National Interest Analysis [2012] ATNIA 7

with attachment on consultation

Agreement between Australia and the European Union Amending the Agreement on Mutual Recognition in relation to Conformity Assessment, Certificates and Markings between the European Community and Australia

done at Brussels on 23 February 2012

[2012] ATNIF 2

NATIONAL INTEREST ANALYSIS: CATEGORY 2 TREATY

SUMMARY PAGE

Agreement between Australia and the European Union Amending the Agreement on Mutual Recognition in relation to Conformity Assessment, Certificates and Markings between the European Community and Australia

done at Brussels on 23 February 2012

[2012] ATNIF 2

Nature and timing of proposed treaty action

1. The proposed treaty action is for Australia to bring into force the *Agreement between the European Union and Australia Amending the Agreement on Mutual Recognition in relation to Conformity Assessment, Certificates and Markings between the European Community and Australia*, done at Brussels on 23 February 2012 ('the proposed Amending Agreement'). The *Agreement on Mutual Recognition in relation to Conformity Assessment, Certificates and Markings between the European Community and Australia* ('the MRA', [1999] ATS 2) was signed in Canberra on 24 June 1998 and entered into force on 1 January 1999. The proposed Amending Agreement has been agreed in line with Article 15(2) of the MRA, which provides for amendments where there is mutual agreement between the Parties. ('European Community' is replaced by 'European Union' in the proposed Amending Agreement, as requested by the European Union.)

2. Pursuant to its Article 2, the proposed Amending Agreement 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.

Overview and national interest summary

3. The underlying principle of the MRA is that both the European Union (EU) and Australia recognise and accept the technical competence of each other's conformity assessment bodies (CABs) to test and certify products for compliance with the standards and regulatory requirements of the other Party, largely eliminating the need for duplicative testing or re-certification when the goods are traded.

4. The MRA provides for conformity assessment (testing, inspection and certification) of certain products to be undertaken in the exporting Party rather than in the destination Party.

5. The proposed Amending Agreement simplifies the MRA's administrative arrangements and introduces greater flexibility into the MRA. The proposed amendments remove the rule of origin restriction from the MRA, accord less-than-treaty status to the Sectoral Annexes, and extend the role of the Joint Committee to amend the Sectoral Annexes in response to regulatory and industry developments.

6. The proposed amendments would enhance the benefits of the MRA, enable timely maintenance of the Sectoral Annexes and allow Australian export businesses in the designated product areas, as well as CABs, to more readily benefit from the operation of the MRA.

Reasons for Australia to take the proposed treaty action

7. Since the MRA's entry into force in 1999, certain administrative aspects of the MRA have proved to be unwieldy and inefficient, particularly the requirement that changes to the MRA's Sectoral Annexes undergo the domestic treaty amendment process in both Parties. As such, many of the Sectoral Annexes are now out of date and do not reflect current Australian or EU requirements, particularly in terms of applicable technical and regulatory arrangements.

8. Additionally, the inclusion of the rule of origin provision in Article 4 of the MRA, which specifies that the products covered by the MRA must originate in the Parties to the Agreement, has limited the opportunities for Australian manufacturers and testing bodies to utilise the MRA. This provision has potentially restricted where Australian businesses can source their inputs and the markets where Australian CABs can compete for conformity assessment work.

9. It is likely that failure to remove the rule of origin provision and to streamline the administrative aspects of the MRA to enable the Joint Committee to maintain and update the Sectoral Annexes would result in the MRA remaining under-utilised as EU Directives and Australian legislation change over time.

Removal of the Rule of Origin Restriction

10. The current rule of origin in Article 4 of the MRA limits the coverage of the MRA to products originating in the Parties according to non-preferential rules of origin. Products covered by the MRA include: medicinal products to which good manufacturing practice (GMP) requirements apply; medical devices; telecommunications equipment; electromagnetic compatibility; automotive products; pressure equipment; machinery; and low voltage equipment.

11. The proposed Amending Agreement will remove the rule of origin restriction in Article 4 of the MRA, while retaining the restriction in the Sectoral Annex on Medicinal Products GMP Inspection and Batch Certification and inserting a similar restriction into the Sectoral Annex on Medical Devices. This is to ensure greater certainty in terms of quality assurance and safety with regard to high-risk medical products.

