

CMA Submission to the Australia and United Kingdom Free Trade Agreement (AU-UK FTA)

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Complementary Medicines Australia

Nature - Science - Health

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Submission to the Department of Foreign Affairs and Trade: the Australia and United Kingdom Free Trade Agreement (AU-UK FTA)

Complementary Medicines Australia (CMA) writes to express its strong support for Australia's engagement in trade liberalisation negotiations with the United Kingdom of Great Britain and Northern Ireland (UK). These negotiations are seen as an important initial step forward in building upon a long-term mutually beneficial economic relationship with the UK.

CMA is the leading voice and industry peak body for manufacturers, raw material suppliers, distributors, retailers, consultants, allied health practitioners and educators in the complementary medicines sector, representing over 80 per cent of all product sales and the full value chain in Australia. CMA promotes appropriate industry regulation and advancement to ensure consumers have access to complementary medicines of the highest quality. Please refer to Appendix 1 for more information about CMA.

Regulated in Australia as medicines under the *Therapeutic Goods Act 1989*, complementary medicines include vitamins, mineral and nutritional supplements, homeopathic, aromatherapy products and herbal medicines. The term 'complementary medicines' also comprises traditional medicines, including traditional Chinese, Ayurvedic, Australian Indigenous and Western herbal medicines.

CMA would like to acknowledge the Government's focus on improving Australia's economic competitiveness, the commitment to a reduction in the regulatory burden on industry, and the deepening of Australia's economic ties with the major countries within the region; ties that are essential for our future prosperity.

CMA also notes and strongly supports the growing focus of Australia's free trade agreement negotiations on helping to address 'behind the border' issues, and the Australian Government's goal of advocating for policy changes beyond other countries' borders in support of greater mutual understanding of national arrangements and a better interface between our regulatory frameworks and those of our neighbours.



The Competitiveness of Australia's Goods Exports

The Economic Contribution of Complementary Medicines Industry

Complementary medicines have been widely embraced by the Australian community, with over 70 per cent of Australians regularly using at least one form of complementary medicine product. The industry generates AUD5.6 billion in annual revenues and directly employs 2,605 high-skilled workers in the Australian manufacturing sector. Australian manufacturers are the global leaders in driving industry best practise, and the sector is recognised around the world for the highest quality and safety standards. Overall, we have seen a six per cent growth rate over the last five years – outpacing growth of the wider Australian economy.¹ Also, over the last five years, the sector has achieved over AUD2 billion in growth, predominantly as a result of strong exports, driven by increasing consumer demand internationally.

In recent years, the exportation of complementary medicines has been an enormous success for Australia. Our export markets have grown from AUD175 million to over AUD1 billion in just five years, mainly thanks to the competitive advantage of Australian complementary medicine firms in holding a well-deserved reputation for products of high quality and safety standards. This trend has boosted jobs in Australia across a range of sectors, including manufacturing, scientific evaluation, and research. Currently, over 60 per cent of Australian complementary medicines companies are engaged in exporting to 84 different countries across the globe.

Official exports of complementary medicines have risen 15 per cent in the last year, with over 20 per cent of all complementary medicine products manufactured in Australia being exported to other countries.² The top ten export countries sit in the Asian-Pacific region, dominating over 95 per cent of Australia's complementary medicines exports. Asia continues to drive growth, accounting for the lion's share of exports. While the industry is happy with the growth in exports to the Asia-Pacific region, it is also increasingly aware of the need to diversify export opportunities beyond our immediate region.

Despite the dire economic impacts of the COVID-19 pandemic across the world, and the resulting sharp down-turn in growth over the last six months, Australian complementary medicines exports remain comparatively strong. The latest official export figures for Australian complementary medicines show only a 4.5 per cent drop compared to the last financial year (2018-19). In light of the current challenging situation, particularly the extreme limits and price hikes placed on freight movements, this figure shows adaptation and resilience, especially compared to other sectors.

