

EXPLANATORY STATEMENT

Issued by the authority of the Minister for Industry, Science and Technology

Competition and Consumer Act 2010

Competition and Consumer Amendment (Australian Consumer Law—Country of Origin Representations) Regulations 2020

Purpose and Operation

The Australian Consumer Law (ACL) is set out in Schedule 2 of the *Competition and Consumer Act 2010* (the Act). Each State and Territory government in Australia has enacted legislation to apply the ACL as a law of its own jurisdiction. The ACL provides for consumer protection.

The *Competition and Consumer Amendment (Australian Consumer Law—Country of Origin Representations) Regulations 2020* (the Regulations) are made under section 139G of the Act, which allows the Governor-General to make regulations prescribing matters required or permitted by Schedule 2 of the Act to be prescribed, or necessary or convenient to be prescribed for carrying out or giving effect to that Schedule.

The purpose of the Regulations is to amend the *Competition and Consumer Regulations 2010* (the Principal Regulations) by repealing the existing regulation 92AA and substituting a new regulation 92AA to prescribe a process that complementary medicines have undergone in Australia, authorised by a licence, to be substantially transformed for the purposes of paragraph 255(2)(c) of the ACL.

Section 255 of the ACL provides that a representation about the country of origin of goods does not constitute misleading or deceptive conduct under section 18, or paragraph 29(1)(a) or (k) or 151(1)(a) or (k) of the Act, if the claim satisfies the requirements set out in the table under subsection 255(1) of the ACL. The provisions are commonly referred to as ‘safe harbour provisions’.

Relevantly, one of the safe harbour provisions requires that the goods ‘were last substantially transformed in that country’, within the meaning of subsection 255(2) of the ACL, for a representation to be made that goods were made or manufactured in that country.

Paragraph 255(2)(c) of the ACL provides that regulations may prescribe one or more processes that result in the substantial transformation of those goods. Meeting the requirements of the regulations made under paragraph 255(2)(c) means a person may make representations ‘that goods were made or manufactured in, or otherwise originate in, a particular country’ without contravening section 18, or paragraph 29(1)(a) or (k) or 151(1)(a) or (k) of the ACL (assuming that they do not already meet the definition of ‘substantially transformed’ in either paragraph 255(2)(a) or (b) of the ACL).

The process prescribed in the Regulations provides circumstances that may be relied upon when assessing substantial transformation for the purposes of making an Australian Made, or Made in Australia or similar, country of origin claim in relation to complementary medicines.

Regulation 92AA has been inserted partially in response to the Federal Court's decision in *Nature's Care Manufacture Pty Ltd v Australian Made Campaign Limited* [2018] FCA 1936. In that decision, the Court held that fish oil and vitamin D which were imported from overseas but mixed together and encapsulated in Australia were not 'substantially transformed' in Australia for the purposes of Part 2.3 of the ACL. Regulation 92AA is intended to change the existing law so that complementary medicines that complete the last step in the manufacture of dosage form step in Australia, in compliance with TGA regulatory requirements, will meet the definition of 'substantially transformed' in Australia (assuming that they do not already meet the definition of 'substantially transformed' in either paragraph 255(2)(a) or (b)).

The Regulations only apply to complementary medicines that are regulated as medicines under the *Therapeutic Goods Regulations 1990* and which are either listed or registered on the Australian Register of Therapeutic Goods. These may include vitamin, mineral or herbal products.

Under the Regulations, for a complementary medicine to rely on the safe harbour provisions in section 255 of the ACL, the complementary medicine will need to have undergone the last process in the manufacture of dosage form step of its manufacture in Australia. In addition, the manufacture must be authorised by a licence to occur at those premises. The manufacture of dosage form step encompasses the key transformative processes regulated by the Therapeutic Goods Administration under the *Therapeutic Goods Act 1989* (the TG Act).

In Australia, the TG Act requires, with certain exceptions, that manufacturers of medicines (a type of therapeutic goods) hold a licence. A licence is required regardless of whether the medicine ingredients are sourced internationally or locally. All manufacturers of medicines, including complementary medicines, are required to comply with the TGA's Manufacturing Principles (<https://www.tga.gov.au/publication/manufacturing-principles-medicinal-products>).

The Regulations rely on Part 3-3 of the TG Act relating to the manufacture of therapeutic goods which provides, amongst other things:

- for the Minister for Health to determine Manufacturing Principles that are to be applied in the manufacture of therapeutic goods;
- requirements for the grant of a manufacturing licence in relation to therapeutic goods; and
- that it is an offence in Australia to manufacture therapeutic goods, including complementary medicines, without a licence that:
 - (i) is in force; and

- (ii) authorises the carrying out of that step in relation to the goods at those premises.

Each manufacturer that carries out any activities under the manufacture of dosage form step is required to hold a manufacturing licence for that activity. The intent of the Regulations is to ensure that complementary medicines that complete the last step in the manufacture of dosage form in Australia, in compliance with TGA regulatory requirements, will receive the protections of the ‘safe harbour’ provisions if an Australian country of origin claim is made for that product.

Authority

The Regulations are made under section 139G of the *Competition and Consumer Act 2010*.

Consultation

In developing the Regulations, the former Department of Industry, Innovation and Science (now Department of Industry, Science, Energy and Resources (the Department)) undertook consultation with the Australian Competition and Consumer Commission, IP Australia, State and Territory ministers from the Legislative and Governance Forum on Consumer Affairs, the public and the complementary medicines sector through a Consultation Regulation Impact Statement (RIS).

In developing the specific wording of the Regulations, the Department consulted with the Treasury and the Therapeutic Goods Administration.

Regulatory Impact

A Decision RIS has been completed (OBPR reference number 25192) and is included at the end of this Explanatory Statement.

Details of the *Competition and Consumer Amendment (Australian Consumer Law—Country of Origin Representations) Regulations 2020*

Section 1 – Name

This section provides that the name of the Regulations is the *Competition and Consumer Amendment (Australian Consumer Law—Country of Origin Representations) Regulations 2020* (the Regulations).

Section 2 – Commencement

This section provides for the Regulations to commence on the day after the instrument is registered on the Federal Register of Legislation.

Section 3 – Authority

This section provides that the Regulations are made under section 139G of the *Competition and Consumer Act 2010* (the Act). Section 139G provides that the Governor-General may make regulations prescribing matters required or permitted by Schedule 2 of the Act to be prescribed, or that are necessary or convenient to be prescribed for carrying out or giving effect to that Schedule.

Section 4 – Schedules

This section provides a machinery clause that enables the Schedule to amend the *Competition and Consumer Regulations 2010* and to have effect according to its terms.

Schedule 1 – Amendments

Competition and Consumer Regulations 2010

Item 1 – Regulation 92AA

Item 1 repeals regulation 92AA and substitutes a new regulation 92AA, which prescribes a process for substantially transforming complementary medicines in Australia for the purposes of paragraph 255(2)(c) of Schedule 2 (the Australian Consumer Law) of the Act.

Paragraph 255(2)(c) of the ACL creates an explicit power to prescribe one or more processes which will be deemed to satisfy the definition of ‘substantially transformed’ for the purposes of the country of origin provisions of the Act.

The intended effect of regulation 92AA is to provide manufacturers of complementary medicines with a well-defined path to make Australian country of origin claims for complementary medicines manufactured in Australia from imported ingredients, by prescribing the process of substantial transformation specific to the manufacture of complementary medicines in Australia.

Subregulation 92AA(2) deals with the scope of the application of the new provision. It applies to complementary medicines which are listed or registered in the Australian Register of Therapeutic Goods.

Subregulation 92AA(2) incorporates by reference the definition of **complementary medicines** within the meaning of the *Therapeutic Goods Regulations 1990*. This definition is incorporated as in force from time to time, as permitted by section 14 of the *Legislation Act 2003*.

Subregulation 92AA(3) prescribes the process for the purposes of subregulation (1), being the carrying out of the last step in the manufacture of the dosage form of medicines. The last step of the process is required to occur at premises in Australia that hold a valid manufacturing licence issued by the Therapeutic Goods Administration for that step.

The last step in the manufacture of dosage form, for the purposes of paragraph 92AA(3)(a), must occur in Australia as it is consistent with the safe harbour provisions in subsection 255(1) of the Act. That provision requires that if a representation is made about the country of origin of the manufacture of goods, that country must be the country in which the goods were last substantially transformed.

Subregulation 92AA(4) specifies steps not considered to be the last step in the manufacture of the dosage form of complementary medicines for the purposes of subregulation 92AA(3). The manufacturing steps listed in subregulation 92AA(4) are not transformative manufacturing steps that would have the result described in paragraph 255(2)(c) of the Act, which defines the substantial transformation of a good for the purposes of a country of origin claim.

The intention is that if the last step in the manufacturing of the dosage form consists of merely putting the medicine in a container or applying a label to it, then it would not meet the definition of ‘substantially transformed’. This is because this is not a transformation of the ingredients into a form suitable for ingestion.

Subregulation 92AA(5) ensures that all terms (except “process”) used in regulation 92AA have the same meaning as in the TG Act. This has the effect of ensuring consistency with the TG Act and commonly accepted industry terminology.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

Competition and Consumer Amendment (Australian Consumer Law—Country of Origin Representations) Regulations 2020

The Regulations are compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Legislative Instrument

The purpose of the *Competition and Consumer Amendment (Australian Consumer Law—Country of Origin Representations) Regulations 2020* is to prescribe a process that complementary medicines have undergone in Australia, authorised by a licence, to be substantially transformed for the purposes of paragraph 255(2)(c) of the Australian Consumer Law (Schedule 2 of the *Competition and Consumer Act 2010*).

The amendments provide that complementary medicines that complete the last step in the manufacture of dosage form step in Australia, in compliance with the Therapeutic Goods Administration's regulatory requirements, would meet the safe harbour defences to make Australian country of origin claims.

Human rights implications

The Regulations do not engage any of the applicable rights or freedoms.

Conclusion

The Regulations are compatible with human rights as they do not raise any human rights issues.