Simplification of the MRA

12. The proposed amendments are designed to simplify the MRA and make it more efficient. They include clarifying and extending the powers of the Joint Committee to include amending the Sectoral Annexes and according less-than-treaty status to the Sectoral Annexes to enable the Joint Committee to update these annexes in a timely manner.

13. Bringing the proposed Amending Agreement into force would also assist in meeting expectations arising out of the less-than-treaty-status Australia-EU Partnership Framework, which was first established in October 2008 and which has as one of its action items the finalisation of the proposed Amending Agreement.

Obligations

14. The proposed Amending Agreement does not significantly alter Australia's core obligations under the MRA. These obligations require Australian regulators in agreed product areas to accept attestations of conformity - including test reports, certificates and authorisations and, where appropriate, marks of conformity - issued in accordance with Australian requirements by specifically designated CABs in the EU. The proposed Amending Agreement will affect the operation and scope of the MRA obligations as they relate to the Sectoral Annexes.

15. The proposed amendments to the MRA are set out in Article 1 of the proposed Amending Agreement. The key amendments are outlined below. This includes an explanation of the proposed amendments as they affect the rule of origin restriction and the MRA's administrative provisions.

Overarching Framework Agreement

Removal of the Rule of Origin Restriction

16. The proposed amendment to Article 4 of the MRA removes the rule of origin restriction and replaces it with a more general 'Scope and Coverage' provision which states that the MRA shall apply to the conformity assessment of products specified in the statement of scope and coverage in each Sectoral Annex.

Simplification of the MRA

17. Article 3(2)(c) of the MRA has been removed and as such the Sectoral Annexes no longer require a list of CABs. Instead, both Parties will retain and update their own lists (revised Article 9(1)).

18. Proposed amendments to Articles 6(1) and 6(2) of the MRA, which refer to the powers of the Parties' 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, previously outlined in Article 6(3) of the MRA (which has now been removed).

19. Article 8(6) of the MRA 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.

20. Article 9 of the MRA provides for the exchange of information between the Parties pertaining to the implementation of, or changes to, legislative, regulatory and administrative provisions identified in the Sectoral Annexes, as well as the imposition of urgent measures warranted to protect safety, health or the environment. The proposed Amending Agreement expands Article 9(1) to ensure that the Parties to the MRA maintain an accurate list of CABs designated in accordance with the MRA. Proposed changes to Article 9(2) and the inclusion of a new Article 9(3) now more clearly reflect the Parties' existing obligations under the World Trade Organization Agreement on Technical Barriers to Trade to provide time to comment where a Party intends to make changes to the legislative, regulatory and administrative provisions relating to the subject matter of the MRA.

21. Article 12 of the MRA establishes the Joint Committee and provides for its powers and responsibilities. The proposed 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 in accordance with the MRA. The proposed amendments provide processes for the designation of a CAB by a Party and the procedure for objecting to a CAB designated by the other Party. Amended Article 12 also gives the Joint Committee power to verify the technical competence of a contested CAB.

22. The proposed amendments to Article 15(1) of the MRA make it clear that the Sectoral Annexes have less-than-treaty status. Proposed amendments to Articles 15(3) and 15(4) empower the Joint Committee to adopt new and amend existing Sectoral Annexes respectively. While the Sectoral Annexes do not have treaty status, changes in the Sectoral Annexes will affect the scope of the obligations of the MRA.

<u>Sectoral Annex on Medicinal Products GMP Inspection and Batch Certification</u>

23. The proposed amendments to the 'Scope and Coverage' section of the Sectoral Annex on Medicinal Products GMP are mainly language changes to ensure consistency following the proposed amendments to the MRA. They do not provide for any new obligations.

24. Section II of this Sectoral Annex has been amended such that the Parties must now maintain their respective lists of official inspection services. Further, a Party may request that the other Party provide the latest lists of official inspection services and that this request must be complied with within 30 days of the receipt of the request.

25. Paragraph 7 of Section III covers the ongoing exchange of information between authorities necessary for the ongoing mutual recognition of inspections. This has been amended to include the right of a Party to request additional specific 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 conformance assessment in accordance with the other Party's regulatory requirements.

