients • Consumers would be informed of the proportion of ingredients that are imported • Consumers are already familiar with the combination of AMAG logo and ingredient proportion bar chart from food labelling, so replicating that style on complementary medicines would require little adjustment from consumers	• Cost to manufacturers to track proportion of imported ingredients and adjust labelling as required • Manufacturers may see the bar charts a detriment to their marketing efforts

Impact analysis

The costs and benefits of the impacts of the options identified below and outlined above in Table 7, are largely unquantified at this time. Responses to this C-RIS will assist in assigning quantitative and qualitative values to the impact of each option.

This section discusses where costs and benefits may occur for the options identified above.

Option 1 – Status Quo

Option 1 maintains a single substantial transformation test applied to all goods and food wishing to claim 'Australian Made' under the safe harbour protections of the ACL. There will be no change for complementary medicines.

The key **benefit** of the status quo option is that there would be no devaluing of the AMAG logo. It follows that Option 1 presumably cannot affect consumer confidence in the logo. Another benefit of Option 1 is that it sends a signal to other sectors of the economy that they should not seek a unique status for use of the AMAG logo, this preserving the logo's integrity. These benefits need to be considered against the potential costs of Option 1.

Other benefits include the benefits realised through the CoOL reforms such as reduced time taken for a consumer to ascertain country of origin information, savings to business from simplifying safe harbour defences and reduced government enforcement costs from clarification of the 'substantial transformation.

The CoOL Decision RIS[12] reported that overall the impact on businesses and government is expected to be positive, with the savings from the removal of the safe harbour production test outweighing the additional costs associated with complying with the new regulation. The benefits to all Australian businesses (food and non-food) from removing the production cost test will be realised at a total of $550 million net present value under either option.

The impact key saving to non-food manufacturers, reported in the CoOL Decision RIS was the removal of the 50% production cost test.

The **costs** that could be attributed to Option 1 include:

- Firstly, there are the costs associated with consumer confusion around the inconsistency between TGA regulations that may acknowledge complementary medicines as being manufactured in Australia, while the ACL may not allow the 'Australian Made' claim.
- Consumers are faced with changed country of origin labelling information who, through the CoOL law changes, now receive different product labelling information compared to the origin claims allowed under the superseded substantial transformation test.

[12]https://ris.pmc.gov.au/sites/default/files/posts/2016/04/Country-of-Origin-Labelling-Decision-RIS-1.pdf

- Changed consumer behaviour may lead to lower sales of Australian manufactured products with the attendant costs to the industry of less income which in-turn will effect investment decisions. Diminished sales are a concern the sector has raised with us, noting that exports exceed $1 billion and the total market for Australian manufactured products is around $5 billion.
- Tangible negative impacts on businesses' exports and domestic sales may become realised as businesses may seek to move manufacturing activities offshore, reducing investment in Australia's manufacturing leading to reduced employment growth or job losses. The cost of unemployment and reduced business investment are impacts that should be considered in developing policy in this area.

For producers of complementary medicines whose products currently do not meet the substantial transformation test, but want to use the AMAG logo must change their manufacturing processes or source their ingredients (where possible) domestically.

Both options will increase the cost of manufacturing in Australia putting their products at a relative price disadvantage. Although this may be seen as a disadvantage for producers of complementary medicines, positive externalities could be realised.

Australian ingredient producers may perceive a market opportunity to scale up and supply domestic complementary medicine manufacturers. Sufficient increased local content removes the need to meet the substantial transformation test. This option would likely result in higher costs for manufacturers, who would make business decisions based on the value of the AMAG logo against the increased cost of production.

Option 2 - Industry-led self-regulated NEW logo

A **benefit** of Option 2 is that any new logo designed by the Sector will be fit for purpose for its products. The Sector will have the opportunity to design a logo that will achieve maximum impact in markets. As the logo will be Sector driven, control over logo use will largely rest with the Sector. A further benefit of an industry led logo is that there will likely be little to no impact on the reputation of the AMAG logo (although responses to this C-RIS may prove otherwise).

A **negative** of Option 2 is that it will not lead to greater AMAG logo use, limiting (at least in the short term) recognisable origin information for to the consumer. The establishment of a new logo or trade mark may provide consumers with origin labelling, however a new logo would take considerable time and investment before consumer recognition of the logo was satisfactory. It is questionable whether a new logo would gain the same brand recognition and consumer confidence that the AMAG logo has established over several decades.