The Hon Karen Andrews MP

Minister for Industry, Science and Technology



Australian Government
**Department of Industry,
Innovation and Science**

Eligibility for origin claims in the Complementary Medicines Sector

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

Department of Industry, Innovation and
Science

November 2019

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Glossary of Terms

Term	Description
ACL	Australian Consumer Law
CAF	Consumer Affairs Forum (COAG)
RIS	Regulation Impact Statement
Consultation RIS	Consultation Regulation Impact Statement (Eligibility for origin claims in the Complementary Medicines Sector 3 October 2019)
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 (including CoOL Decision Regulation Impact Statement – 2016/2017)
ARTG	Australian Register of Therapeutic Goods
GMP	Good Manufacturing Practices (TGA)
VMS	Vitamins, minerals and supplements
ASMI (CHPA)	Australian Self-Medicated Industry (Now Consumer Healthcare Products Australia)
Taskforce	Department of Industry, Innovation and Science Complementary Medicines Taskforce Review – December 2018 to February 2019

Executive Summary

In February 2017, driven by consumer dissatisfaction and mistrust in country of origin claims, changes were made to Country of Origin Labelling (CoOL) laws. These reforms changed the basis for gaining access to “made in Australia” claims and the Australian Made, Australian Grown (AMAG) logo. The key reform of note here is the substantial transformation test as it applies to goods manufactured in Australia from imported ingredients.

The 2016/2017 CoOL reforms and the related Regulation Impact Statement process concentrated on impacts to the food sector. The 2016 CoOL RIS stated that the reforms were expected to have very little effect on other sectors. However the Complementary Medicines Sector (the Sector) claims this is not the case.

The Sector expressed concerns at the time that the CoOL changes meant that many of their products would no longer meet the tightened requirements of the substantial transformation test. Guidance provided by the ACCC in March 2018 and a Federal Court case confirmed these concerns.

The Sector has expressed to government the very real possibility of disinvestment and offshoring of production because the manufacturing activities undertaken in Australia are not recognised as meeting safe harbour “Made in Australia” claims under the *Competition and Consumer Act 2010*. Elements of the Sector have questioned what benefit there is in maintaining a domestic manufacturing presence if they are unable to claim their products are ‘Australian made’ under the safe harbour defences of the *Competition and Consumer Act 2010*. Manufacturers find this especially concerning given all manufacturing activity is regulated by the Therapeutic Goods Administration under the *Therapeutic Goods Act 1989* and transformation of raw imported ingredients is conducted in Australia.

In considering the claims of the Sector, and the Sector’s wishes to have access to the “Australian Made” claim and the AMAG logo available for their Australian manufactured products, the government must also consider the needs of consumers.

That is why the government has engaged in this RIS process. Seeking broad consultation with consumers, consumer representatives, the Sector, governments and non-sector users of the AMAG logo, the government has sought to capture the views of interested parties.

This Decision RIS examines 5 policy options to test whether there is a need for the government action to re-establish the Australian Made claim for complementary medicines.

Table 1: Options presented in this Decision RIS

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

The information and data obtained through this RIS consultation process has been modest. Whilst there has been some engagement with consumers, their representatives, government agencies and the Sector, we have not heard from non-Sector users of the AMAG logo. Minimal data was offered from those who provided submissions. Financial data was only provided by four medicine related businesses.

The impact of options 1, 2, 3a, 3b and 3c have been assessed against limited data and evidence received. It follows that ranking the options in terms of their impact would be problematic. Although we can say there are clear delineations between consumer and Industry preferences.

Option 1 maintains the existing rules on substantial transformation for all products. This option was preferred by consumers. Option 1 is expected to provide the greatest support to Australian origin claims and the AMAG logo as unlike the Option 3 derivatives, it does not create examples of processes that satisfy the substantial transformation test that may be seen as a lesser standard.

Option 2 garnered little interest. One firm in the Sector noted it could be examined in more detail, but only if any of the Option 3 derivatives were not made available through a change to legislation. Option 2 offers flexibility to the Sector to develop branding specific to their needs.

Each of the Option 3 derivatives are likely to offer more benefits to complementary medicine companies than consumers. It is possible Option 3a offers less benefit to consumers while option 3c offers more benefits to consumers but with expected higher costs to manufacturers than Option 3a. The key concern with the Option 3 derivatives is that by defining an example to satisfy the transformation test it could be a lesser standard, and an Australian origin claim of the AMAG logo will be devalued.

Submissions to the Consultation RIS and previous research commissioned by the department through a survey of consumers for a complementary medicines taskforce

conducted in January 2019¹ clearly indicated that consumers want accurate information on the origin of their products. This includes whether or not the products they consume contain imported ingredients. Consumers expressed a preference that if the government is to seek a regulatory outcome to allow for “Australian Made” claims for Australian manufactured complementary medicines, then that origin claim should be accompanied by a representation of the proportion of Australian ingredients. This replicates the CoOL rules for food.

If Option 3c proceeds, complementary medicine manufacturers that meet the current substantial transformation test will not be required to change their labels to display the proportion of ingredients sourced from Australia. Under option 3c, complementary medicines that rely on the new regulation will be required to represent the proportion of Australian ingredients on the label, whereas complementary medicines that meet the current substantial transformation test will not need to meet the ingredients disclosure requirement of 3c.

In short Options 3a and 3c will not apply to complementary medicines that currently meet the substantial transformation test.

However these businesses’ market share could be affected under options 3a and 3c. Complementary medicines that do not meet the existing substantial transformation test, but would meet the proposed regulatory solution will have the choice of being labelled with an Australian origin claim. Such complementary medicines may take market share away from those complementary medicines that do currently meet the substantial transformation test. No responses from current users of the logo or those firms that meet the substantial transformation test were received that noted this as a concern, and as such the impact on them could not be quantitatively assessed.

To achieve that outcome, the government will need the approval of the Legislative and Governance Forum on Consumer Affairs (CAF) and to prosecute a legislative amendment, develop new regulations and rules to ensure the proportion of Australian ingredients is displayed on product labels if a business chooses to use an Australian country of origin claim under those regulatory amendments. This is Option 3c. This will take time with a possible passage through the 2020 winter session of Federal Parliament. If CAF agrees to implement Option 3c, the government will propose an interim measure – Option 3a - a regulation made under the existing legislation to allow a safe harbour Australian origin claim and use of the AMAG logo for complementary medicines that have had at least the last transformative manufacture of dosage form step occur in Australia. Option 3a could be in place prior to the end of 2019. This interim measure also requires CAF agreement.

What is the case for change? Has there been enough time for the data to formalise? Given the ACCC guidance to the Sector, released in March 2018, following the February 2017 change to the substantial transformation test was the key catalyst for removal of origin

¹ Complementary Medicines Taskforce Review Consumer Research Report January 2019

claims and the AMAG logo from the Sector's products. Noting the Natures Care Federal Court case was not decided until December 2018, there has been less than two years for the effect of the changes to flow through the Sector. We do not know if this is enough time for negative effects of the CoOL reforms to present themselves.

On the basis of the scant 'evidence' received to this RIS in the form of data, such as lost jobs, a slowing industry, widespread consumer confusion or plant closures and the like, a clear case for change has not been demonstrated. In circumstances, where there is a lack of evidence of a problem, the maintenance of the status quo is preferred.

Background

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), contained in the *Competition and Consumer Act 2010* and agreed with states and territories.

The amendments to CoOL has changed the rules for ALL products wishing to make an Australian origin claim. This includes complementary medicine products.

The 2016/2017 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 eligible for the Australian origin claim prior to the reforms taking affect would be affected by this new test.

For the \$5 Billion Complementary Medicines industry, the changes have resulted in many of their products no longer meeting the definition of substantial transformation under the ACL as amended in 2017.

The revised definition of substantial transformation removed the 50 per cent production cost test from the 'Made in' safe harbour defence on which the Sector heavily relied to licence the AMAG logo. The revision to the test also changed the definition of what substantial transformation of imported ingredients meant, for origin claims. If a manufacturer does not met the test for substantially transforming imported ingredients, they cannot rely on the ACL safe harbour defence for a 'Made in' country of origin claim. In these circumstances, the AMAG logo cannot be granted.

From earlier research conducted by the Department of Industry, Innovation and Science (the department) through the Taskforce, it is known that country of origin labelling is valued by consumers. The lack of origin labelling therefore may affect consumer purchasing behaviour with a flow-on effect to industry sales.

The Sector states that the AMAG logo is a key marketing tool for both domestic (especially in the Daigou market) and export markets, particularly markets like China, and that Australian companies are being negatively impacted by the new CoOL requirements. Before the 2017 reforms were introduced, there were around 185 licensees of the AMAG logo from the Sector, including firms licenced to use the logo that may not own production or manufacturing facilities in Australia. After the law was amended 34 licences were resigned due to non-compliance with the safe harbour defence.² As noted in the *Eligibility for origin claims in the Complementary Medicines Sector* Consultation RIS (the Consultation RIS),

² Australian Made Campaign Ltd

Complementary Medicines Australia (CMA), one of the Sector's peak bodies, stated that restricted access to the AMAG logo will cause unnecessary and serious impacts on the industry. CMA cite a likely reduction in investment and job losses as potential consequences, jeopardising the growth of the Sector. This position has been supported by submissions made to the Consultation RIS received from firms within the Sector.

More businesses will be forced to relocate manufacturing to overseas and more businesses will seek alternative production from low labour cost countries. These moves will leave to huge job cuts in Australia, leaving large number employees unemployed, causing hardship to their family and bringing pressure to the local and federal Government eventually, and bringing down the GDP of Australia. – Ocean King

The Sector believes the substantial transformation test is not an appropriate measure of the transformation imported raw materials undergo 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 although the Sector has not provided data that supports this contention.