In spite of the challenges related to the COVID-19 crisis, the Australian complementary medicines industry is expected to continue its positive growth trajectory; increasing exports, leading the world in innovation-rich manufacturing practice and providing a significant contribution to the Australian economy. This comparatively strong industry position is thanks largely to Australian's strict manufacturing standards and Australia's well-deserved reputation for clean, well-regulated, and high-quality complementary medicines.

¹ CMA Complementary Medicines Industry Audit June 2020, available by request.

² Austrade (2020) Annual Exports Statistics: Vitamins & Supplements. Year ended June 2020



International Reputation for Quality and Safety Standards

Australia's complementary medicines industry is backed by a risk-based regulatory regime that is regarded as one of the strongest in the world. The regulation of complementary medicines falls within the remit of the Therapeutic Goods Administration (TGA), an arm of the Department of Health, which also regulates over-the-counter medicines, medical devices, and prescription medicines. The TGA has responsibility for the oversight of product safety, quality, claims, listings, post-market monitoring and setting standards for manufacturing. Complementary medicines must be manufactured under pharmaceutical-standard Good Manufacturing Practice (GMP) in TGA-approved and licensed facilities. Under this stringent regulatory paradigm, Australian complementary medicines are recognised as meeting the highest global standards of quality, safety, and efficacy. In fact, the Australian regulatory regime for complementary medicines is such that it is viewed by most countries as the consumer protection benchmark.

The benefits of the AU-UK FTA

Trade with international markets is crucial for the long-term prosperity of the Australian complementary medicines industry. This growth, based on exports, crucially supports further local investment in research and manufacturing, and job creation and job security in the industry. Continued trade liberalisation will present sizeable opportunities for the Australian complementary medicines industry as the sector is well positioned to compete for emerging opportunities.

Mutual Benefits Between Australia and the UK

The AU-UK FTA provides an opportunity to expand bilateral trade and investment and facilitate regulatory cooperation on a range of issues in the post-Brexit environment, including complementary medicines. The opportunity is mutual – a successful Australian industry can improve access into a growing market, diversifying export opportunities; and the UK can more closely align itself with Australia's best practice regulatory framework once it leaves the EU, providing certainty to trading arrangements with Australia and rest of the world.

CMA, therefore, strongly supports the specific inclusion of Australian complementary medicines into all future free trade negotiations and regulatory framework discussions.

Australia's complementary medicines exports to the UK are currently low in absolute terms and compared to Australia's exports to Asia. Australia's total complementary medicines exports were valued at AUD1.08 billion for the year ending 2019, 85.5 per cent of which went to Asia. Exports to the UK represented just 3 per cent of this total.³ Despite this, in 2019, the AUD23.7 million worth of exports to the UK was more than double that of the previous year.⁴

³ CMA Complementary Medicines Industry Audit June 2020, available by request

⁴ Austrade (2019) Annual Exports Statistics: Vitamins & Supplements. Year ended December 2019



With an ageing population and a growing awareness of health and wellness in the UK, complementary medicines are highly attractive for UK consumers. According to the latest Health Food Manufacturers' Association (HFMA) 'Health of the Nation Survey' in 2019, about 70 per cent of the adult population take food supplements, with 41 per cent of these on a daily basis, which equates to 16.5 million people. Over a quarter of these have started taking supplements in the last year, and around two-thirds are planning to take more food supplements as they get older. The sale of food supplements in the UK is expected to reach £500 million (AUD910 million) by 2022,⁵ and grow over the next five years.

Due to these factors, once the FTA between Australia and the UK is in place, Australia's trade and investment in complementary medicines with the UK is expected to grow, with UK consumers benefiting from high quality Australian complementary medicines products. Additionally, the post-COVID environment, in which consumers have increased awareness of the need to maintain good general health, offers Australian complementary medicine increased opportunities for expansion. Moreover, greater trade with the UK will support greater diversification of Australia's exports from Asia to new growth markets, and this growth crucially supports further local investment in research and manufacturing, and job creation and job security in the industry.