The sector would also bear costs of managing compliance of the logo, ensuring correct use and taking actions where there have been compliance breeches.

This option would not address the impacts of current rules regarding origin claims to assist Australian manufacturers eligibility to use the AMAG logo. Risks remain that Australian manufacturing and jobs may move offshore whilst the benefits of a new brand was attempting to gain recognition and value in the market.

Option 3a, 3b and 3c

Option 3 has three variants – Options 3a, 3b and 3c. The pros and cons specific to each are discussed under separate heading below. However each variant has pros and cons common to all, those common features will be discussed below.

Common features of Options 3a, 3b and 3c

- require regulatory changes to the ACL to recognise such activities as eligible to make an origin claim
- link AMAG logo availability to regulated TGA manufacturing processes
- allow AMCL to continue to license the logo as it currently does in accordance with the 'Australian Made, Australian Grown Code of Practice'

Even though the TGA certifies production of Australian regulated complementary medicines offshore, the AMAG logo would only be available where manufacture takes place onshore. This preserves the intent of the AMAG logo which is to be a designator of Australian manufacture.

The TGA 'manufacture of dosage form' step was chosen as the key marker of manufacture. Manufacture generally involves the transformation of an input into an output different in some way from the input. Activities of this nature occur under the 'manufacturer of dosage form' step and therefore links with the AMAG logo requirement of manufacturing.

The **benefits** common to all three options are that producers of complementary medicines will have access to the AMAG logo for their products if they conduct at least the last manufacturing activity of the TGA 'manufacturer of dosage form' step in a TGA licenced or certified manufacturing facility in Australia.

Use of the 'manufacture of dosage form' step, results in a clear regulated evidence trail identifying what activities have occurred on any given product in any given processing plant. The manufacturing evidence trail could prove advantageous when determining compliance with the terms of AMAG logo usage, providing rigor to the origin claim. Measuring the beneficial impacts of an easily implemented compliance framework both from a data collection standpoint and a licensor perspective will assist in informing the Decision RIS's recommendation.

The Sector has noted that the loss of the AMAG logo has, or will result in loss of sales with the follow-on effects of lower production and lower employment levels. The beneficial impact of greater use of the logo by the sector will be crucial in determining the benefits associated with the three Option 3 derivatives.

Use of the logo will result in greater country of origin labelling, thus providing consumers with more information and reducing the time taken for consumers to determine the origin of a product. Consumer research undertaken through the complementary medicines review conducted by us through the Complementary Medicines Taskforce, found that consumers valued origin labelling. However consumers ranked the importance of origin labelling behind other factors such brand and price.

The key possible **detriment** associated with the Option 3 derivatives is the impact they may have on the value of the AMAG logo as a country of origin label. Creating an alternative test for one industry sector to access the logo could be perceived as devaluing the logo, especially where that test may be perceived as lowering the requirement to gain logo access.

This C-RIS seeks to determine if and to what extent creating an alternative test to use the logo diminishes the value of the logo. As food is the largest single sector to use the logo it is conceivable that were there to be negative consequences associated with the Option 3 variants, then presumably, those effects would be felt greatest in the food sector. It is anticipated that this C-RIS will be informed by submissions from the food sector and any other sector that thinks it would be affected by the Option 3 variants.

Licensing the label is an obvious cost to business however, as logo use will be voluntary, it will be businesses themselves that decide whether the license cost is outweighed by the perceived advantages of using the logo on their product label.

Option 3a

Option 3a would result in the logo's availability without the need to disclose the incorporation of imported ingredients. The main **benefit** of Option 3a compared to Options 3b and 3c is that 3a is less expensive to apply for complementary medicine AMAG logo users. Option 3a does not require any labelling acknowledging imported ingredients and the attendant administrative costs businesses would face tracking imported ingredient use.

Option 3a's main benefit is also its key **detriment**. Under Option 3a, consumers would not be informed of imported ingredients in their product, even though the AMAG logo was present. Option 3a would be at odds with current practice under the food labelling requirements (noting that complementary medicines are not regulated as a food).

Option 3b

Option 3b replicates Option 3a but introduces a need to acknowledge imported ingredients (if present) on the packaging alongside the AMAG logo.

The key **benefit** of 3b falls to consumers. Purchasers of complementary medicines will be informed if the product they seek to purchase consists of at least some imported ingredients. This option goes some way to satisfying consumer wishes as identified in the consumer survey, conducted as part of the Complementary Medicines Taskforce noted earlier in the C-RIS.

