Trade Issues...

Technical Barriers to Trade

Mutual Recognition Agreements and Agreements on Conformity Assessment and Acceptance of Industrial Products

Newsletter N°11

Foreword

This is the eleventh edition of a Newsletter[1] on Mutual Recognition Agreements (MRAs) concluded between the European Union (EU) and third countries. MRAs are instruments that facilitate market access by reducing costs and time associated with mandatory product certification.

Traditional MRAs enable Conformity Assessment Bodies (CABs) nominated by one Party to certify products for access to the other Party's market, according to the other Party's technical legislation. They provide for the mutual recognition between trading partners of mandatory test results and certificates for certain industrial products.

No regulatory convergence is implied by a traditional MRA. In other words, there is no implication that the regulations imposed on products by the Parties are to be approximated or aligned at any stage. However, there are exceptions to this, such as the MRA with Switzerland, which deals for the most part with mutual recognition of certificates in areas where Swiss and EU regulations are deemed "equivalent". Another example of such an exception is the EU-US MRA on marine equipment, for which the underlying regulations are International Maritime Organisation (IMO) Conventions, transposed by both the US and the EU's Member States. MRAs only confer benefits on importing parties for products subject to mandatory certification.

There is a certain amount of evolution in the operation of MRAs, for example, in the case of Canada. Accordingly, it is intended that this Newsletter will be issued from time to time to reflect the evolution of the current position.

Agreements on Conformity Assessment and Acceptance of Industrial Products (ACAAs) are a specific type of MRA based on the full alignment of the legislative system, including standards, and implementing infrastructure of the country concerned with those of the EU. The conclusion of an ACAA is the end-result of extensive transformation, dialogue and assistance in the field of quality infrastructure for industrial products. The adoption of the EU system by third countries contributes to the elimination of technical barriers to trade, thereby increasing the accessibility of third countries' markets to products from the EU and vice versa.

The Newsletter provides information on the current status of MRAs with the United States, Canada [which has been replaced by the Protocol on conformity assessment included in the Comprehensive Economic and Trade Agreement between the EU and Canada (CETA)], Japan, Switzerland, Australia and New Zealand and, as it concerns Israel, the Annex to the ACAA on Good Manufacturing Practices (GMP), as well as the Agreement on chemical Good Laboratory Practice. It also covers the agreement with the US on marine equipment. It has been compiled from a trade perspective, on the basis of information provided by the Directorates General for Trade, for Internal Market, Industry, Entrepreneurship and SMEs, for Health and Food Safety and for Mobility and Transport.

An overview of the ACAAs currently agreed and under consideration with countries in the European neighbourhood is also included.

If you have suggestions or want to make a contribution, please contact DG Trade, Unit E4, Regulatory Cooperation and Public Procurement.

[1] This Newsletter is provided to enhance public access to information with the goal to keep this information timely and accurate. However, the Commission accepts no responsibility or liability whatsoever with regard to the information in this Newsletter.

UNITED STATES

1. Signature

Council Decision 1999/78/EC of 22 June 1998 on the conclusion of an Agreement on Mutual Recognition between the European Community and the United States of America (OJ L 31, 4.02.1999, p.1), as amended by Council Decision 2002/803/EC of 8.10.2002 (OJ L 278, 16.10.2002, p.22). Entered into force in December 1998.

View the text of the Agreement.

Sectoral Annexes	Operational since	Number of CABs
Telecommunications equipment	14 December 2000	13 EU CABs and 17 US CABs
Electromagnetic compatibility (EMC)	14 December 2000	78 EU CABs and 15 US CABs
Electrical safety	Not in operation	Nil
Recreational craft	Not in operation	Nil
Pharmaceutical Good Manufacturing Practices (GMPs)	Nominally in operation 1 December 2001 (see below) The amended Annex became applicable on 1 November 2017	Not applicable (the legislation does not refer to CABs)
Medical devices	Not in operation	Not in operation

For a complete list of the designated CABs under the MRA with the United States, see the European Commission's Web site

2. Joint Committee meetings

The last Joint Committee meeting was held by videoconference on 24 February 2009. However, the Joint Sectoral Group on EMC & Telecom was held by video conference on 26 September 2013.

3. State of play

"Traditional" type MRA: Mutual recognition of conformity assessment certificates without alignment of the relevant requirements.

Electrical Safety: Not in operation. The Annex (and the EU's obligations under it) remains suspended because of the position of the Occupational Safety and Health Administration (OSHA). In any case, the EU makes no mandatory requirements for third-party certification in the area of electrical safety.