The AU-UK FTA has the potential to substantially benefit UK complementary medicines businesses. A high standard FTA can both remove/address barriers to Australian exporters and advance closer regulatory alignment on complementary medicines trade between Australia and the UK post-Brexit. It is widely recognised that Australia's TGA approach to regulating complementary medicines represents a prudent balance between the overly restrictive and complicated EU approach, and the 'laissez faire' approach to complementary medicines regulation observed in the United States and some developing countries. By seeking closer alignment with the TGA approach, the UK's complementary medicines industry could unlock significant commercial opportunities at home and abroad, while ensuring product safety, efficacy and improvement in health outcomes.

Additionally, closer integration into Australia's complementary medicines and food manufacturing sector will allow UK suppliers, including UK suppliers of complementary medicines, infant formula and processed foods, to share in the preferential access Australia has via its FTAs with fast growing Asian markets. Closer alignment of trade regulation based on open policy settings is complementary to regional FTAs involving Australia, including the CPTPP, to which the UK has expressed an intention to join. Moreover, a stronger trade relationship can support development of the UK food sector. Closer regulatory alignment and expanded trade with Australia will support the development of open and sound regulatory frameworks for trade in complementary medicines post Brexit. The UK can draw on Australia's TGA regulatory system to further build the UK food supplements and manufacturing and sector.

The FTA can also strengthen the bilateral investment relationship in food and food supplements and enhance growing UK-AU cross investment. Closer industry cooperation on research, development and

⁵ Health Food Manufacturers' Association <https://hfma.co.uk/media-events/>



technology will provide opportunities for greater UK participation in and development of the Australian industry.

Finally, Australia can continue to grow its complementary medicines manufacturing industry. Greater bilateral trade and investment in complementary medicines will help grow Australian manufacturing and create jobs at home. Australia's complementary medicines industry is worth AUD5.6 billion and with the right supports, has the potential to flourish and help build a resilient economy into the future. The Australian Government has developed a whole of government strategy to re-emerge stronger after the COVID-19 pandemic, recently announcing \$1.5 billion investment over four years as part of its Modern Manufacturing Strategy.⁶

Aside from providing the economies of Australia and the UK opportunities for freer movement of goods and services, completion of the Australia-UK FTA would certainly be advantageous to the Australian economy. CMA members are also looking at ways in which they can provide raw materials to their global supply chain from Australia. The finalization of the Australia-UK FTA, should provide further business confidence in this area and with the support of AgriFutures Australia, see an even greater impetus in emerging industries and the sourcing raw materials from Australia for use in global supply chains.

Trade Barriers with UK

Below, details of the issues identified by industry stakeholders concerning tariff rates and technical requirements and controls are summarised.

1) Tariffs

Tariffs applied to Australian complementary medicine products and ingredients can be as high as 12 per cent. These tariffs will continue to apply on a Most Favoured Nation (MFN) basis when the UK leaves the EU, whereas Australia's applied tariffs on these products are at lower rates (average between 2.5 and 3 percent) according to the WTO Tariff Database.

It is vital that the agreement should allow duty free entry, or at least at reduced levels from their current ones of 8 – 12 per cent, for all complementary medicine exports from Australia.

2) Non-Tariff Measures (NTMs) – Technical requirements and controls

Australian exporters of complementary medicines currently face barriers when selling to the UK market, deriving from the multitude of complex regulations at the EU level which currently apply to exports to the UK.

⁶ Make it Happen: The Australian Government's Modern Manufacturing Strategy: <https://www.industry.gov.au/data-and-publications/make-it-happen-the-australian-governments-modern-manufacturing-strategy>



In the EU, complementary medicine products are regulated as ‘food supplements’, thus they must comply with horizontal rules for all foods in addition to specific rules for food supplements.⁷ Regulatory requirements are multiple, prescriptive and sometimes uncertain in their application and scope (e.g. overlap with food additives, medicines). Product composition (related to maximum levels of ingredients; use of botanical ingredients; and use of other substances) is not regulated in the UK, nor harmonised at the EU level, creating gaps in regulation.