In addition, unlike option 3a, AMAG logo use under Option 3b results in **more** information to consumers than AMAG logo use in non-food sectors where ingredients or materials are not required to be disclosed.

Negatives associated with Option 3b include costs to business in tracking imported ingredient use and additional labelling costs.

A further potential downside to this approach is that the Sector reports that consumers will primarily focus that fact ingredients are imported, without recognising the benefits of the highly regulated (Australian) manufacturing processes the industry operates within.

Option 3c

Option 3c is different to Option 3b as it requires complementary medicine businesses to visually represent the proportion of imported ingredients if they wish to use the AMAG logo on their product packaging. This replicates the requirements of the food labelling ruler/bar chart.

Benefits associated with 3c include a greater level of information available to consumers. As consumers would be familiar with the bar chart/ruler used on food products, a consumer's interpretation of a similar chart on a complementary medicine label would be likely be swift.

Option 3c provides more information to consumers than Option 3b, as it requires a proportion of imported ingredient to be identified rather than the simply acknowledgement that some ingredients have been imported.

As with Option 3b, Option 3c assists in underpinning the integrity of the AMAG logo by acknowledging Australian manufacturing while requiring the representation imported ingredients on the product label.

A *detriment* of option 3c like that of option 3b is that logo users would need to track which ingredients are imported and which are sourced domestically. Option 3c may be marginally more expensive for business compared to option 3b given the near exact proportion of imported ingredients would need to be known for each batch, rather than what would be required under 3b which would be a simple acknowledgement of imported ingredients.

The approach to adjusting labelling as proportions of domestically or internationally sourced ingredients change is practice already managed well within the food sector. Lessons learned in this regard could be transferred to support manufacturers of complementary medicines.

7. Appendix A: Consultation RIS Questions

Stakeholders lodging formal submissions are encouraged to refer to these questions in their submissions. Where possible, DIIS encourages stakeholders to provide data and evidence to support their views.

Stakeholders may respond to any issues in this paper, or any of those questions outlined below. The questions below are categorised to assist with your input to this consultation.

Additional views and comments on any matter contained within this C-RIS is welcomed.

Questions for consumers

The current rules for use of the Australian Made, Australian Grown (AMAG) logo requires imported ingredients to be substantially transformed before they can carry the logo. In other words, those imported ingredients need to be, as a result of one or more processes, fundamentally different in identity, nature or essential character from all of their imported ingredients or components. The definition of substantial transformation under Australian consumer law (ACL) is the same across all products across industries.

The production of complementary medicines in Australia is regulated by the Therapeutic Goods Administration (TGA). The TGA regulates the stages of production of complementary medicines including testing of ingredients and the step where ingredients are manufactured into the final form marketed for sale – for example, the creation of the capsule or pill.

Many complementary medicines in Australia are manufactured from imported ingredients.

The complementary medicines sector believes that the 'one size fits all' approach of the substantial transformation test does not take into consideration the specific manufacturing steps of their sector. The Sector rightly states that the test does not acknowledge the role the TGA plays in regulating manufacture of complementary medicines.

Earlier, the C-RIS reports examples of food substantial transformed and allowed to use the AMAG logo (see Table 4 and p.35). The complementary medicines sector believes these examples highlight anomalies between the transformation of imported ingredients for food that can carry the AMAG logo, and the transformation of imported ingredients for complimentary medicines that cannot carry the AMAG logo.

1. Do you consider that a product regulated by the TGA and manufactured in Australia from imported ingredients should be eligible to use the AMAG logo? Y/N

2. Would you consider a complementary medicine, made primarily from imported ingredients to be 'Australian Made' if key steps in the manufacture of the medicine into its final dosage form (e.g. manufacture of the pill, capsule etc.) takes place in Australia? Y/N

3. What proportion of total ‘manufacturing’ of a product do you consider should take place in Australia to qualify for meeting a substantial transformation test and an ‘Australian Made’ claim?

4. Option 2 involves the industry developing its own symbol to designated products as Australian Made. Would such a symbol help you understand the country of origin of a product, or would the AMAG logo be a better indicator of a product’s country of origin?