Pharmaceutical GMPs: The previously non-operational Annex on Good Manufacturing Practices was comprehensively revised and amended. The amendment entered into force on 1 March 2017. The EU has finalized the assessment of the FDA and recognized it as an equivalent authority on 11 August 2017 (OJ L 237/36 15.9.2017.). The operational parts of the amended GMP Annex became applicable on 1 November 2017, when the FDA concluded the assessment and recognition of eight Member States authorities (Austria, Croatia, France, Italy, Malta, Spain, Sweden and the United Kingdom). The remaining EU Member State authorities were assessed on a rolling basis until mid-2019. On 11 July 2019, in advance of the legal deadline, the FDA recognised all 28 EU Member State authorities for human medicines. The authorities in charge of medicines at both sides of the Atlantic can now rely on each other's inspection results of manufacturers for human pharmaceuticals. These inspections cover good manufacturing practices applied by pharmaceutical companies to ensure the quality of medicinal products. On the same day, the batch-testing waiver started to apply. This means that the quality control testing of human pharmaceuticals, when carried-out in the US, will no longer need to be repeated in the EU. This facilitates bringing human medicines faster and at a lower cost to the market. With the implementation of the Agreement, the industry and public authorities on both sides are able to free resources to inspect facilities in other large producing countries like China and India, and are able focus more on higher risk manufacturers of human pharmaceutical products.

As foreseen in the amended GMP Annex, the EU and US now focus on extending the product scope to veterinary medicines and have started assessing national authorities responsible for veterinary medicines and dual competent authorities that are responsible for both human and veterinary medicines. The timeline for recognition of these assessed authorities remains to be agreed and adopted. In parallel, the EU and US agreed to start work with a view to possible expansion of the scope to vaccines for human use, and blood derived medicines by conducting joint inspections. However, a firm engagement from both sides is yet to be reached in this field.

Telecommunications: The US is requesting regular reassessments of CABs. In general, this Annex is working satisfactorily. The EU adopted new legislation - Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62), applicable as from 13 June 2016. On this date, the old Directive 1999/5/EC was repealed and replaced by Directive 2014/53/EU. As the new legislation provides new requirements for CABs, the designated US conformity assessment bodies have been re-designated in accordance with the requirements of the new EU legislation. From 13 June 2016, CABs notified following the procedures set out in the new Directive are entitled to carry out conformity assessment under the new Directive. The bodies notified under Directive 1999/5/EC were automatically withdrawn from the NANDO database[2] as of 13 June 2017 (the end of the transitional period specified in Article 48 of Directive 2014/53/EU) and thus, as of that date, were automatically de-notified.

Medical devices: Regulatory cooperation between the US and the EU on medical devices is taking place. The Annex is regarded as superseded by this co-operation.

[2] The New Approach Notified and Designated Organisations database, in which all of the accredited CABs are listed. More information on the NANDO database can be found here.

EMC: The EU has eliminated mandatory requirements for third-party testing in EMC (although the US maintains them): the EMC Directive 2004/108/EC of 15 December 2004, (OJ L 390, 31.12.2004, p. 24), amending Directive 89/336/EEC of 3 May 1989 (OJ L 139, 23.05.1989, p. 19) imposes no third-party certification obligation on manufacturers - and thus there is no need for a MRA on the part of the EU (though *voluntary* third-party involvement is still envisaged in the Directive). Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (recast) (OJ L 96, 29.3.2014, p. 79), which also imposes no third-party certification obligation on manufacturers, applies from 20 April 2016. On this date, the old Directive 2004/108/EC was repealed and replaced by Directive 2014/30/EU. As the new legislation provides new requirements for CABs, the designated US CABs have been re-designated in accordance with the requirements of the new EU legislation. This Annex is still needed for EU access to the US market.

Recreational Craft: This Annex is not operational; in any case, the US has stated that it does not impose third-party certification requirements.

UNITED STATES: MARINE EQUIPMENT

1. Signature

Council Decision 2004/425/EC of 21 April 2004 on the conclusion of an Agreement between the European Community and the United States of America on the Mutual Recognition of Certificates of Conformity for Marine Equipment (OJ L 150, 30.04.2004, p.42).

View the text of the Agreement.

The Agreement has been recently amended by Decision No 1/2018 of the Joint Committee established by the Agreement between the European Community and the United States of America of 18 February 2019 on the mutual recognition of certificates of conformity for marine equipment amending Annexes I, II and III [2019/996] (OJ L 162, 19.06.2019, p.1).