Australian complementary medicines exporters are facing the large regulatory chasm that exists between the Australian and the UK markets, as quality control of finished goods is far behind Australia’s advanced PIC/S GMP-based model. Our industry is therefore highly concerned that any FTA may have the potential to competitively disadvantage Australian-made complementary medicines if UK-made food supplements were given preferential treatment whilst underpinned by the current UK food supplements regulatory system. These concerns are amplified following the UK’s exit from the EU, whereas the EU, albeit still falling short of Australian regulatory standards, at least has a comparatively (to UK) sophisticated (though not widely enforced) regulatory framework.

Given it is still uncertain what food laws will apply in the UK from 2021 when the transition period for the UK leaving the EU is over, and how or if regulation of food supplements and complementary medicines will change or if the UK will develop its own model of regulation, our industry asks for clear rules to provide regulatory certainty to exporters and address barriers that impede trade.

Australia has a well-established regulatory framework for complementary medicines under the TGA that sets strict standards without the regulatory complexity and burden of the EU system. Australian complementary medicine products are globally recognised for their quality and safety and considered with high regard to be ‘clean, green, safe and secure’.⁸

Thus, the compliance burden on exports should be avoided or significantly reduced if Australian complementary medicine products are to be imported into the UK, particularly based on the fact that Australian complementary medicine products are manufactured to pharmaceutical standard under GMP in TGA approved and licensed facilities, which ensures consumer protection.

This would remove the requirement to meet prescriptive EU rules on product composition and ingredients for products that are already approved for sale in Australia. Many TGA-approved products have been safely used in Australia for decades; the FTA should reflect that such products are also safe for use in the UK.

⁷ There are more than 15 EU-wide laws on food that Australian producers must comply with plus specific laws on food supplements under Directive 2002/46/EC on Food Supplements (the Directive). This provides for partial EU-wide regulation of food supplements containing vitamins and minerals. Key aspects of product composition (e.g. the use of other substances such as botanical extracts, essential fatty acids or fibre, or maximum permitted levels) are not covered by the Directive and remain the sole competence of the EU Member States.

⁸ Clinical Research Corporation (CRC), Complementary Medicines in Australia – a Benchmark for Best Practice Regulation, Industry Paper, June 2018.



The FTA can facilitate this through commitments which recognise Australian conformity assessment procedures (and GMP) and/or TGA standards for complementary medicines products as ‘equivalent’ to UK standards. These commitments can form part of an FTA or can be negotiated in parallel as stand-alone agreements.

Recognition of conformity assessment and GMP

Recognition of conformity assessment and GMP of complementary medicine products would give Australian exporters certainty that their products can be tested in Australia against UK regulations and sold in the UK. Australia has negotiated a Mutual Recognition Agreement (MRA) on conformity assessment with the UK that carries over the terms of the existing Australia/EC MRA from 2021.⁹ This covers medical devices and GMP for pharmaceuticals. It could be built on to also recognise GMP and testing for complementary medicines.

Australia is recognised globally as having one of the most rigorous certification processes for manufacturing complementary medicine products. Australian complementary medicine products are made to world-leading quality and safety standards and best practice in manufacturing processes; Australia is the only market in the world that prescribes that these products must be made to pharmaceutical standard GMP in Government-licensed and audited pharmaceutical-grade facilities. Australia has recently concluded bilateral MRAs with the UK for other products, such as trade in wine,¹⁰ to ensure continuity of open and certain trading arrangements post Brexit.

Regulatory equivalence

Going beyond conformity assessment and GMP, the UK could recognise Australia’s TGA regulation of complementary medicines as ‘equivalent’ to UK regulations. This would further expand trade in safe and quality products and enhance regulatory certainty. The objective is not to change UK or Australian regulations, but to secure recognition that the two jurisdictions have equivalent systems for the purpose of trade – i.e. the UK agrees to accept TGA authorisation as evidence a complementary medicine meets UK requirements for the import, sale and marketing of complementary medicine products on that basis.