26. 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

27. The 'Scope and Coverage' section of the Sectoral Annex on Medical Devices provides that the Sectoral Annex will apply to medical devices exported to Australia only if they are 'manufactured in the EU'. This is a more restrictive rule given the high risk nature of the products involved and will provide confidence that only EU bodies with quality assured and monitored manufacturing practices will fall within the scope of the MRA.

28. Proposed amendments to paragraph 1 of Section V updating and strengthening confidence-building measures help to 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's operation.

29. 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

30. No changes to Australian legislation are required to implement the proposed Amending Agreement. State and Territory Governments are responsible for regulating the low voltage equipment, machinery and pressure equipment sectors covered by the 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 MRA. The proposed Amending Agreement does not affect this Inter-Governmental Cooperation Agreement.

Costs

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

32. Removal of the rule of origin restriction clause for all but two of the Sectoral Annexes will allow Australian firms potentially greater flexibility in sourcing inputs more competitively and give Australian testing and certification bodies greater scope to compete on world markets in relation to products from third countries. The proposed amendments to the MRA can result in potential cost-savings in terms of 'time to market' and fees for testing, inspection and certification. The MRA is designed to ensure, through its procedures for the designation and monitoring of CABs, that these bodies are sufficiently competent to provide the necessary quality of testing, particularly where products are sourced from third countries.

33. In the case of the Sectoral Annexes on Medicinal Products GMP and Medical Devices, for Australian importers using overseas manufacturing sites in MRA countries, there is a significant reduction in regulation and the regulatory cost burden,

largely associated with the cost of on-site Therapeutic Goods Administration (TGA) inspections.

34. The TGA has advised that, as the proposed amendments to the MRA 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 revised MRA.

35. The Australian Pesticides and Veterinary Medicines Authority (APVMA) has advised that, from a regulatory perspective, the savings to industry from the amended MRA will be partly offset by the cost of confidence-building and confidence-maintaining measures associated with the proposed Amending Agreement. However, ongoing maintenance activities have increased the effectiveness of the APVMA's regulatory activities and led to efficiencies and cost-savings. These include improved inter-agency communication, including with overseas regulatory agencies not a Party to the 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 market by another agency.

36. Administrative costs under the MRA, including meetings of the Joint Committee, are covered within the normal appropriations for the Department of Industry, Innovation, Science, Research and Tertiary Education, the lead agency for the MRA and the Australian member of the Joint Committee.

Regulation Impact Statement

37. The Office of Best Practice Regulation, Department of Finance and Deregulation, has been consulted and confirms that a Regulation Impact Statement is not required (Reference No 3169).

Future treaty action

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

39. Under the proposed amendments to the MRA, however, the eight Sectoral Annexes would be accorded less-than-treaty status and any changes to these Annexes would be at the discretion of the Joint Committee (comprised of EU and Australian representatives) in consultation with relevant government and industry bodies, and would not require treaty amendment.

Withdrawal or denunciation

40. Under Article 14(2) of the MRA, either Party may terminate the MRA by giving the other Party six months notice in writing. This provision will not be affected by the proposed Amending Agreement.

Contact details

Standards and Conformance Policy Section
Trade and International Branch
Enterprise Connect Division
Department of Industry, Innovation, Science, Research and Tertiary Education

ATTACHMENT ON CONSULTATION

Agreement between Australia and the European Union Amending the Agreement on Mutual Recognition in relation to Conformity Assessment, Certificates and Markings between the European Community and Australia

done at Brussels on 23 February 2012

[2012] ATNIF 2

CONSULTATION

41. The consultation process for the proposed amendments to the MRA has included State and Territory Governments, relevant Commonwealth Departments and industry bodies.

State and Territory Governments

42. State and Territory departments were consulted at officials' level in 2006 and gave in-principle agreement before negotiations for the proposed Amending Agreement formally commenced with the EU in early 2007.

43. Since then, States and Territories have been kept informed of progress with negotiations through the biannual meeting of the Commonwealth-State-Territory Standing Committee on Treaties (SCOT) and through the Department of Foreign Affairs and Trade's *Schedule of Treaties under Negotiation, Consideration or Review by the Australian Government*.