5. If complementary medicines consist primarily of imported ingredients, should this be acknowledged on the label? Y/N

6. If imported ingredients had to be acknowledged on the label of the product, would you prefer?

    a. A statement acknowledging that the product consists of imported ingredients (Option 3b)

    b. A ruler/bar chart (or similar symbol) showing the proportion of imported ingredients in the product (similar to the ruler/bar chart used on food products) (Option 3c)

    c. A different form of acknowledgement of imported ingredients - please provide details.

7. Do you consider that Options 3b and/or 3c, if instituted, would diminish or improve the perceived value and status of the AMAG logo?

    a. By how much would the value/status of the logo be diminished?

        None/A little/Somewhat/ A lot?

    b. By how much would the value/status of the logo be improved?

        None/A little/Somewhat/ A lot?

8. A fully formed meat pie can be imported and then cooked in Australia and meet the current substantial transformation test. It is then also eligible for use of the AMAG logo. Do you consider this pie to be more or less ‘Australian Made’ than a complementary medicine consisting of imported ingredients but produced through a TGA certified Australian manufacturing facility? Please comment.

9. Do you have any further views or comments?

Questions for manufacturers of complementary medicines

1. What are the benefits and detriments of Option 1?
    a. Do you support the adoption of option 1? Why/why not?
2. What are the benefits and detriments of Option 2?
    a. Do you support the adoption of option 2? Why/why not?
    b. What would prevent the complementary medicines sector from adopting its own symbol for packaging to demonstrate its connection with Australian manufacturing?
3. What would be the annual costs (by dollar value) to your business under Option 2?
4. What would be the annual benefits (by dollar value) to your business under Option 2?
5. What are the benefits and detriments of Option 3a?
    a. Do you support the adoption of option 3a? Why/why not?
6. What are the benefits and detriments of Option 3b?
    a. Do you support the adoption of option 3b? Why/why not?
7. What are the benefits and detriments of Option 3c?
    a. Do you support the adoption of option 3c? Why/why not?
8. If you are supportive of proposed changes in options 3a, 3b or 3c, what level or proportion of Australian based manufacturing do you consider should be required in order to make an origin claim?
9. Are the activities under the Good Manufacturing Practice (GMP) step 'Manufacture of Dosage Form' (MDF) a good basis for identifying the transformation of imported ingredients into an Australian product? Please provide reasons to your response.
10. If the use of activities under the GMP step MDF are not good measure of the transformation of imported ingredients into a product that should carry the AMAG logo, then what should be the measure to carry the logo?
11. What activities under MDF do you undertake overseas?
12. What activities under MDF do you undertake in Australia?
13. By value, what proportion of your products that currently are not able to carry the AMAG logo, have their last MDF step performed in Australia?

14. What steps or manufacturing processes in Australia, excluding GMP processes, could/should also be considered to qualify a complementary medicine to meet the requirements of the substantial transformation test and a ‘Made in Australia’ claim?

    a. What are those indicators and how would you describe the manufacturing process?

    b. Are these alternative manufacturing processes common to all complementary medicines manufactured in Australia? If not, which part of the sector or which products are these alternative manufacturing processes applicable to?

15. What proportion of total ‘manufacturing’ (not cost) of a product do you consider should take place in Australia to qualify for meeting a substantial transformation test and a ‘Made in Australia’ claim?

16. If the AMAG logo becomes available to your products under Options 3a, 3b or 3c, will you use it? Y/N

    a. If yes, what percentage of value of sales will use the logo?

    b. If yes, what proportion of your product lines would use the logo?

    c. If no, why would you not use it?

17. Which option would you be more likely to use the logo:

    a. Option 3a

    b. Option 3b

    c. Option 3c

18. If there was no change to AMAG logo use rule, how likely would it be that you would change your production processes or source ingredients domestically to conform to AMAG logo requirements?

    a. Very likely

    b. Likely

    c. Neither Likely nor unlikely

    d. Unlikely

    e. Very unlikely

19. If your products are currently eligible to use the AMAG logo, but you choose not to use the logo, why do you not use the logo?

20. By value, what do you expect your lost income in the 2019/20 financial year to be because some or all of your complementary medicine products are not allowed to carry the AMAG logo?

a. Domestically (please provide values and reasoning for your response)

b. Internationally (please provide values and reasoning for your response)

21. Prior to the changes in the substantial transformation test, did you use the AMAG logo?

    a. If you did use the logo, why did you use the logo?

    b. If you didn't use the logo, why didn't you use the logo?