Consumers have made various assumptions regarding the meaning of the AMAG logo. It is not uncommon for consumers to assume that a product displaying the logo is comprised of Australian only components or ingredients. Research conducted by the Department in January 2019 for the Complementary Medicines Taskforce³ showed a strong assumption by consumers that a vitamin tablet, or similar, that claimed to be of Australian origin was made from Australian ingredients, in an Australian manufacturing facility. Through this research it is apparent that consumers assume this of all products that make an Australian origin claim. Typical consumer responses to the Consultation RIS indicated that to qualify for AMAG logo use, the proportion of Australian ingredients should be above 75 per cent.

Consumer expectations of an 'Australian Made' claim far exceed the ACL's requirements to make such a claim. Under the ACL, a product can be comprised entirely of imported components, and meet the Australian origin claim as long as those imported components have been substantially transformed into the finished product. Whereas consumers generally

³ Hereafter referred to as the Complementary Medicines Taskforce. The Complementary Medicines Taskforce was set up by the government to investigate claims by the Complementary Medicines Sector that the CoOL reforms of 2017 were causing distress to the industry. The Taskforce comprised representatives from multiple Australian Government agencies.

believe a product displaying Australian Made will be comprised mostly of Australian ingredients and manufactured in an Australian facility.

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.

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 2 and 3 below.

Table 2: 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 3: 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 4 below, Australian consumers primarily gain access to complementary medicines through in-store sales.

Table 4: 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

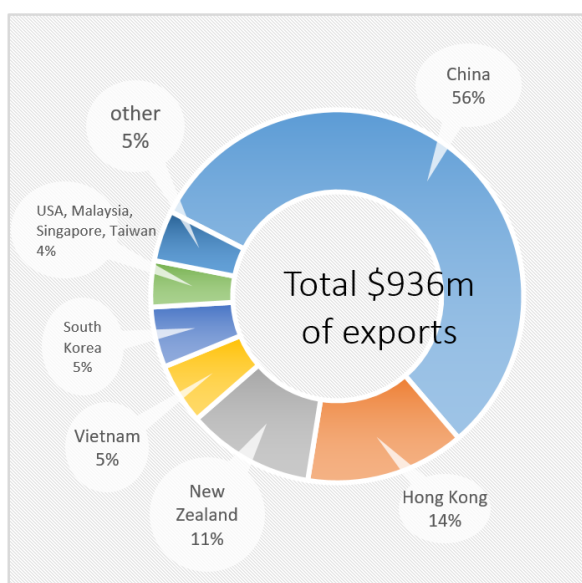
Source: Euromonitor, Consumer Health in Australia 2019

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 per cent 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 Daigou⁴ trade. From research provided to the CMA, this accounts for roughly 20 per cent 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 highly reliant on imports of raw ingredients for the production of complementary medicine products. Firm level commercial-in-confidence provisions have restricted access to the exact proportion of Australian ingredients in complementary medicines, however the department is aware through confidential submissions that some firms source some of their actives and excipients from Australian suppliers.

Distribution of imported ingredients may be through direct sourcing by Australian manufacturers from overseas producers, or be through Australian based distributors. The value and sales chains of Australian producers of expedients, actives or other ingredients in a complementary medicine are have not been identified in this RIS.

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 per cent (\$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 competition with its Asia-Pacific rivals, operators have been positioning themselves as world-class drug manufacturers backed by R&D capabilities.⁵ 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.

⁴ 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>).

⁵ <http://clients1.ibisworld.com.au/reports/au/industry/industryoutlook.aspx?entid=188>

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.

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

Some of TGA licensed facilities may also be licensed to manufacture non-complementary medicine medicines. Data on the product mix for each facility was not obtained for this RIS.

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 supplements⁶. This is in line with the DIIS Office of the Chief Economist

⁶ IBISWorld Industry Report OD5417 Vitamin and Supplement Manufacturing in Australia September 2018

estimates based on ABS data that there are about 2,000 people employed in the vitamin only manufacturing segment of the complementary medicine Sector⁷.

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 (including shipping, transport, warehousing, logistics and retail)⁸. This 13,200 would include the 2,000 involved in manufacturing. The RIS has not verified CMA's supply chain employment figures.

Domestic production of ingredients for complementary medicines

There is little information available on domestic production of ingredients for complementary medicines. Rural Industries Research and Development Corporation, in a 2006 publication noted the medicinal herbs sector is small.

"The Australian market is too small to support an active industry which means that for growers to achieve any volume they will need to concentrate on overseas opportunities. The pursuit of such a strategy will require significant investment in the development of export capabilities among local growers" - Rural Industries Research and Development Corporation, Prospects for medicinal herbs, 2006

The report went on to note that Australian suppliers face high costs pressures.

"The supply of raw medicinal herbs globally is highly competitive and organised. There is a diverse range of countries supplying raw plant materials and extracts. In Australia, growers are increasingly finding it difficult to compete against cheaper imports. Processors and manufacturers are increasingly preferring to source imported raw materials due to better supply consistency, quality and price. The unpredictability of supply and demand coupled with significant price fluctuation has led to diminishing local grower interest in the cultivation of medicinal herbs. Interviews with leading industry stakeholders showed the Australian medicinal herbs industry is predominantly confined to 'hobby farmers' with

⁷ Office of the Chief Economist calculations; Euromonitor International Passport Database, Consumer Health 2019; ABS cat. no. 8155 Australian Industry, 2016-17; ABS cat. no. 6291.0.55.003 - Labour Force, Australia, Detailed, Quarterly, Nov 2018.

⁸ CMA Australia's Complementary Medicines Industry Snapshot 2018.

no more than 1-2 acres dedicated to medicinal herbs. Medicinal herbs cultivation in Australia could be hard to measure as there is very little consistency in production volume with growers continuously rotating between other horticultural crops to yield best returns.”- Rural Industries Research and Development Corporation 2006

Publicly available data on the proportion of domestic versus international ingredients used in Australian manufactured complementary medicines is not available. Reports from the Sector’s peak bodies and firms suggests Australian derived ingredients comprise a small proportion of all ingredients used in the Sector’s products.

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’s 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 sponsor⁹ 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.

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

⁹ 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.

require products regulated as 'listed medicines' in Australia to comply with these GMP principles¹⁰.

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.

Consumers found terms like 'Made in' and 'Product of' particularly confusing. Almost 60 per cent 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 per cent 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.

¹⁰ For example many products considered as complementary medicines in Australia are considered in other countries as food supplements and regulated according to food regulations

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. Specifically, the changes 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.

Existing laws

A number of laws, regulations and rules create the governance framework for safe harbour Australian origin claims, the use of the AMAG logo, and TGA regulation of the Good Manufacturing Principals including the manufacture of dosage form step.

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 per cent 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:

'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 Option 3 derivatives discussed later in the RIS seek to create both a regulation under the *Competition and Consumer Act Regulations 2011* to provide an example of substantial transformation in the case of option 3a, and amend the *Competition and Consumer Act 2010* to create a regulation making power to allow a finer definition of substantial transformation as it might apply to specific transformative circumstances as per Option 3c.

Option 3c also creates a regulation providing a specific example of substantial transformation. Option 3c will also require the department to create an information standard (or similar) to describe how product labels should represent the proportion of Australian ingredients of a complementary medicine.

The complementary medicines sector and the substantial transformation test

In considering the issues outlined in this Decision 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 oxidation) 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 Australian Made Campaign Limited (AMCL) to assist them to decide which products can carry the AMAG logo. A Federal Court case¹¹ 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

¹¹ <http://www.judgments.fedcourt.gov.au/judgments/Judgments/fca/single/2018/2018fca1936>

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.

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 5, below is an indication of the ACCC's view on what may or may not meet substantial transformation in the food sector.

Table 5 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

Processing	Substantially transformed?
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 per cent recognition level amongst Australian consumers and is considered a very strong marker that the product that carries it is of Australian origin.¹²

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*.¹³ 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

¹² Roy Morgan Research, 2017

¹³ The Food Information Standard is available at <https://www.legislation.gov.au/Details/F2017C00920>

administration of the AMAG logo. AMCL regulates use of the logo by issuing 12-month renewable licences which allow businesses to use the logo.¹⁴ Over 2,700 companies are currently licensed to use the AMAG logo on more than 16,000 products.

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 2017 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

¹⁴ AMCL 2019. Website About Australian Made

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 per cent of domestic sales of the vitamins, minerals and supplements subset of complementary medicines in 2018.¹⁵ 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 per cent 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 per cent of VMS products sold in Australia) at least 73.6 per cent 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 per cent. Beauty, skin care and cosmetics represents 15 per cent of total logo usage with food and beverage (12 per cent) 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 per cent of logo usage falls into the broad 'other consumer' category.¹⁶

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 per cent production cost test.

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. - CMA July 2015

¹⁵ *ibid*

Consumer Healthcare Products Australia (CHP formally known as 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.

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 February 2016

The AMAG logo is managed by AMCL. 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. However use of the 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.

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 6) and employee numbers (Table 7). Most firms that answered the survey had a wholly Australian-based workforce, or very close to it.

Table 6: 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 7: 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 per cent or more of their raw material, while four firms imported less than 40 per cent of their raw material.
- Meanwhile, only a fifth of respondents imported less than 40 per cent of their bulk or raw ingredients from overseas.
- For products in a finished or near finished state, 88 per cent 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 per cent 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 per cent or more of their total production, while nearly half of respondents exported less than 50 per cent 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 per cent or more of their product ranges. Only two respondents reported using such claims on less than 30 per cent of their ranges.

The above data was based on responses to our industry survey conducted through the Taskforce. The same respondents had the opportunity to respond to our call for submissions on the Consultation RIS. However we received less responses to the more recent call than responses to the Taskforce.

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 per cent 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.'
- The highly regulated manufacturing chain was cited as underpinning consumer's perception of quality Australian products.

