NATIONAL INTEREST ANALYSIS: CATEGORY 1 TREATY

Agreement between Australia and the Republic of Iceland, the Principality of Liechtenstein and the Kingdom of Norway amending the Agreement on Mutual Recognition in relation to Conformity Assessment, Certificates and Markings between Australia and the Republic of Iceland, the Principality of Liechtenstein and the Kingdom of Norway

(Brussels, 21 September 2018)

[2020] ATNIA 5
[2020] ATNIF 8

Nature and timing of proposed treaty action

1. The proposed treaty action is the entry into force of the *Agreement between Australia and the Republic of Iceland, the Principality of Liechtenstein and the Kingdom of Norway amending the Agreement on Mutual Recognition in relation to Conformity Assessment, Certificates and Markings between Australia and the Republic of Iceland, the Principality of Liechtenstein and the Kingdom of Norway* ('the Amending Agreement'), done at Brussels on 21 September 2018.

2. The Amending Agreement has been agreed in line with Article 15(2) of the *Agreement on Mutual Recognition in relation to Conformity Assessment, Certificates and Markings between Australia and the Republic of Iceland, the Principality of Liechtenstein and the Kingdom of Norway [European Free Trade Association – European Economic Area]* ([2000] ATS 17)[1] ('the Australia-EFTA EEA MRA'), which provides for amendments where there is mutual agreement between the Parties.

3. As per Article 2 of the Amending Agreement, it will enter into force on the first day of the second month following the date on which the Parties have exchanged diplomatic notes confirming the completion of their respective procedures for entry into force. It is proposed that Australia provide such notification, as soon as practicable, following consideration by the Joint Standing Committee on Treaties (JSCOT).

Overview and national interest summary

4. The purpose of the Amending Agreement is to amend and simplify the existing Australia-EFTA EEA MRA, such that its terms are consistent with those of the *Agreement on Mutual Recognition in relation to Conformity Assessment, Certificates and Markings between the European Community and Australia*, including its Annex and Sectoral Annexes ([1999] ATS 2),[2] as amended in 2012 ([2013] ATS 2)[3] ('the EC-Australia MRA').

5. Under the Australia-EFTA EEA MRA, Australia and the other Parties recognise and accept the technical competence of each other's conformity assessment bodies (CABs) to

[1] Available at: http://www.austlii.edu.au/au/other/dfat/treaties/2000/17.html
[2] Available at: http://www.austlii.edu.au/au/other/dfat/treaties/ATS/1999/2.html
[3] Available at: http://www.austlii.edu.au/au/other/dfat/treaties/ATS/2013/2.html

test, inspect and certify products for compliance with each other's respective regulatory requirements. This eliminates the need for duplicative re-testing or re-certification when the goods are traded.

6. The Amending Agreement simplifies the Australia-EFTA EEA MRA's administrative arrangements and introduces greater flexibility. The amendments remove the rule of origin restriction, accord less than treaty status to the Sectoral Annexes that form the administrative arrangements for the Australia-EFTA EEA MRA, and extend the role of the Joint Committee to amend these Sectoral Annexes in response to regulatory and industry developments.

7. The amendments will enhance the benefits of the Australia-EFTA EEA MRA by enabling timely maintenance of the Sectoral Annexes and allowing Australian export businesses in the designated product areas, as well as CABs, to more readily benefit from the operation of the Australia-EFTA EEA MRA.

Reasons for Australia to take the proposed treaty action

8. The proposed amendments will bring the Australia-EFTA EEA MRA into line with the EC-Australia MRA, ensuring consistency between Australia's mutual recognition arrangements with Member States of EFTA EEA and the EU.

9. Since the Australia-EFTA EEA MRA's entry into force, certain administrative aspects of the MRA have proved to be unwieldy and inefficient, particularly the requirement that changes to the Sectoral Annexes undergo both Parties' domestic treaty amendment processes.

10. The inclusion of the rule of origin provision in Article 4 of the Australia-EFTA EEA MRA, which specifies that the products covered must originate in the Parties to the Agreement, had limited the opportunities for Australian manufacturers and testing bodies to utilise the agreement. This provision potentially restricted where Australian businesses could source their inputs and the markets where Australian CABs could compete for conformity assessment work.

11. A failure to amend the Australia-EFTA EEA MRA to streamline administrative updates to the Sectoral Annexes may lead to further under-utilisation of the agreement, as changes to Australian legislation and the EC-Australia MRA would continue to require treaty-level amendments to the Australia-EFTA EEA MRA Sectoral Annexes, rather than less than treaty administrative amendments, to remain up to date.

Obligations

12. The Amending Agreement does not significantly alter Australia's core obligations under the Australia-EFTA EEA MRA. These obligations are set out in the National Interest Analysis for that agreement,[4] and require Australian regulators in agreed product areas to accept attestations of conformity – including test reports, certificates, authorisations and where appropriate marks of conformity – issued in accordance with Australian requirements by specifically designated CABs in the EFTA EEA States. The Amending

[4] Available at: http://www.austlii.edu.au/au/other/dfat/nia/1999/9.html

Agreement will affect the operation and scope of the Australia-EFTA EEA MRA obligations as they relate to the Sectoral Annexes.