Regulatory recognition is not new as a means to facilitate trade. Aside from longstanding experience with mutual recognition in the EU internal market, the UK (through the EU) has equivalence agreements that recognise food regulations of other trading partners. Recent FTAs of the EU and Australia also include specific provisions for ‘cross recognition’ or ‘mutual recognition’ of technical regulations.

⁹ https://www.aph.gov.au/Parliamentary_Business/Committees/Joint/Treaties/MRA-UK/Report_187/section?id=committees%2Freportjnt%2F024326%2F27698

¹⁰ The bilateral Agreement between the UK and Australia is based on the existing Agreement between the European Community and Australia on Trade in Wine, of 2008. The provisions of the UK Agreement replicate the agreement with the EC. They include the continued recognition of existing winemaking techniques, labelling requirements, certification requirements, and continued recognition of and protection for geographical indications and traditional expressions.



Examples of regulatory equivalence in recent trade agreements

EU/UK bilateral agreements. In 2017 the EU and Chile concluded an agreement on trade in organic (agricultural and food) products, whereby both parties agreed to mutually recognise the equivalence of their respective organic production standards and allow imports into each other's territory of certain organic products. The UK and Chile concluded a bilateral agreement in 2019 to continue the terms of this agreement between them, post Brexit.

Australian and EU FTAs. The Canada/EU FTA (CETA) provides for equivalence of certain SPS measures, and the Singapore/Australia FTA (SAFTA) the acceptance of equivalence of food standards, when certain conditions are met. The Comprehensive Progressive Trans Pacific Partnership Agreement (CPTPP) encourages regulatory recognition for cosmetic products, pharmaceuticals and medical devices as set out in sectoral annexes.

Source: ITS Global 2019

Though they differ in scope and complexity, these agreements have common elements that can guide an agreement on regulatory equivalence as part of an Australia/UK FTA. Please refer to Appendix 2 for more details.

A flexible and tailored approach can be adopted to allow each party to identify regulations/laws and products it will recognise as 'equivalent', as well as take into account any concerns of regulatory variance.

For example, partial recognition (in terms of regulations and product coverage) could be considered, focusing on a select number of well-known and safe premium complementary medicine products that are traded between Australia and the UK (e.g. multivitamins, single ingredient botanicals), and/or areas that are currently not regulated in the UK at the EU level (e.g. permitted botanical ingredients and claims).

Regulatory Cooperation Agenda

Concurrent to the outcomes above, Australia and the UK should commit to a Trade and Cooperation Agenda on Complementary Medicines / Food Supplements, focused on expanding trade; facilitating regulatory cooperation and alignment of standards; and enhancing cross investment in complementary medicines and food supplements.

The FTA should include a mechanism to support this, such as a Working Group or Committee that brings together regulators and industry from both countries to address issues of specific trade interest. This could include, for example, initiatives to further cooperation on regulation of permitted use and health claims for botanical ingredients.



Regulatory cooperation on botanical ingredients and claims

Australia's TGA has a safe and proven system regulating the use of botanical ingredients and claims on complementary medicines; within Australia's strict regulatory framework, permitted ingredients used in complementary medicine products, including 'permitted indications', are pre-assessed and pre-approved.

The UK (EU) does not yet have an agreed or harmonised approach to the use of botanical ingredients in food supplements. A common list of approved plants in food supplements has been developed by Belgian, French and Italian authorities - the 'BELFRIT' list. Permitted types of botanical ingredients have been considered by European Food Safety Authority (EFSA) since 2016, with no legislative outcomes to date. However, there are recent indications that the EU could consider moving closer toward regulation of permitted indications for botanicals that are more closely aligned with the Australian TGA system.

A cooperation agenda would provide an effective platform for UK and Australian counterparts to further explore this alignment in the interests of expanding trade.