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 competitiveness (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, although this was not assessed by the RIS.
- 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 per cent higher in overseas market than the Australian RRP. This includes brands that have a strong Australian brand but contain no origin labelling. Contained within the price will be the wages of shoppers, transport and so on, contributing to the price premium.
- 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 per cent 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 per cent 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 per cent) and brand (50 per cent). 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 per cent 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 per cent of Australians expect the quality of onshore manufactured complementary medicines to be better than products made elsewhere, while 22 per cent felt they would be the same. Further to that, 54 per cent of Australians felt that the effectiveness of locally made complementary medicines would be better than those made elsewhere, while 32 per cent 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 per cent 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.

If product is made in Australia, from 100% Australian ingredients:



If product is made in Australia, from a mix of local and imported ingredients



If product is not made in Australia:



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.

The problem

The Consultation RIS theorised a problem was created through the changes to the substantial transformation test in the 2017 CoOL reform effects two broad segments – consumers of complementary medicines and the Sector.

In summary, the associated Consultation RIS suggested consumers face a reduction in country of origin labelling and possible confusion as well-known Australian manufactured complementary medicines are no longer able to display the Australian made claim. While complementary medicine manufacturers have lost access to the safe harbour Australian made claims and the AMAG logo, manufacturers also feel disadvantaged by seemingly stricter safe harbour defence rules placed on them relative to food producers (discussed below).

The consumer problem

Consultation for this RIS has not identified an obvious consumer problem to be solved through regulation.

Prior to February 2017 when the definition of substantial transformation changed, the AMAG logo or an Australian origin representation was displayed on many labels of complementary medicines manufactured in Australia. The CoOL law changes resulted in many of these representations removed from labels which, as we report below has resulted in some consumer confusion.

The change to the CoOL laws inadvertently created a contradiction where a complementary medicine is deemed to be manufactured in Australia under one Australian law (the *Therapeutic Goods Act 2010* and regulated by the TGA), but not meeting Australian origin laws (i.e. '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'.

Submissions provided by consumers under this RIS did not identify the mismatch between TGA regulation of manufacturing and the substantial transformation laws as contributing to consumer confusion or that the 2017 law change affected consumers in any way.

Consumer confusion was reported by businesses when surveyed for the Complementary Medicines Taskforce. 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 Australia's new 'made in' definition being different to that applied in other countries (e.g. China, with respondents arguing the definition used for exports should be that of the target country).

Also, it is difficult to draw clear conclusions on consumer perception of the stated problem given the small number of consumer responses.

One problem not stated in the Consultation RIS was the cost to consumers of the greater time they would take to ascertain the country of origin of a complementary medicine. The CoOL Decision RIS noted that time savings for consumers were an important benefit in the use of the AMAG logo, as the logo was easily recognised.

As reported in the CoOL Decision Regulation Impact Statement (3 March 2016):

“The ease of interpretation created by the visual display of information...will create time savings for consumers who seek country of origin information.”

The CoOL RIS went on to note:

“If the required dollar saving is expressed as a required time saving per consumer, this is equivalent to 11 seconds per shopping trip (one trip per week) based on the standard estimate of the value of leisure time of consumers at \$29 per hour...This time saving is considered conservative, and for many consumers, the time saved will be much greater.”

All derivatives of Option 3 have the potential to assist consumers with the problem of determining the origin of the product. Option 1 also achieves this outcome but does not acknowledge to the same extent as Options 3a, 3b, and 3c the manufacturing activity undertaken in Australia on complementary medicines.

It was expressed in the report that 4 minutes and 48 seconds was the average time consumers spent during 1 hour of grocery shopping looking for Country of origin labelling, that a visual representation of an Australian made symbol would likely lead to a saving of more than 11 seconds per shopper per 1 hour shopping trip each week. The CoOL RIS placed a value on the time saved to the consumer.

The CoOL RIS looked at the total shop for a consumer, rather than the time a consumer spent looking for origin labelling on individual products or complementary medicines. We know from previous consumer survey research conducted by the Complementary Medicines Taskforce that a little over a third of purchasing decisions by consumers are based on the country of origin of a complementary medicine. For the CoOL reforms, time saved for consumers was considered a valid cost saving. Greater use of the logo on complementary medicines would likely translate into greater time saved by consumers as the logo under the Option 3 derivatives represents Australian manufacturing. We can only assume it will be a small time saving with an attendant small cost saving.

"I look for it [AMAG logo] on everything I buy, it takes me hours to shop. I look at every ingredient on everything." Complementary Medicines Taskforce Review Consumer Research Report

As access to the logo and Australian origin claims under Options 3a, 3b and 3c will not be mandatory, the magnitude of savings will be dependent on degree of origin claims take up.

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.

The Sector reports 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 recent changes have resulted in us removing the logo of a significant number of our products and have negatively impacted sales. Measuring the exact decline is hard as we have invested in significant marketing activity so cannot separate the positive effect of this from the negative impact of removing the AMAG logo, but we estimate it reduces sales by 20% per annum on a 'like for like' basis. – Homart Pharmaceuticals.

Other companies have also reported negative impacts associated with the changes to the CoOL laws. The following was received in response to the Consultation RIS.

We have to destroy our current stocked label and cartons and re-design new marketing and packaging materials. As the process in Australia is not valued, we are considering moving offshore. - Confidential submission

The Sector had reason to believe the CoOL changes would not affect their ability to make origin claims. The CoOL Consultation RIS speculated there would be little effect of proposed changes on existing claimants of Australian origin. 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 CoOL Decision 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

Following the legislating 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. Businesses within the Sector have also expressed these view directly to the department and representatives of the Australian Government.

Problems for non-complementary medicines AMAG users

No problems have been identified for non-complementary medicine firms that use the AMAG logo or claim Australian country of origin status.

The Problem – Conclusion

The existence of a problem as evidenced by data and information received through this RIS process has not been proven.

If a problem does exist, the extent of the problem cannot be accurately determined, as valuing each element of the problem is highly problematic. For instance the cost to the Australian economy of lower Australian manufactured complementary medicine sales (domestically and internationally) would need to be offset by benefits associated with redistribution of investments and possible investment in processes that do meet the substantial transformation testing allowing the safe harbour claim of 'Australian Made'.

We have not attempted to put a financial measure on the extent of the problem due to the lack of quantitative information. However the key problems that exist with the current laws are:

the cost to consumers (if one exists) of less origin labelling on complementary medicines has not been measured

the potential loss of sales of Australian manufactured complementary medicines may not be fully realised yet and can only be estimated at this time

the follow-on effects of reduced investment and job losses to the wider economy is not fully realised

Policy Objective

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.

Consultation Process

The Department engaged in a public consultation process seeking the views of stakeholders on the options put forward in the Consultation RIS. Public consultation opened on 3 October 2019 and closed on 30 October 2019. Consultation was conducted on behalf of CAF in order to allow the state and territory ministers responsible for consumer affairs to make a decision on a way forward for the safe use of Australia Made origin claims for the complementary medicines sector.

The Consultation RIS was hosted on the department's Consultation Hub, mirrored on the Office of Best Practice Regulation RIS updates site.

The Department expected to receive submissions from a number of stakeholders. These included:

- 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

Notification of the consultation process was extensive. The Hon. Minister Andrews, Minister for Industry, Science and Technology publicised the consultation through social media announcements and a notification to state and territory ministers responsible for consumer affairs. This followed public statements on the issue by the Minister.

The Department notified a broad range of stakeholders that the consultation period was open, including consumer representatives, Sector participants, peak bodies for the Sector, AMCL, Commonwealth agencies represented on the Complementary Medicines Taskforce and the key contacts in the state and territory governments concerned with consumer affairs and industry.

Of the stakeholder groups identified above, state and territory government agencies, and non-complementary medicine businesses using the AMAG logo, did not provide submissions.

The Department received 30 submissions. Of the over 80 complementary medicine manufacturers/suppliers in Australia, 10 put forward a submission. Most industry submissions were from smaller players in the sector, however two larger player also provided information. The ACCC, CSIRO and AMCL also submitted responses.

It was not completely clear how many submissions were received from consumers. Of the 13 submissions where the consumer questions were answered, a number of these responses appear to have been completed by small players in, or related to the complementary medicines sector. The actual number of submissions from consumers or consumer representative groups appears to be less than ten.

This Decision RIS sites extensive evidence collected through earlier consultation on this matter. The department engaged Colmar Brunton to conduct research to examine consumer preferences for the use of the AMAG logo on a range of complementary healthcare products. Colmar Brunton conducted qualitative research, through a number of small face-to-face focus group conversations involving 78 consumer participants, and quantitative research, carried out through an online survey of 2091 consumer respondents.

The Complementary Medicines Taskforce also undertook a survey to gather industry views on the CoOL legislation changes from members of the complementary medicines industry.

The survey was distributed to members of both CMA and ASMI (now Consumer Healthcare Products Australia – CHPA) – the Sector’s peak bodies. Austrade also provided notification of the consultation to 40 non-CMA members which are active in the Sector and have received export market development grants. AMCL also provided notification of the survey to relevant licensees of the AMAG logo. 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; and

- Impact of the CoOL changes, including any impact on production methods.

The survey received 26 responses, of which 24 were from businesses were related to the Sector. This decision RIS also cites consultation from the 2016 CoOL Decision RIS.

Policy Options and Impact Analysis

This Decisions RIS sets out five options for CAF to consider to address the problem of Australian manufactured complementary medicines not being able to claim Australian made under the Australian Consumer Law safe harbour defences.

Impact of the options

Firm level impact – from Consultation responses

Four businesses related to either the supply of ingredients, manufacture of complementary medicines, or who contract their complementary medicine manufacturing to Australian facilities, provided financial data regarding the financial impact and benefit the options would have on their businesses.

Table 8: Cost Benefit Analysis

	Annual Costs	Annual Benefits	Net Annual Benefit
Option 1	\$1,950,000	\$1,250,000	-\$700,000
Option 2	\$1,710,000	\$300,000	-\$1,410,000
Option 3a	\$60,000	\$810,000	\$750,000
Option 3b	\$310,000	\$300,000	-\$10,000
Option 3c	\$650,000	\$850,000	\$200,000

A fifth business (supplier/brand owner) indicated a *reduction* in product sales of 20 per cent for Options 1, 2, 3b and 3c, and an *increase* in product sales of 40 per cent if Option 3a were to be implemented, for both the domestic and international markets.