22. If the AMAG logo became available for use on a wider range of complementary medicine products and logo usage required an acknowledgement of the proportion of imported ingredients, would you use the logo? Y/N. Why/Why not?

23. Why would you want/not want to acknowledge imported ingredients on packaging (3b)?

24. Why would you want/not want to display the proportion of imported ingredients on the label (3c)?

25. If disclosure of imported ingredients was a requirement to use the AMAG logo, how will this affect packaging costs? Can you estimate the annual cost (by dollar value) to your business of disclosing imported ingredients for:

    a. Option 3b

    b. Option 3c

    Please provide the rationale for your calculation.

26. Please estimate the total cost/impact (by dollar value) to your firm based on the following options for one full financial year:

    a. Option 1

    b. Option 2

    c. Option 3a

    d. Option 3b

    e. Option 3c

    Please provide the rationale for your calculation.

27. Please estimate the total benefit (by dollar value) to your firm based on the following options for one full financial year:

    a. Option 1

    b. Option 2

c. Option 3a

d. Option 3b

e. Option 3c

Please provide the rationale for your calculation.

28. What did you do to prepare your business to implement the Country of Origin Labelling Reforms?

    a. How much did this activity cost your business – please provide details?

29. What proportional change is expected to occur to the price for the consumer compared to the current price a consumer pays under:

    a. Option 1

    b. Option 2

    c. Option 3a

    d. Option 3b

    e. Option 3c

    Please provide the rationale for your calculation.

30. Please describe the effect on Australian employment under:

    a. Option 1

    b. Option 2

    c. Option 3a

    d. Option 3b

    e. Option 3c

    Please provide the rationale for your calculation.

31. If there was a requirement to undertake at least the last activity under the MDF step in Australia would you:

    a. Be more likely to employ more staff

    b. Be less likely to employ more staff

    c. It wouldn't affect your employment numbers significantly

32. If AMAG logo availability was linked to MDF activities being carried out in Australia, rather than being linked to the substantial transformation test, what impact would this have on the value of the AMAG logo, given the logo would available under two separate qualification processes? Please provide details in your response.

33. Do you have any further views or comments?

Questions for businesses who are not manufacturers of complementary medicines

Questions below may relate to businesses that work to provide services to the complementary medicines sector, or are active in industries not related to the sector.

1. Do you currently use the AMAG logo on any of your products? Y/N
2. Are you a supplier or brand owner of complementary medicines? Y/N
3. Are you a supplier, manufacturer or brand owner of 'orthodox' pharmaceutical or over-the-counter medicines? Y/N
4. If you answered yes to question 3, do you consider that any of the options represented should apply to your sector? Please outline pros and/or cons of the suggested options as they relate to your business.
5. For business not within the complementary or 'orthodox' medicines sector, do you support any of the options put forward in this consultation?
6. Does your business/institution interact with the complementary medicines sector in any way? If yes, please explain.
7. What proportion of total 'manufacturing' of a product do you consider should take place in Australia to qualify for meeting a substantial transformation test and a 'Made in Australia' claim?
8. Do you believe that recognising the Australian based manufacturing processes for complementary medicine products will be beneficial for the brand of the AMAG logo?
9. Do you believe a different AMAG logo eligibility criteria for complementary medicine products will have an impact on food producers, consumers or other sectors that use the logo? If yes, please explain.
10. Do you consider that Options 3a, 3b or 3c, if instituted would diminish or improve the perceived value and understanding of the AMAG logo? If so by how much:
    a. A lot
    b. Somewhat
    c. A little
    d. Not at all

    Please provide the rationale for your calculation.
11. Please estimate the total cost (by dollar value) to your firm based on the following options for one full financial year:

a. Option 1

b. Option 2

c. Option 3a

d. Option 3b

e. Option 3c

Please provide the rationale for your calculation.

12. Please estimate the total benefit (by dollar value) to your firm based on the following options for one full financial year:

    a. Option 1

    b. Option 2

    c. Option 3a

    d. Option 3b

    e. Option 3c

    Please provide the rationale for your calculation.

13. Please describe the effect on Australian employment under:

    a. Option 1

    b. Option 2

    c. Option 3a

    d. Option 3b

    e. Option 3c

    Please provide the rationale for your calculation.

14. What difficulties and challenges will affect your business under the following options (please provide examples):

    a. Option 1

    b. Option 2

    c. Option 3a

    d. Option 3b

    e. Option 3c

15. Do you have any further views or comments?