*Source: <https://www.iadsa.org/food-supplements-containing-botanicals-important-issues-to-consider-in-the-development-of-regulatory-measures>
https://ec.europa.eu/food/safety/labelling_nutrition/claims/refit_en*

Conclusion

The WHO's Traditional Medicine Strategy 2014-2023 highlights the potential contribution that complementary medicines can make to health, wellness and people-centred healthcare through the appropriate integration of complementary medicines into the healthcare system. The increasing importance of the complementary medicines industry to global health can be seen in the increase in global regulatory standards and regulatory alignment, and the increase in economic and political discourse about the integration of complementary medicines with conventional medicine.

The global economic crisis has highlighted the high degree of interdependence of economies worldwide and the degree to which growth depends on open markets. The complementary medicines industry recognises the importance of a strategic, collaborative approach to International market engagement, via leveraging our strengths, facilitating strong commercial ties, and opening up opportunities.

With an ageing population and a growing awareness of health and wellness in the UK, the AU-UK FTA has the potential to significantly increase Australian exports of complementary medicines to the UK by removing or reducing regulatory and tariff controls in the UK market.

Thank you for the opportunity to express our support for the AU-UK FTA. We would be pleased to provide further comment as required by the Free Trade Agreement Division.



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Appendix 1

Complementary Medicines Australia

Complementary Medicines Australia (CMA) is the peak industry body for the complementary medicines industry. CMA is unique in representing the entire supply chain including:

- manufacturers
- importers
- exporters
- raw material suppliers
- sponsors
- wholesalers
- practitioners
- consultants
- research & educational institutions
- distributors, and
- retailers

We are the principal reference point for our members, the government, the media and consumers to communicate about issues relating to the complementary medicine industry.

Complementary medicines and natural healthcare products include vitamins, mineral and nutritional supplements, special purpose foods, herbal and homeopathic medicines, aromatherapy products, and natural cosmetics using herbals and botanicals. The term 'complementary medicines' also comprises traditional medicines, including Traditional Chinese Medicines, Ayurvedic and Australian Indigenous medicines.

Complementary medicines are generally available for self-selection by consumers and can be obtained from retail outlets such as pharmacies, supermarkets and health food stores. The majority of complementary medicines are indicated for the relief of symptoms of minor, self-limiting conditions, maintaining health and wellbeing, or the promotion or enhancement of health.

Currently there are approximately 92 TGA licenced medicine manufacturers in Australia, with the majority of manufacturers located in NSW.



Appendix 2

REGULATORY EQUIVALENCE IN FREE TRADE AGREEMENTS

What is 'equivalence'?

Regulatory equivalence is achieved when each party recognises the laws/regulations of the other regarding a specified regulatory goal – such as the safety of complementary medicines/food supplements - as 'equivalent' to its own. To be 'equivalent' laws do not need to be identical; however, they need to be capable of meeting the same objectives. Where these differing laws are judged to achieve the same outcomes, then they can be mutually accepted. Equivalence is different to harmonisation, whereby both parties adopt identical rules.

Mutual recognition or acceptance of equivalence is possible where regulations are based on similar perceptions of risks and, hence, aim for a similar level of protection. Equivalence can be 'full' or 'partial' in terms of the scope of technical standards and coverage of products.

The equivalence of regulations is recognised as a means of overcoming technical barriers to trade (TBT) without the need for regulatory harmonisation (and therefore without the need to parties to change their domestic regulations). The WTO TBT Agreement encourages members to accept the technical regulations of other Members as equivalent to their own, where they are satisfied that the regulations adequately fulfil the objectives of their own regulations.¹¹ Similar provisions exist in bilateral and regional FTAs.

Has it been done before?

The EU has longstanding experience with mutual regulatory equivalence. The principle lies at the heart of the European Common Market. By law, the principle of mutual recognition applies in areas where EU law is not harmonised.¹² In theory, any product lawfully sold in one Member State can be marketed in any other Member State.

