

***BREAKING DEVELOPMENTS - Country of Origin Labelling
New Regulations for Complementary Medicines***

Complementary Medicines Australia (CMA) are pleased to announce that after our advocacy and submissions to the Country of Origin taskforce, the Government has today confirmed that it will bring in new regulations to give complementary medicines greater access to Australian origin claims and the Australian Made logo.

On Friday the government's regulations to create greater access to an Australian origin claim for Australian manufactured complementary medicines passed the Federal Executive Council and were signed by the Governor-General. The new regulations are an interim measure, supported by the states and territories and will provide immediate access to an Australian origin claim.

The Regulations will be titled: *Competition and Consumer Amendment (Australian made Complementary Medicines) Regulations 2019* and will include an example of a process undertaken in Australia for complementary medicines that meets the substantial transformation test under the Australian Consumer Law (ACL). It is anticipated that the Regulations will come into force mid this week after it is registered on the Federal Register of Legislation. When registered, the regulations will be available [here](#).

As members would be aware, CMA has continued its strong advocacy for the complementary health sectors continued access to make an 'Australian Made' claim. With our members' support we have worked collaboratively with stakeholders and government, aiming to provide Australian manufacturers of complementary medicines with a practical resolution and way forward. We are pleased that business certainty has been provided in the form of these regulation changes.

How it will work

The Regulations are intended to allow complementary medicines to claim Australian origin and satisfy the substantial transformation test where the complementary medicine has had at least the last step in the manufacture of the dosage form occur at sites in Australia. If a product satisfies this example under the substantial transformation test, then the product can seek to license the Australian Made Logo (AMCL).

The Regulations will not make it mandatory to claim Australian origin if a product satisfies the new example and they do not affect any existing or future claims under the substantial transformation test as it exists now.

Ongoing measures

The interim measure provides immediate access to an Australian origin claim, with further ongoing measures anticipated.

The longer-term solution is expected to create two pathways:

- 1) The existing pathway (i.e. not relying on these new regulations); and
- 2) A new pathway where if a product needs to rely on the new pathway to meet the substantial transformation test, and it wishes to claim Australian origin, it may be expected it will need to display the proportion of Australian ingredients.

The ongoing measures are yet to be formed in detail and will require ongoing CMA advocacy and support.

Resources

[Australian Made Country of Origin Claims 26 August 2019](#)

[Decision Regulatory Impact Statement](#)

[Country of origin food labels](#)

[Complementary Medicine Country of Origin Labelling survey](#)

For further questions, please contact us at: technical@cmaustralia.org.au

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 the complementary healthcare sector gaining access to the premium Australian Made, Australian Grown (AMAG) logo for an origin claim.

Specific guidance for the complementary healthcare sector describing the interpretation of the new law, was published by the ACCC in March 2018, which in light of previous guidance, took a significantly more conservative stance as to what may be called 'Made in' Australia. The revised ACCC guideline resulted in a significant variation in interpretation as to what the ACCC consider met the substantially transformed test and was not consistent with guidance for other industries. For example, guidance for other sectors take a far less stringent approach to the application of *substantial transformation*. This includes, baking a frozen raw imported pie and curing imported pork and claiming Australian Made.

The unintended consequences of the Country of Origin labelling reforms on the Complementary health care sector impacted approximately 200 Australian Made licensees. In many cases this has resulted in businesses having to remove the Australian Made logo from their products and marketing materials.

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