We did not receive data from non-complementary medicine businesses that use the AMAG logo.

Based on the limited information provided, the cost versus benefits of each option has resulted in Option 3a providing the greatest net benefit. With such a small number of data points to draw on we caution against drawing conclusions from the analysis. In addition, as the data was confined to Sector participants, wider effects of the options is unknown.

Industry Level Costs

The Complementary Medicines sector is estimated to have achieved \$4.9 Billion in revenue in the 2018 year. The represents over 29,000 jobs supported by the Sector and around \$170 million in wages paid. Based on research CMA commissioned, of the 29,000 jobs just over 13,000 people are associated with the product supply chain. The Sector's annual growth rate is 3.9 per cent.

A slowdown in the growth of the Sector, a reduction in penetration into key markets or a fall in gross sales will have a detrimental impact on the Sector. Loss of any marketing advantage, especially when selling into key overseas markets is assumed to have a negative effect on the Sector. The Sector is strongly export focused with about 20 per cent of all sales made offshore. This figure does not include, Australia domestic sales, where the product is destined to be sent overseas. As noted earlier, the Daigou trade is significant and is thought to represent around 20 per cent of all domestic sales.

Concentrating only on direct employees of the Sector, which numbers around 2,700, using the Australian Bureau of Statistics (ABS) input output tables, and assuming revenue per employee remains consistent, a decrease in revenue of 1 per cent will lead to a reduction of employment of 27 people. The effects on employment in the broader supply and sales chains are more difficult to estimate, however employment is expected to be decreased should revenues fall, or not increase as expected

The table below sets out the relative impact of each option against a series of criteria around which the options may be judged.

Table 9: Impact matrix

Options	Benefit to Consumers	Benefit to complementary medicine manufacturers	Protection for the AMAG logo brand	Benefits to Australian business that manufacture/provide raw ingredients and/or actives
Option 1 - Status quo	High	Low	High	High
Option 2 Industry-led regulated branding	Medium	Low	High	High
Option 3a - Complementary medicines manufactured in Australia are eligible to use the AMAG logo based on TGA regulation	Low	High	Low	Low
Option 3b - Option 3a plus statement noting imported ingredients	Medium	High/Medium	Medium	Low

Option 3c - Option 3a plus a visual representation of proportion of imported ingredients	Medium	Medium	Medium	Low
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The above table is primarily a subjective assessment of the relative benefits of each option as consultation did not provide enough quantitative data to provide a meaningful comparison across comparison categories.

Option 1 offers no additional information to assist consumers regarding the origin of some of the complementary medicines they purchase but does not create examples of processes that meet the substantial transformation test unique to one industry sector.

This option, by itself does not offer most manufacturers of complementary medicines the ability to demonstrate to consumers that their products have been manufactured in a TGA certified, Australian facility. Under Option 1 the substantial transformation test is not augmented by examples expressed in a regulation under the *Competition and Consumer Act 2010* of manufacture that will meet the substantial transformation test - meaning there are no changes to current understandings of safe harbour origin claim rules and as a consequence, no change to the access of the AMAG logo.

Option 2 builds on Option 1 in that it in-part relies on the maintenance of existing laws to give new branding the space to develop. This option is thought to strongly uphold the value and integrity of the AMAG logo, Australian origin claims, and producers of Australian raw ingredients and/or actives. Consumers could benefit from the proposal, but this is likely to be a slow process, requiring significant additional investment from the sector into the branding. The great opportunity for the Sector is that, subject to Australian laws and regulation, the branding could be made to fit the precise needs of the sector.

Options 3a, 3b and 3c offer significantly greater benefits to Australian manufacturers of complementary medicines compared Options 1 and 2. Reestablishment of Australian origin claims for the Sector's products may promote consumers greater confidence in those products benefiting the Australian manufacturing industry. However Option 1 offers consumers the consistency of a single Australian origin test. Conversely, the Sector, claims the test is imperfectly applied, allowing products that are less substantially transformed than complementary medicine (in the Sector's estimation) to carry the AMAG logo.

Any benefits that flow from the Option 3 derivatives will be dependent on the take up of origin claims from the Sector. However the benefits will not just accrue should products use the AMAG logo, there will also be benefits from the claim of "Australian Made" or "Made in Australia". Conversely, use of the origin claim without the logo will mean consumer will not benefits a greatly, as time saved in recognising the logo will not be realised.

While overall, complementary medicine manufacturers are expected to benefit from Options 3b and 3c due to being able to use the AMAG logo, those benefits are expected to be tempered by the need to acknowledge the proportion of imported ingredients on the label if they wish to make an origin claim under the safe harbour defences.

Acknowledging imported ingredients will likely mean that for many, labels will show a high proportion of imported ingredients (for Option 3c), which may have variation between production batches. Responses to the Consultation RIS noted that batch-to-batch variations in ingredient sources may require different labelling.

Commensurate with this tempering of benefits for complementary medicine manufacturers will be a flow of benefits to consumers who gain more information on the origin of the product they consume as well as information on the imported ingredients.

Option 1 Maintain the status quo

As flagged earlier, in circumstances, where there is a lack of evidence of a problem, the maintenance of the status quo is preferred. Information presented to this RIS during consultation was limited and consequently, a problem with existing laws was not demonstrated.

Under this option, existing laws would continue to operate without amendment. All manufacturers of complementary medicines would continue to interpret the ACL safe harbour defences and apply the law to their complementary medicines as applicable.

Option 1 preserves the benefits expected to accruing to the CoOL reforms. These benefits included:

- savings from the removal of 50 per cent production cost test
- simplification of safe harbour tests
- time savings for consumers when shopping
- consumers will be able to use the information to make purchases that better match their preferences, reducing the number of purchases which would not otherwise have been made had more information been available
- consumers may benefit from the knowledge of the proportion of Australian ingredients in their food even if it does not change purchasing decisions

Option 1: Impact analysis

Impact on Consumers

From the limited consumer responses, it was clear consumers would prefer Option 1 over the other options presented. What is not clear is how the intended benefits of the CoOL reforms (summarised above) have materialised. The CoOL reforms are expected to be reviewed in 2020–21 at which time there will be opportunity to consider their effectiveness.

Maintenance of the status quo would appear, in the minds of the majority of consumer respondents to the Consultation RIS to be a protection of the Australian origin claim and AMAG logo.

This finding aligns with research conducted through the Complementary Medicines Taskforce which generally found that consumers place a very high value on the AMAG logo and have expectations of the limits of its use far in excess of what laws allow. Consumers generally expect the AMAG logo to represent a very high proportion of Australian ingredients/inputs, whereas existing laws regarding AMAG use and a safe harbour Australian origin claim can occur even if the product contains no Australian ingredients.

Consumers indicated a preference for a very high test for claiming Australian origin. This in practice would result in substantially higher requirements to prove Australian origin than the current substantial transformation test – the status quo. For instance to gain access to the AMAG logo, consumers expressed a need for Australian ingredients as a proportion of the finished product to be between 75 per cent and at least 90 per cent.

A reoccurring theme expressed by consumers surveyed through the Complementary Medicines Taskforce was that:

“...the wording in both versions of the [previous and current substantial transformation] rules was confusing and subjective, but overall consumers felt that even if something is fundamentally changed but the ingredients are from overseas then it shouldn't be able to make an AM [Australian Made] claim.” – Complementary Medicines Taskforce Consumer Research Report 2019

However some consumers believe that the final medicinal product that is manufactured in Australia from imported ingredient can be labelled as ‘Made in Australia’.

“I think about the end products being made in Australia... packaging, pills, labels, but may doubt that the ingredients are Australian.” - Complementary Medicines Taskforce Review Consumer Research Report January 2019

This view is not alone. Research conducted through the Complementary Medicines Taskforce, found 22 per cent of consumer respondents:

“...felt that a product could claim to be ‘Made in Australia’ if the ingredients, wherever they are grown are substantially transformed or changed in Australia.” - Complementary Medicines Taskforce Review Consumer Research Report January 2019

A potential positive impact for consumers of this option is the consistent application of the substantial transformation test across industries. Consumers may benefit from a consistent interpretation of the test when comparing products across multiple sectors, knowing that the fundamentals of what determines Australian origin is applied to all products.

Confirmation of this impact on consumers was unable to be determined from the consultation.

The Consultation RIS sought consumer thoughts on whether the transformation of imported ingredients for complementary medicines exceeded the transformation of a fully imported meat pie that goes through a heating or ‘thermal transformation’ in Australia. Although the rules applying to food are not being examined here, all consumers (13 in total) agreed that a fully formed meat pie, imported and then cooked in Australia was less ‘Australian Made’, than a complementary medicines consisting of imported ingredient and manufactured in TGA certified Australian manufacturing facility.

Given the disconnect between the very high expectations of consumers on what the logo or an Australian origin claim should represent and what is allowed under law, a case could be made that providing an alternative definition for the complementary medicines sector to claim Australian origin for their products manufactured in Australia is not a substantial move from what is currently a lawful claim.

Impact on complementary medicine businesses

The acceptance of the status quo option is claimed by the Sector as continuation of a negative outcome for manufacturers. Manufacturers and brand owners reported through this RIS process and through consultation undertaken through the Complementary Medicines Taskforce, that maintenance of existing laws will negatively impact domestic and export sales, leading to lower investment and possible offshoring of manufacturing with associated job losses.