44. The former Department of Innovation, Industry, Science and Research (DIISR) provided SCOT with briefings on the proposed Amending Agreement on 15 October 2008 and 18 October 2010, informing the States and Territories of the status of negotiations and seeking comments. A copy of the draft National Interest Analysis was included with the latter. Comments were received from Queensland and Western Australia, largely in relation to removal of the rule of origin and its possible effect on consumer safety in the area of low voltage equipment and the need to ensure the competency of CABs through adequate auditing and monitoring activities.

45. DIISR advised that the decision to remove the rule of origin restriction from the overarching agreement arose out of a joint declaration made by both Parties at the time the MRA was signed in 1998. Removal of the origin restriction would allow Australian manufacturers to source inputs and components more competitively while Australian-designated CABs would be able to compete for laboratory testing and certification business in relation to products from third countries. In addition, Australia had concluded an MRA with Singapore covering electrical products (the *Mutual Recognition Agreement between Australia and the Republic of Singapore*, done at Canberra on 26 February 2001, [2001] ATS 9) and was also a signatory to the APEC Mutual Recognition Arrangement on Conformity Assessment of Electrical and Electronic Equipment, neither of which contained a rule of origin restriction. Both instruments were endorsed by the States and Territories.

46. With regard to consumer safety, DIISR noted that the MRA already stipulated procedures for the designation and monitoring of CABs to ensure that they were competent to assess and certify products. The MRA also provided for regulatory authorities to maintain market surveillance programs to ensure that products continued to meet the health and safety requirements set out in law. Where Parties to the MRA were concerned about the competency of accredited CABs to test products, provisions were being strengthened under the proposed Amending Agreement to enable such bodies to be challenged and, if warranted, suspended, in a timelier manner until their competency was re-established to the satisfaction of both Parties.

Commonwealth Departments

47. Commonwealth Ministers with a portfolio interest in the MRA have also been consulted and have approved the proposed amendments under the proposed Amending Agreement. These portfolios are: the Department of Broadband, Communications and the Digital Economy; the Department of Agriculture, Fisheries and Forestry; the Department of Health and Ageing; the Department of Foreign Affairs and Trade and the former Department of Infrastructure, Transport, Regional Development and Local Government.

Industry bodies

48. Relevant industry bodies were also consulted on the proposed amendments and, in particular, on the removal of the rule of origin provision. These bodies included: the Australian Information Industry Association (AIIA); the former Australian Electrical and Electronic Manufacturers Association; the Australian Industry Group; the Business Council of Australia; the Australian Chamber of Commerce and Industry; the Federation of Automotive Products Manufacturers; the Federal Chamber of Automotive Industries; and the National Association of Testing Authorities (NATA).

49. The AIIA and NATA supported the removal of the rule of origin restriction. No objections were received from the other industry groups.

50. Medicinal product and medical device groups were consulted by the TGA on the removal of the rule of origin restriction from the MRA and its inclusion under the Sectoral Annex on Medical Devices. Each of the key industry associations were contacted, including the Australian Self-Medication Industry, Medicines Australia and the Medical Technology Association of Australia. All three associations supported the removal of the rule of origin restriction from the MRA, with Medicines Australia also supporting its inclusion in the Sectoral Annex on Medicinal Products.

51. The remaining amendments to the MRA for medicinal products and medical devices do not affect mutual recognition or existing confidence-building arrangements and are aimed at simplifying operating requirements. The TGA has kept industry associations informed of the progress of the revisions to the MRA through its industry consultative committee.

52. The APVMA, which has an interest in the Sectoral Annex on Medicinal Products GMP (which also relates to medicinal products for use in animals), has

advised that it consulted with industry members through the Manufacturers Licensing Scheme Industry Liaison Committee. The Committee contains representatives from two peak bodies: the Animal Health Alliance and the Veterinary Manufacturers and Distributors Association. Industry members have been broadly supportive of the proposed amendments to the MRA, particularly those relating to the strengthening of confidence-building measures. These measures help ensure that foreign manufacturers comply with the same manufacturing standards as those required of Australian manufacturers.