13. The proposed amendments are set out in Article 1 of the Amending Agreement. The key amendments are outlined below, including an explanation of how they affect the rule of origin restriction and administrative provisions.

Removal of the Rule of Origin Restriction

14. The proposed amendment to Article 4 of the Australia-EFTA EEA MRA removes the rule of origin restriction and replaces it with a more general 'scope and coverage' provision. This states that the MRA will apply to the conformity assessment of products specified in the statement of scope and coverage in each Sectoral Annex. The proposed amendment thereby retains the rule of origin restriction in the scope and coverage statement for the Sectoral Annex on Medicinal Products Good Manufacturing Practice (GMP). It also inserts a similar restriction into the scope and coverage section of the Sectoral Annex on Medical Devices.

Simplification of the Australia-EFTA EEA MRA

15. Article 3(2)(c) of the Australia-EFTA EEA MRA has been removed such that the Sectoral Annexes no longer require a list of CABs. Instead, both Parties will retain and update their own lists of CABs (amended Article 9(1)).

16. Amendments to Articles 6(1) and 6(2), which refer to the powers of the Designating Authorities, remove inconsistencies in the language between the two Articles and reflect the inclusion of processes in relation to the suspension of a CAB, as previously outlined in Article 6(3) (which has now been removed).

17. Article 8(6) has been amended to provide that unless decided otherwise by the Joint Committee, the suspension of a CAB now occurs from the time its competence or compliance is challenged by a Party, rather than when suspension has been agreed by the Joint Committee. The suspension runs from this time until either agreement has been reached in the Joint Committee, or the challenging Party notifies the other Party and the Joint Committee that it is satisfied as to the competency of the CAB in question.

18. Article 9(1) has been expanded to ensure that the Parties to the agreement maintain an accurate list of CABs designated in accordance with the Australia-EFTA EEA MRA. Changes to Article 9(2) and the inclusion of a new Article 9(3) clarify that when considering amendments to legislative, regulatory and administrative provisions that relate to the subject matter of the Agreement, each Party must provide a reasonable time for other Parties to comment on the proposed amendments. Further, in case of urgent amendment measures, Parties must notify each other of the measures and reasons for their immediate imposition. These updates to Articles 9(2) and 9(3) broadly reflect the Parties' existing notification obligations for conformity assessment procedures under Article 5 of the World Trade Organization Agreement on Technical Barriers to Trade.

19. Amendments to Article 12 expand the powers of the Joint Committee, granting it the ability to amend the Sectoral Annexes and to adopt new Sectoral Annexes. Amendment to Article 12(6) provides processes for the designation of a CAB by a Party and the

procedure for objecting to a CAB designated by the other Party. Amendment to Article 12(6)(c) also gives the Joint Committee power to verify the technical competence of a contested CAB.

20. Amendments to Article 15(1) make it clear that the Sectoral Annexes have less than treaty status. Amendments to Articles 15(3) and 15(4) empower the Joint Committee to adopt new and amend current Sectoral Annexes, respectively. While the Sectoral Annexes do not have treaty status, changes to them will affect the scope of obligations.

Sectoral Annex on Medicinal Products GMP Inspection and Batch Certification

21. The amendments to the 'Scope and Coverage' section are primarily language-related, ensuring consistency with amendments to the main body of the Australia-EFTA EEA MRA. They do not provide for any new obligations.

22. Section II has been amended such that the Parties must now maintain respective lists of official inspection services. A Party may request that the other Party provide the latest lists of official inspection services. The other Party must comply with this request within 30 days of receipt.

23. Paragraph 7 of Section III has been amended to include the right of a Party to request additional information about the capability of official inspection services or their programs where significant changes to regulatory systems have occurred. This is to ensure that these services are sufficiently competent to carry out conformity assessment in accordance with the other Party's regulatory requirements.

24. Amended Section IV provides that the Parties may be required to provide information to verify programs for the mutual recognition of inspections for the entry of a new official inspection service or where there have been significant changes to an official inspection service.

Sectoral Annex on Medical Devices

25. The Amended 'Scope and Coverage' section provides that the Sectoral Annex will apply to medical devices exported to Australia only if they are "manufactured in the European Economic Area (EEA) EFTA States". This is a more restrictive rule given the high risk nature of the products involved and will provide confidence that only bodies with quality assured and monitored manufacturing practices will fall within the scope of the amended Australia-EFTA EEA MRA.

26. Amendments to paragraph 1 of Section V update and strengthen confidence-building measures, helping ensure that CABs can demonstrate their experience in assessing conformance to Australian requirements. The confidence-building period will be reviewed after two years of the amended Sectoral Annex being in operation.