Complementary medicine businesses overwhelmingly reported negative impact from continuation of the status quo. Complementary medicine manufacturers and brand owners feel the strict but world-class regulatory guidelines they must adhere to for the manufacturing of complementary medicines in Australian facilities is not widely recognised under the current country of origin labelling laws and therefore consumers are mostly unaware of the

transformative process undertaken on imported ingredients to form the final product in Australia. For instance, submissions noted:

The impact of not having the use of the AMAG logo to validate the work we do here in Australia is already being felt by a number of brands and will impact on future decisions on our Australian manufacturing of Complementary Medicines. Such decisions could result in loss of employees, especially in science and innovation as the site may potentially be moved offshore. These considerations will include reduction in investment into Australian manufacturing and thus if moved offshore there would be no planned improvement to site or equipment which would affect the hiring and use of Australia workers, construction and/or trades. – Confidential submission (manufacturer and brand owner of complementary and pharmaceutical medicines)

Others stated that they were:

Currently unable to declare the critical steps that are carried out in Australia. Consumers will not identify products as Australia made, even if most of the critical steps are performed locally. – (Confidential submission)

And that the...

current regulation does not recognize the manufacturing process in Australia and in turn does not recognize the value of TGA regulation in the complimentary medicines industry. It's harmful for the complimentary medicines industry. (Confidential Submission)

The company that provided the above submission also noted they are now considering moving offshore. Less take up of Australian manufacturing was cited by another business as a possible consequence of Option 1.

[The status quo]...will not stimulate products manufactured in Australia, [leading to] less products will be able to meet the requirement of substantial transformation to make this claim. Therefore, companies have no incentive to continue to use Australian manufacturers, and may move products to overseas manufacturers, impacting Australian business and

*reducing employment opportunities in Australia – Confidential submission
(Brand owner of complementary medicines)*

Others in the complementary medicines sector also noted the damage this CoOL laws are doing to the industry:

The current definition of “Australian Made” does not meet its literal meaning and has caused confusion among the consumers. The current definition has denied access to use of AM logo for most of the Australian businesses in the vitamin supplement industry and have devastating impacts and damages to the well-established Australian Made reputation and the genuinely Australian Made industries, including complementary supplement industry. – Ocean King

One significant manufacturer and brand owner in the Sector stated:

We cannot stress enough the serious adverse commercial consequences this option will have across all Australian manufacturers and businesses in the multi-billion-dollar Complementary Medicine industry. (Confidential submission)

The impacts already felt by the Sector should the status quo be maintained include:

-
- *Halt a booming industry: discourage investment/expansion/innovation in Australia - one of Australia’s few growing manufacturing sectors*
 - *Uncertain future for industry: Manufacturing arrangements taken to offshore locations with more accommodating production costs and market entry.*
 - *Cost to business: relabelling, modified marketing, lower retail price point.*
 - *Loss of jobs: no investment means no future industry.
(Complementary Medicines Australia)*
-

The department’s Complementary Medicines Taskforce survey of Sector participants conducted at the start of 2019 found that while only one respondent reported already having experienced a reduction in sales, most other respondents anticipated reduced sales in the short to medium term. The survey had 24 Sector respondents.

They noted that an inability to use Australian origin claims suppressed their main competitive advantage in overseas markets.

The same survey identified activity from complementary medicine manufacturers to offshore their activities. Around a quarter of respondents were considering this move and 1 had already taken action to offshore production.

From the industry survey conducted through the Complementary Medicines Taskforce, 'Australian made' goods are seen as a significant marketing tool for complementary medicine manufacturers.

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

"[Options 1, 2, 3b and 3c will cause] potential decrease of sales by 20%. Discouragement of local and international customer to buy products if existing conditions are unchanged, and "Australia made" claim cannot be made. Source products from international manufacturers, will decrease the benefit of Australian industry". - Confidential submission (manufacturer of complementary medicines

When the department surveyed complementary medicine businesses in January 2019 for the Complementary Medicines Taskforce, 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 the segment of their range affected by the new legislation.

Responses to the Consultation RIS from Sector participants indicated that 1 firm had relocated some of its production offshore as a result of the 2017 CoOL law changes. A small number of manufacturers and brand owners from the sector supplied data on the cost and benefits of this option. Annual costs associated with lost sales ranged from \$20,000 to \$500,000 and as noted under the cost benefit table, another brand owner identified an expected loss of 20 per cent in annual sales. Turnover data was not

volunteered by most respondents, however one respondent who noted the \$500,000 loss in sales had a turnover of \$3 million per annum.

The single Australian ingredient supplier who responded to the survey, indicated no net costs of Option 1.

No submissions from large players in the Sector provided costs or benefits data for any of the options.

The Sector also points to uneven application of the substantial transformation test to food and complementary medicines. The Sector contends even though many of its products are more substantially transformed than the examples listed below, their products cannot claim Australian origin status or use the logo.

Possible unequal application of Substantial Transformation test: Food products versus complementary medicine products (as identified by the Complementary Medicines Sector)

Examples the sector cites as unequal application of test 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 such as: blending; compression; film coating; or sterilisation cannot currently claim to be substantially transformed for the purpose of making an origin claim.

Impact on non-complementary medicine businesses using the AMAG logo

No information was received from non-complementary medicine businesses who use the AMAG logo, therefore the impact of Option 1 can only be assessed at a theoretical level. Conceivably, Option 1 provides a good outcome for businesses currently using the logo. The outcome of the expansion of methods to make an Australian origin claim and successfully apply for use of the AMAG logo under Options 3a, 3b, and 3c on businesses currently using the logo is untested.

Table 10: Impact Analysis of Option 1

	Benefits	Costs
Consumers	<ul style="list-style-type: none"> maintains the policy settings achieved through the Country of Origin Labelling (CoOL) reforms unlikely to affect consumer confidence in the AMAG logo due to different standards of use for one sector 	
Complementary medicines Businesses		<ul style="list-style-type: none"> maintains loss of AMAG logo and Australian origin safe harbour defence for many complementary medicines products stated risk of de-investment and offshoring of production with the accompanying loss of jobs
Non-complementary medicine businesses using the AMAG logo	<ul style="list-style-type: none"> 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 	

Option 2 Industry-led regulated branding

Consumers were more in favour of use of industry-led branding over the AMAG logo on complementary medicines by a ratio of 2 to 1.

As stated throughout the Consultation RIS industry are against acknowledging imported ingredients on the labels of their products. There is a risk that industry-led development of a brand may not include acknowledgement of imported ingredients on the labels of products manufactured in Australia. As the TGA certified offshore manufacturing, there is a risk that the brand could be used on these products, potentially misleading consumers.

Industry was generally not supportive of Option 2, although one submission from a smaller Sector firm expressed conditional support for industry led branding on the basis that the Option 3 derivatives would not be available. The submission rejected the status quo as Option 1 will lead to offshoring of manufacture. Another company estimated the impact of Option 2 of approximately \$1.2 million per year over a period of ten years. Another company indicated Option 2 will take a long time to implement.

If there is a benefit it will be long term, as it will take time to create logo and its conditions. Long time to implement, educate consumers on the new logo. Unable to review perception of new logo with local and international consumers. – Confidential submission

Impact on Consumers

Consumers would be exposed to another brand in the market place. It is unclear how they would react. If consumers perceive the branding to represent Australian manufacturing and the inherent quality controls associated with domestic manufacturing, then presumably, presence of the brand could reassure consumers that the product they are purchasing has been made to high standards and is safe to consume.

Option 2 does not alter consumer perceptions of Australian origin claims or what the AMAG logo represents.

Impact on complementary medicine businesses

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 the C-RIS may prove otherwise).

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 breaches.

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.

Three manufacturers/brand owners from the sector supplied data on the cost and benefits of this option. Excluding the Australian supplier of actives/excipients, the other two firms annual costs associated with Option 2 ranged from \$10,000 to \$200,000. Both of these firms noted benefits from Option 2 ranging from \$50,000 to \$250,000 per annum. For these firm, benefits outweigh costs.

The single Australian ingredient supplier who responded to the survey, indicated a net cost of \$1.5 million per annum for Option 2. They did not identify any benefits from Option 2.

Impact on non-complementary medicine businesses using the AMAG logo

It is unknown what impact Option 2 would have on existing AMAG logo users. It is unlikely that an industry driven logo would attain the presence and brand recognition that the AMAG logo has, at least in the short term.

Table 11: Impact Analysis of Option 2

	Benefits	Costs
Consumers	<ul style="list-style-type: none"> maintains the policy settings achieved through the Country of Origin Labelling (CoOL) reforms unlikely to affect consumer confidence in the AMAG logo due to different standards of use for one sector 	<ul style="list-style-type: none"> may not result in acknowledgement of imported ingredients with the potential to mislead consumers
Complementary medicines Businesses	<ul style="list-style-type: none"> Industry can define use of the logo, as allowed though appropriate regulators 	<ul style="list-style-type: none"> time and cost 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

Non-complementary medicine businesses using the AMAG logo

- 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

Option 3a, 3b, 3c – Australian origin claims for Australian manufactured complementary medicines

Complementary medicines manufactured in Australia are eligible to use the AMAG logo based on TGA regulation

The Option 3 derivatives do not change any product's ability to claim Australian origin under the substantial transformation test as it stands. Option 3 does not create a new test. Option 3 creates an example of processes that meet the substantial transformation test.

Under the Option 3 derivatives, it is expected, that for a complementary medicine to rely on the safe harbour provisions and claim Australian origin status, the complementary medicine would need to have undergone at least the last transformative process in the manufacture of dosage form step of its manufacture in a licensed Australian facility ensuring no further transformative activity takes place offshore.

The manufacture of dosage form step encompasses the key transformative processes regulated by the Therapeutic Goods Administration under the *Therapeutic Goods Act 1989*.

Examples of transformative processes and industry understood descriptions of processes under the manufacture of dosage form step include:

- Blending
- Bulk manufacture
- Manufacture of dosage form
- Preparation of bulk product
- Finished Product Manufacture
- Sterile Finished Product Manufacture - Excluding Release for Supply and Testing

Other steps under GMP are less transformative than the manufacture of dosage form step. For instance, testing of products and packaging and labelling which critical steps in the manufacture of a complementary medicine product, do not to any significant step involve the transformation of ingredients into a finished product that is taken or applied and so on, by the consumer.