The EU also has bilateral equivalence agreements that recognise the equivalency of food regulations - and in some cases, veterinary standards - of its trading partners. The EU has also negotiated bilateral trade agreements with third countries that recognise the regulations of the other country as equivalent to those in the EU, sufficient for entry of the foreign product into the EU market. Approaches in FTAs tend to build on existing equivalence arrangements. They differ by partner country and product. The UK has transposed many of these EU wide agreements to bilateral agreements with the trading partner involved in preparation for when the UK leaves the EU.

Australia has made commitments on recognition of conformity assessment and for regulatory equivalence for food products in its bilateral FTAs, though to varying degrees. The most specific provisions are included in the bilateral agreement with Singapore.

¹¹ WTO TBT Agreement Article 2.7

¹² Mutual recognition currently applies under [Regulation \(EC\) No 764/2008](#). The EU has recently updated and its regulations on mutual recognition to improve the operation of the process. Pursuant to Regulation (EU) 2019/515 of 19 March 2019, new rules will apply from 2021.



Regulatory equivalence in EU/UK trade agreements

The EU has already entered into regulatory equivalence arrangements on certain products with several trading partners, for example on the regulation of organic products and veterinary standards. The arrangements demonstrate flexibility in the types of standards and products that can be recognised as equivalent, depending on the relevant traded products and applicable SPS risk. They tend to be replaced and incorporated into more comprehensive trade agreements.

EU equivalence arrangements for organic products

EU import rules for organic products allow for a range of equivalence arrangements. The EU recognizes competent regulatory control bodies in third countries to verify the compliance of individual products with EU rules, cross-checked through EU controls.¹³

Australia is currently unilaterally recognised as a third country from which imported (Australian) products can be sold into Europe as organic.¹⁴ Bilateral individual organic equivalence agreements exist with several other countries.¹⁵

While the arrangements operate EU-wide, there is some diversity in the details of scope, coverage and implementation among the Member States.¹⁶

A new EU regulation on organic production is scheduled to enter into force in January 2021.¹⁷ The new regulation effectively harmonises law on organic products across the EU.

Recently the EU has moved to upgrade equivalency arrangements by incorporating them in trade agreements. It now has an agreement with Chile on trade in organic products. Equivalency provisions feature in the SPS provisions of the Canada/EU trade pact (the Comprehensive Economic Trade Agreement - CETA). Both build on existing bilateral arrangements. Though they differ in scope and complexity both agreements have common elements.

EU (UK) /Chile Agreement on Trade in Organic Products - In 2017 the EU and Chile concluded an agreement on trade in organic (agricultural and food) products, replacing the existing equivalency arrangement.¹⁸ This was the first of the 'new generation' agreements on trade in organic products concluded in line with the new EU Regulation. Both parties agreed to mutually recognise the equivalence of their respective organic production standards and allow imports into each other's

¹³ Simplified rules apply to all organic products of a country if rules regulating the entire production process are considered to be equivalent to EU requirement. In this case, product-specific verification is not required. See Bettina Rudloff (2014), *Food standards in Trade Agreements, Differing Regulatory Traditions in the EU and US Tips for the TTIP*, German Institute for International and Security Affairs

¹⁴ along with Argentina; Costa Rica; India; Israel; NZ and Tunisia. Pursuant to Regulation (EC) 1267/2011, together with regulation (EC) 1235/2008. See <https://www.aco.net.au/Pages/Operators/EuropeStandards.aspx>

¹⁵ For example, Switzerland (1997); Japan (2010); Canada (2011); US (2012); Korea (2015); and Chile (2018).

¹⁶ The current arrangements allow for Member States to give 'derogations' to sectors that cannot fully meet EU organic standards, as well as exceptions to equivalence for certain products or production methods. See USDA FAS (2017) New EU Organic Regulations for Early 2018, GAIN Report Number E17076, November 2017.

¹⁷ Regulation (EU) 2018/848 provides that control bodies will certify organic products that comply with EU rules and that the recognition of equivalent third countries will be granted through international agreements between the EU and the third country concerned.

¹⁸ Entry into force January 2018.



territory of certain organic products. In 2019 the UK and Chile concluded a bilateral agreement which transposes the terms of the EU Agreement as they apply between the UK and Chile post Brexit.