27. Paragraph 5 of Section V provides that the Sectoral Annex shall not constrain a Party from implementing measures necessary to protect public health and safety.

Implementation

28. No changes to Australian legislation are required to implement the Amending Agreement. State and Territory Governments are responsible for regulating the low voltage equipment, machinery and pressure equipment sectors covered by the Australia-EFTA EEA MRA. An Inter-Governmental Cooperation Agreement between the Commonwealth and the States and Territories signed in 1998 commits the States and Territories to the terms of the Australia-EFTA EEA MRA, and is not affected by the Amending Agreement.

Costs

29. There will be minimal financial costs associated with bringing the Amending Agreement into force.

30. Removal of the rule of origin restriction for all but two of the Sectoral Annexes, namely the Sectoral Annex on Medicinal Products GMP and the Sectoral Annex on Medical Devices, will allow Australian firms greater flexibility and competitiveness in sourcing inputs, and enable Australian testing and certification bodies greater scope to compete on world markets in relation to products from third countries. The amendments will result in potential cost-savings in terms of 'time to market' and fees for testing, inspection and certification.

31. In the case of the Sectoral Annexes on Medicinal Products GMP and Medical Devices, there will be a significant reduction in regulation and regulatory cost burden for Australian importers using overseas manufacturing sites in EFTA EEA countries, largely associated with the cost of on-site Therapeutic Goods Administration (TGA) inspections.

32. The TGA has advised that as the proposed amendments are largely mechanical, it does not anticipate any additional costs associated with confidence-building and confidence-maintenance for Medicinal Product GMP inspections. Existing processes are expected to carry over into the amended Australia-EFTA EEA MRA.

33. The Australian Pesticides and Veterinary Medicines Authority (APVMA) has advised that, from a regulatory perspective, the savings to industry from the Amending Agreement will be partly offset by the cost of confidence-building and confidence-maintaining measures. However, ongoing maintenance activities have increased the effectiveness of the APVMA's regulatory activities and led to efficiencies and cost savings such as improved inter-agency communication, including with overseas regulatory agencies not a Party to the Australia-EFTA EEA MRA, and Rapid Alerts. Rapid Alerts are a process whereby regulatory agencies are promptly advised when defective batches of medicinal products are removed from the marketplace by another agency.

34. Administrative costs under the current Australia-EFTA EEA MRA, including meetings of the Joint Committee, are covered within the normal appropriations for the Department of Industry, Science, Energy and Resources, the lead implementing agency and Australian member of the Joint Committee.

Future treaty action

35. In accordance with Article 15(2) of the Australia-EFTA EEA MRA, any further amendments to the main body of the agreement or its Annex would require the approval of each Party and be subject to Australia's domestic treaty making requirements.

36. Under the proposed amendments to Article 15 of the Australia-EFTA EEA MRA, the eight Sectoral Annexes would be accorded less than treaty status. Any changes to these Annexes would be at the discretion of the Joint Committee (comprised of Australian and EFTA EEA representatives), in consultation with relevant government and industry bodies.

Withdrawal or denunciation

37. Under Article 14(2) of the Australia-EFTA EEA MRA, either Party may terminate the agreement by giving the other Party six months' notice in writing. This provision will not be affected by the Amending Agreement.

Contact details

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ATTACHMENT ON CONSULTATION

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CONSULTATION

38. Consultation for the Amending Agreement has focused on Australia's State and Territory Governments, peak national standards and conformance technical infrastructure bodies, and key industry associations.

39. All of the State and Territory Departments of Premier/Chief Minister and Cabinet were advised by letter of the proposal to negotiate an Amending Agreement and invited to comment on issues of importance to them, in addition to the Australian Capital Territory Treasury and Economic Development Directorate.

40. Australia's peak national standards and conformance quality infrastructure bodies were advised by letter of the proposal to negotiate an Amending Agreement and invited to comment on issues of importance to them, including: Standards Australia, the National Association of Testing Authorities (NATA), and the Joint Accreditation System of Australia and New Zealand (JAS-ANZ).

41. Australia's key industry associations were advised by letter of the proposal to negotiate an Amending Agreement and invited to comment on issues of importance to them. These were: the Australian Chamber of Commerce and Industry, Australian Industry Group, Business Council of Australia, Australian Information Industry Association, Federal Chamber of Automotive Industries, and Federation of Advanced Products Manufacturers.

42. No significant objections to the Amending Agreement were raised during consultations, and stakeholders were supportive of updating the Australia-EFTA EEA MRA. A number of jurisdictions suggested updates to references to legislation in the Sectoral Annexes to the Australia-EFTA EEA MRA. It is the intention of the Parties to consider appropriate updates to these Sectoral Annexes after the Amending Agreement enters into force, when these annexes will become less than treaty status.

43. The proposed Amending Agreement was first included in the Schedule of Treaties provided to the Commonwealth-State Territory Standing Committee on Treaties (SCOT) ahead of the February 2019 SCOT meeting.