Impact on Consumers

Feedback to the Consultation RIS showed consumers were generally not supportive of use of the AMAG logo on complementary medicine products where the products were manufactured with a majority of, if not most of imported ingredients. The Consultation RIS stepped out for consumers some of the regulatory activities the TGA undertook and the manufacturing processes conducted by manufacturers in Australia using imported ingredients, but consumers were not convinced that the AMAG logo could be appropriately applied.

Many Complimentary medicines (CM) are sold in Australia and contain fully imported ingredients, and they are falsely using the AMCL logo. Such use of the logo and many false claims/branding/labelling are clearly false representations of their products to consumers. Peter Nichols – Consumer/CSIRO

The consumer sentiment expressed through this consultation, closely aligns with consumer sentiment from other surveys. The Complementary Medicines Taskforce survey of consumers found that many thought the AMAG logo guarantees them a wholly Australian product – from the sourcing of ingredients through to the manufacture and packaging. The logo was also associated with ill-defined safeguards:

“This logo shows that something is tried and tested... it’s trustworthy and familiar.”

“This [logo] has rules and quality control around it.”

Consumers were surprised when told the AMAG logo did not represent their understandings.

“When told about current AMAG labelling rules that contradicted consumers’ expectations, consumers were doubtful of how high the standards are in Australia when it comes to regulation of complementary healthcare products, given some products can be claimed as ‘Australian Made’ when they contain imported ingredients. Many assumed that the complementary healthcare products they purchased, [and were labelled] ‘Made in Australia’, were from local ingredients and were surprised when they heard others [in the focus group] saying this was not necessarily the case.

When the participants were made aware of the changes to the AMAG logo labelling laws, there was some debate around the definition of CoOL, with some understanding it as referring to where ingredients are sourced, others felt that it represented where products were manufactured, and others thought it was a combination of both.” – Complementary Medicines Taskforce Review

The ACCC provided a submission on the RIS. In the ACCC’s estimation, the creation of additional criteria to satisfy origin claims under Options 3a, 3b and 3c:

“...may confuse consumers, and may allow products which have only undergone minimal processing in Australia to be labelled ‘Made in Australia’. This would be to the detriment of Australian consumers and Australia manufacturers.” ACCC submission

The ACCC’s qualified (‘may confuse’) view, reiterates concerns the Department expressed in the Consultation RIS. The risks of instituting one of the three Option 3 derivatives is understood, but given the lack of evidence of how this risk could materialise, the concerns we share with the ACCC remain unproven.

Based on a non-persuasive number of consumer responses, the extent of risk to the AMAG logo and Australian origin claims expressed by the ACCC, may not be significant. From responses to the Consultation RIS, we note, even though the AMAG logo is held in high regard, and in with an understanding that most ingredients in complementary medicines are imported, when asked if Option 3b or 3c were instituted, would that choice diminish the perceived value and status of the AMAG logo, consumers were split on the effect on the logo. The majority (8) of responses said there would be no effect on the value of the logo. Three responses said the logo would be somewhat diminished and 2 responses though the logo would be a lot diminished.

The 2017 changes to the safe harbour substantial transformation test for country of origin claims were never about the source of inputs, but about the level of acceptable transformation of products from their original imported materials/ingredients, into their immediate or final form. The Option 3 derivatives seek to identify processes currently regulated as manufacturing, to satisfy the substantial transformation test and therefore allow an Australian origin claim.

This transformation of imported materials however, as earlier identified, is not deemed Australian Made by some consumers.

However not all consumers feel this way. A not insignificant 22 per cent of consumers¹⁶ accepted that where the transformative process took place rather than the origin of the ingredients was the defining characteristic of a final products country of origin claim.

As mentioned above in Option 1, many consumers expect a very high level of Australian ingredients in a product to have access to the AMAG logo (and by extension the right to claim “Australian Made” or “Made in Australia”). If the source of the ingredients or proportion of Australian ingredients is not acknowledged with the AMAG logo or Australian origin claim, consumers will feel misled.

It was hypothesised in the Consultation RIS that linking TGA manufacturing regulatory practices and Australian origin claims may provide consumers with additional assurance and

¹⁶ Complementary Medicines Taskforce Review Consumer Research Report January 2019

confidence that a complementary medicine sold in Australia or exported with an Australian origin claim meets TGA's application of GMP and substantially transforms the imported ingredients. Consumers responding to the RIS did not agree with this proposition.

We identified earlier under "The Consumer Problem" that consumers could save time if they could more easily identify the origin of a product. Should manufacturers choose to use the AMAG logo under the Options 3 derivatives, consumers may realise a time saving benefit when purchasing complementary medicines as the AMAG logo is highly recognisable and a clear symbol of an Australian transformed or manufactured product.

Although the country of origin of a complimentary medicine is not a top ranked consideration for consumers, 36 per cent of purchases involved consumers searching for country of origin labelling on their complementary medicine products¹⁷. The 2016/2017 CoOL reform process estimated the time saved for consumers when consumers were provided with greater visual clues as to the origin of a product. The AMAG logo, being highly recognisable, was expected to contribute to the time saved during a 1 hour weekly grocery shop that include both food and non-food products.

The current RIS has not conducted research to estimate the time, and therefore cost saving for consumers if greater origin labelling was available on complementary medicines. However given over a third of complementary medicine purchases involves consumers considering the country of origin of products, providing easier identification of origin, may speed up a consumer's purchasing decision, saving them time.

Of note, a small number of consumer responses to the RIS consultation flagged potentially incorrect Australian origin claims from fish and marine oil brands where those brands did not use fish/marine/squalene/shark liver oil derived from Australian sources. The benefits of the Option 3 derivatives, is that even without sourcing ingredients from Australia, if TGA licensed processes under the 'manufacture of dosage form' step takes place in Australia, with at least the final process occurring in Australia, then those products could safely and correctly claim to be 'made in Australia'.

Impact on complementary medicines businesses

Complementary medicines businesses argue they would benefit from the option to use the AMAG logo and make safe harbour "Made in Australia" claims. Submissions to the Consultation RIS, surveys conducted for the Complementary Medicines Taskforce and other communications with the sector, have indicated the key impact of using the AMAG logo, and by extension, making a safe harbour country of origin claim are higher sales domestically and especially internationally.

¹⁷ Complementary Medicines Taskforce Review Consumer Research Report January 2019

“For small businesses and start-ups, the cost of starting new business and using an Australian manufacturing facility can be cost prohibitive in Australia. The benefits of using the AMAG logo to penetrate new markets, thereby facilitating the ability to create and maintain a viable local business, is seen as an exciting possibility for innovation in the sector. Further, it stimulates the opening of new manufacturing facilities that can support the needs of sponsors who initially need smaller batches, or those seeking specialty services.” – Complementary Medicines Australia

Consumer perception of the quality and safety implied with ‘Australian made’ goods is seen as a significant marketing tool for complementary medicine manufacturers. From research conducted through the Complementary Medicines Taskforce:

All firms that used the logo believed it to be beneficial to their firm.

Only three respondents did not believe the use of the logo increased their international competitiveness (although these firms still believed it to be beneficial to their business).

The use of the logo influenced a majority of the firms’ business decisions (employment, marketing or investment).

“Manufacturers are currently having to make business decisions on the regulatory landscape as to whether business survival is best served by remaining or even expanding facilities in Australia, or whether to move offshore into New Zealand, China, other countries in the Asia Pacific, or even further abroad.” – Complementary Medicines Australia

Option 3 derivatives align existing manufacturing regulatory practice with the definition of substantial transformation in the ACL. Manufacturers only need rely on interpreting one set of regulated practices for both compliance with TGA requirements and origin claims. Options 3b and c however, add further regulatory burden requiring reporting the source of ingredients (Option 3b) or the proportion of Australian ingredients (3c).

“For large [complementary medicines] businesses, the application of a simple recognition of an established Government process (licenced Australian GMP manufacture)...produces a straightforward, low-red-tape option...” – Complementary Medicines Australia

Table 12: Annuals costs benefits for Option 3 derivatives

	Annual Costs	Annual benefits
Option 3a	\$10,000 to \$50,000	\$10,000 to \$500,000
Option 3b	\$10,000 to \$200,000	\$100,000 to \$200,000
Option 3c	\$50,000 to \$200,000	\$50,000 to \$600,000

One respondent estimated Option 3b would lead to an increase in sales of up to 40 per cent. This same respondent felt Option 3c would not have no benefits and would confuse consumers.

Impact on non-complementary medicine businesses using the AMAG logo

The Consultation RIS theorised that a possible detriment associated with the Option 3 derivatives was the possible impacts 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. Information provided through submissions to the RIS or Complementary Medicines Taskforce has not led to a definitive position on the potential for damage to the AMAG logo. If these risks were likely or significant, we expected AMCL as the brand owner, to raise any concerns they might have regarding a policy that may lead to a loss of faith in the logo. No such concerns were received.

Concerns for a reduction in the value of an Australian origin claim, and a reduction in the value of the AMAG logo was presented by the South East Trawl Fishing Industry Association (SETFIA). The organisation noted:

Allowing an increased amount of imported seafood products into the country by falsely stating that they are made in Australia would place the brand (mark) at risk.

It also places the Australian seafood consumer trust in Australian seafood in jeopardy. If consumers cannot trust complementary medicines that contain seafood, they may lose trust in the origin of all "Australian" seafood.

As explained, the Australian fishing industry is trade exposed and for this reason is particularly vulnerable. If implemented, allowing imported

complimentary medicines containing seafood to be labelled as made in Australia, when they are not, may have devastating impacts on the Australian seafood manufacturing sector. – SETFIA

Option 3 derivatives also create a risk to Australian producers of actives, excipients, fillers and the like as complementary medicine manufacturers will potentially be able to source these ingredients cheaper from overseas and continue to use the AMAG logo.