Equivalence of organic production rules in the EU (UK) /Chile Agreement Trade in Organic Products

The scope of recognition in the Agreement is both limited and partial. The grant of equivalence is limited to the laws of each party and covers products (of the other) which are positively listed in annexes to the agreement. Product specific exceptions and conditions apply as noted in the Annexes, with some products expressly excluded.

Products must meet an origin requirement and comply with labelling requirements in the country of export, as set out in recognised laws. They also must be accompanied by a certification of inspection that is issued by a recognised national certifying body/authority in order to be recognised.

The agreement provides for a system of cooperation, exchange of information and dispute settlement in organic trade.¹⁹ A Joint Committee is established to resolve disputes, supervise the operation of the agreement, and update or expand lists of products.

Sources: [https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:22017A1214\(01\)&from=IT](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:22017A1214(01)&from=IT)
and

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/776721/CS_Chile_1.2019_Trade_Organic.pdf

EU/Canada Comprehensive Economic Trade Agreement (CETA) - The EU and Canada have also agreed to recognise some of each other's laws on animal health as equivalent for the purpose of trade in the CETA. Parties commit to accept certain SPS measures of the other as equivalent to their own for the purposes of trade. Equivalence is based on the exporting Party objectively demonstrating to the importing Party that its measure achieves the importing Party's appropriate level of SPS protection.²⁰

These equivalence arrangements are significant in demonstrating the capacity and willingness of trading partners to facilitate trade through binding and specific provisions for equivalence in a bilateral FTA. This is so even in SPS areas which generally involve a higher level of associated health and safety risks than those posed by manufactured products.

Regulatory equivalence in Australia's trade agreements

There are also commitments for regulatory equivalence and mutual recognition of conformity assessment in some of Australia's FTAs. Some examples are highlighted below.

Australia/Singapore FTA - The TBT Chapter of the Australia/Singapore FTA TBT obliges the parties to accept the results of conformity assessment and approval procedures of the other Party as set out in Sectoral Annexes. The Annexes set out details governing the procedures for accepting the results of

¹⁹ European Parliament (2018) Modernisation of the trade pillar of the EU-Chile Association Agreement, Briefing: International Agreements in Progress, November 2018.

²⁰ CETA Article 5.6. <https://ec.europa.eu/trade/policy/in-focus/ceta/ceta-chapter-by-chapter/>



the conformity assessment and approval procedures; and the regulatory authorities designated by each Party.

The Annex on Food Products to the SAFTA provides for equivalence of mandatory food standards between Australia and Singapore. It obliges parties to accept the food standards of the other party as equivalent where they achieve same objective, and to follow international procedures for determining equivalence.²¹

Regulatory recognition of food products in the Australia/Singapore FTA

The TBT Chapter to the Agreement obliges the parties to accept equivalence of the mandatory requirements, of the other Party in accordance with the respective Sectoral Annexes.

The Annex on Food Products commits the parties to accept food standards of the other party as equivalent where they achieve the same objective, even if that standard differs from its own, or from those used by other countries trading in the same food product, if the exporting Party objectively demonstrates to the importing Party that its food standard achieves the purposes of the importing Party's food standards.

Source: Australia/Singapore FTA, TBT Chapter, Annex on Food Products

The Comprehensive Progressive Trans Pacific Partnership Agreement (CPTPP) encourages regulatory recognition for cosmetic products, pharmaceuticals and medical devices as set out in sectoral annexes. For example, the Annexes on Cosmetics and on Medical Devices include general provisions to support alignment of regulations and regulatory activities for cosmetic products. The Annex on Organic Products has an obligation to consider requests from other parties for recognition or equivalence of a technical regulations, standards or conformity assessment procedures related to the production, processing or labelling of organic products.

²¹ Annex 5: Technical Regulations and Sanitary and Phytosanitary Measures, Sectoral Annex 5A on Food Products, Article 3.