Table 13: Impact Analysis of Option 3 derivatives

	Benefits	Costs
Consumers	<ul style="list-style-type: none"> • consumers would have greater access to origin labelling • consumers may benefit from unification of TGA and ACL laws - recognising Australian manufactured products as being 'Australian Made' 	<ul style="list-style-type: none"> • creates potential confusion over a dual qualification for the AMAG logo (substantial transformation test, or complementary medicine product specific qualification process) • consumers may feel deceived of an Australian origin claim or use of the AMAG logo given the unique rule that will apply to complementary medicines •

<p>Complementary medicine businesses</p>	<ul style="list-style-type: none"> • <i>complementary medicines manufactured in Australia would have access to the AMAG logo</i> • <i>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</i> • <i>evidence of manufacture easily established as records are kept in accordance with the regulator's requirements.</i> 	
<p>Non-complementary medicine businesses using the AMAG logo</p>		<ul style="list-style-type: none"> • <i>risk that current licencees of the AMAG logo may suffer from restricted competition.</i> • <i>risk that a new test for Australian origin and use of the AMAG logo may devalue to the logo for existing users</i>

Option 3a Impact Analysis

Option 3a creates a benefit for complementary medicines manufacturers and brand owners as they will have an additional avenue to meet substantial transformation required to use a "Made in Australia" claim and access to the logo without the need to disclose where ingredients have come from or the proportion of imported ingredients. Although not

supported by extensive data from industry, as noted earlier under 'Impact of options' Option 3a is estimated by firms to have a lower cost impact than Options 3b or 3c. Firms noted administrative cost impacts for Options 3b and 3c of tracking and recording import data and changing labels on an ongoing basis.

Manufacturers will benefit from simplified origin rules and an origin claim reliance on information the manufacturer already collects under TGA's GMPs. One respondent from the Sector noted:

"Unable to claim a benefit [for 3c] as ingredients of complementary medicines are normally sourced from different countries and only few manufactured in Australia. Unable to identify origin of each ingredient, this will incur an additional cost, if this will be required from existing manufacturers" – Confidential Submission

Option 3a's main benefit is also its key detriment. Under Option 3a, consumers would not be informed of imported ingredients in their complementary medicines, even though an Australian origin claim or the AMAG logo was present. This is contrary to consumer expectations. Consumers want more rather than less disclosure of imported ingredients and expressed in their submissions to the Consultation RIS that Option 3c was the preferred Option 3 derivative.

Should consumers become broadly aware that many complementary medicines making an Australian origin claim contain few Australian sourced ingredients, the complementary medicines sector could face negative sentiments. The commercial effect of this is unknown.

Priority-food products are the only sector that are mandated to label its products, which includes a mandatory display of the proportion of Australian ingredients. All non-food products (which includes complementary medicines) are not required to label items with country of origin. Implementing Option 3a would be consistent with the rules for non-food products where it is not mandatory to disclose the imported materials/ingredients or the proportion of Australian ingredients/materials. This sentiment was expressed by some who provided submissions to Consultation RIS. For instance, one respondent stated:

"It would be easier and clear for consumer without different standards of use of the logo." Tess Hu, Knight Pharmaceuticals

The expected benefit to consumers of a simpler approach to labelling is unlikely to be appreciated by consumers who repeatedly state they want more, not less origin information.

"We see that consumers are looking for information about where the products are manufactured. They are not necessarily asking where the

ingredients are sourced from, but the country where the product is manufactured/made, due to perceived differences in quality standards during the manufacturing process. Therefore, the ability to use the AMAG logo gives consumers the information that they are looking for, which adds value to both the product and the logo.” Confidential submission (supplier or brand owner of complementary medicines)

Table 14: Impact Analysis Specific to Option 3a

	Benefits	Costs
Consumers		<ul style="list-style-type: none"> consumers may feel less informed of the origin of the ingredients in the products they consume relative to Options 3b and 3c.
Complementary medicine Businesses	<ul style="list-style-type: none"> potentially lower labelling costs as labels would not be required to display the information of options 3b or 3c, which potentially requires tracking of supply chain. potentially lower labelling costs as labels would not need to be updated as the proportion of ingredients change. 	
Non-complementary medicine businesses using the AMAG logo		<ul style="list-style-type: none"> concerns that an alternative definition for an origin claim and AMAG logo use may devalue the AMAG logo.

Option 3b Impact Analysis

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

Complementary medicine businesses may incur higher costs than option 3a for the reasons identified above in Option 3a. More mandatory labelling may also reduce the package space for the business to display other information.

One submission from industry expressed concerns that a potential exists for consumers to focus more on the reporting of imported ingredients on the label than the Australian transformation of those ingredients leading to negative consumer sentiment.

During the CoOL consultations in 2016, one significant player in the Sector noted that they would not be supportive requirement to identify the proportion of Australian ingredients on labelling for therapeutic goods.

The requirement to acknowledge imported ingredients will not apply to any product that meets the existing substantial transformation test. Policy Option 3b does will not impose additional labelling and compliance costs on any product that meets current laws.

Table 15: Impact Analysis Specific to Option 3b

	Benefits	Costs
Consumers	<ul style="list-style-type: none"><i>more information is available to consumers on imported ingredients</i>	<ul style="list-style-type: none"><i>the origin of ingredients will not be disclosed, only the proportion of Australian ingredients</i>

<p>Complementary medicine businesses</p>		<ul style="list-style-type: none"> • <i>manufactures may not want to provide information on the label noting ingredients are imported</i> • <i>more information on the label may be a cost to manufacturers and complicate information for consumers</i> • <i>consumers may be misled by acknowledgment of imported ingredients and not understand the transformative processes undertaken in Australia</i>
<p>Non-complementary medicine businesses using the AMAG logo</p>	<ul style="list-style-type: none"> • <i>the requirement to acknowledge imported ingredients will not apply to products that meet the current substantial transformation test</i> 	

Option 3c Impact Analysis

Of the 12 responses to the Consultation RIS consumer question that asked for their preference between 3b and 3c, the overwhelming majority (10) would prefer to see 3c chosen.

“If products contain ingredients from other countries, the consumer must be informed of this by displaying appropriate labelling on the product.”

- Tony Gutierrez, Associate Professor

Option 3c differs from Option 3b as it requires firms to visually represent the proportion of imported ingredients on complementary medicine packaging if they wish to make a safe harbour Australian origin claim or use the AMAG logo on their product packaging. This replicates the requirements of the food labelling ruler/bar chart.

“For any complimentary medicine (health food supplement) wishing to carry the “Australian Made” logo, there clearly needs to be an attached mechanism such as a bar chart or ingredients list showing the percentage of Australian ingredient content.” – Dr Peter Nichols, CSIRO

Benefits associated with 3c will include a greater level of information available to consumers relative to Options 3a or 3b, which may add to integrity of the logo. As consumers are familiar with the bar chart/ruler used on food products, a consumer’s interpretation of a similar chart on a complementary medicine label would likely be swift.

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 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. However consultation did not indicate any significant cost difference between options 3b and 3c.

“First of all [for 3b and 3c], the cost involved in labelling and packaging will be heavy. Second, customers will be confused with a lot of information...” –

Confidential submission

From the limited information provided by the small Sector respondents to the Consultation RIS, Option 3c was seen to be substantially (20 to 50 times) more expensive for complementary medicine manufacturers compared to option 3a.

The requirement to acknowledge imported ingredients will not apply to any product that meets the existing substantial transformation test. Policy Option 3c will not impose additional labelling and compliance costs on any product that meets current laws.

Table 16: Impact Analysis Specific to Option 3c

	Benefits	Costs
Consumers	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • the origin of ingredients will not be disclosed, only that the product contains imported ingredients
Complementary medicine businesses		<ul style="list-style-type: none"> • 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

***Non-complementary
medicine
businesses
using the
AMAG logo***

- *the requirement to display the proportion of Australian ingredients may demonstrate that many products have little Australian ingredient content. This could negatively affect the perception of consumers towards the AMAG logo or “Australian origin claims casting doubts over existing users of the logo who satisfy the current stringent substantial transformation test, or those who source most of the ingredients domestically.*

Key Findings

The consultation process resulted in the following key findings:

Figure 2: Key Findings

There are reported instances of complementary medicine companies offshoring or seriously considering offshoring production if their manufacturing activity in Australia is not recognised as “Australian Made”

Consumers want more information on the origin of the products they consume

Complementary medicines companies undertake significant manufacturing tasks, regulated by the TGA, in Australia to transform imported raw ingredients

Consumers were in favour of option 3c if regulations are amended to allow complementary medicines to claim “Australian Made” although their preference was for the status quo.

Complementary medicine companies have genuine concerns over their ability to differentiate their products without access to the “Australian Made” or “Made in Australia” claim

Conclusion

This Decision RIS has outlined a number of options that could be pursued to achieve the policy objective of ensuring consumers and business are provided greater certainty regarding Australian Made claims for complementary medicines, while protecting consumer interests on the country of origin of such products.

The RIS consultation process did not add substantially to the stock of knowledge on this matter. It was well understood that consumers expect very high standards to be met for a product to claim Australian origin. We already understood the high regard that an Australian origin claim and especially the AMAG logo was held by consumers and the consultation confirmed the already held views that consumers would favour more disclosure of a product's origin over less disclosure.

Also well understood were the concerns the Sector had regarding the impact of the loss of an "Australian Made" claim and AMAG logo. Claims made in submissions to the Consultation RIS supported previous statements that the sector was at real risk of reduced investment in Australia.

The position of non-medicine businesses that use the AMAG logo remains relatively unknown. Through the consultation, it was asked of the wider industry how they would perceive a regulatory solution that created a specific example under the substantial transformation test specifically for complementary medicines. Unfortunately, the consultation process did not shed significant light on the views of non-sector logo users.

On the basis of the limited evidence presented during the RIS process a clear case for change has not been demonstrated. In circumstances, where there is a lack of evidence of a problem, the maintenance of the status quo is preferred.

Based on the limited cost benefit analysis undertaken in this RIS. Options 3a and 3c represent positive net benefits. Options 1 and 2 recorded negative net benefits.

Option 3a stood out as the favoured outcome for industry. And while consumers would prefer to maintain the status quo (Option 1), Option 3c was the next most favoured option for consumers.