View the text of Decision No 1/2018

2. Joint Committee meetings

The latest meeting of the US-EC Marine Equipment MRA Joint Committee was held by video conference on 24 February 2009.

3. State of play

The EU-US MRA is intended to facilitate transatlantic trade in marine equipment. Under its terms, designated products which comply with EU requirements will be accepted on board of US flagged ships without any additional testing or certification and vice versa. Notified bodies under the Marine Equipment Directive are all entitled to certify according to this MRA, together with the US Coast Guard. Marine equipment falling under the MRA can therefore display an appropriate US Coast Guard Approval Number (allocated by the Coast Guard or an EU Notified Body), as well as the EU's Wheelmark.

Both parties have based their respective legislations on the Conventions of the International Maritime Organisation (IMO) and the relevant international standards. The European Maritime Safety Agency (EMSA) carries out the technical work for the EU relating to the maintenance of this Agreement.

The Agreement currently covers 72 types of marine equipment, ranging from life-saving equipment (distress signals, rigid life rafts), to fire protection equipment (flame-retardant materials) and navigational equipment (GPS equipment, echo-sounding equipment).

The EU Directive underlying the MRA has been revised. Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment and repealing Council Directive 96/98/EC (OJ L 257, 28.8.2014, p. 146) is applied by the Member States from 18 September 2016. References to the repealed Directive shall be construed as references to the new Directive.

The US and the EU have recently adopted a Joint Committee Decision broadening the scope of the MRA. This amendment is based on a technical agreement between EMSA and the US Coast Guard, taking into account the regulatory and policy developments since the entry into

application of the MRA in 2004. The amendment extends the product scope of the MRA (Annex II) by adding further life-saving appliances, fire protection equipment and navigational equipment, and replaces obsolete products to reflect new market realities. This extension will enable a higher number of manufacturers from both Parties to benefit from the MRA. In addition, the Joint Committee Decision updates EU legislation referred to in Annex I to reflect new EU legislative developments (adoption of Directive 2014/90/EU on marine equipment).

Furthermore, the Parties to the MRA took the opportunity to update the existing list of relevant national regulatory authorities and their contact details, as well as to include the authorities of Member States that have joined the EU since 2004 (Annex III).

CANADA

On 21 September 2017, the Comprehensive Economic and Trade Agreement (CETA) between the EU and Canada entered into provisional application. This Agreement contains a Protocol of Conformity Assessment, which has since replaced the Mutual Recognition Agreement between the EU and Canada. Under the CETA Protocol, a designated EU CAB can test and certify products for export to Canada according to Canadian rules, and vice versa.

The Protocol relies on accreditation and on closer cooperation between the EU and Canadian accreditation systems, as the means to create mutual confidence in the technical competence of CABs[3]. This approach builds on the existence of a European common accreditation framework and rests on the following three main principles:

1. **Government responsibility for the designated CABs** – Canada undertakes the same role and responsibilities as EU Member States for the CABs it designates in terms of initial assessment (backed by accreditation) and subsequent monitoring and supervision. This was already the case under the 1998 MRA.
2. **Equivalent accreditation systems** - like the EU, Canada operates a public-authority, not-for-profit accreditation system. Close cooperation between the Canadian and the EU accreditation systems is provided for in the Protocol.
3. **Anchorage in the international accreditation system** – like all European accreditation bodies, eligible Canadian accreditation bodies must be signatories to the multilateral cooperation and recognition arrangements of the International Accreditation Forum (IAF – for certification and inspection bodies) and the International Laboratory Accreditation Cooperation (ILAC – for testing laboratories).

For the purpose of the smooth implementation of the CETA Protocol, the Standards Council of Canada and European cooperation for Accreditation (EA) signed a cooperation agreement in June 2016. It is important to note that accreditation will always be to the requirements of the importing Party, the same as the product requirements are also always of the importing party.

The arrangements for designation of CABs provide for the quasi-automatic acceptance (i.e. unless objections are raised within 30 days) by one Party of CABs designated by the other Party.

The Protocol enlarges the scope of application to a number of additional sectors (to which the MRA did not apply) and creates the possibility for further expansion of this scope as listed in Annex II to the Protocol based on the market demands (within three years of the entry into force of the Agreement). The sectors to which the Protocol currently applies are listed in Annex I to the Protocol:

[3] With respect to construction products sector, and in line with Construction Products Regulation (EU) No 305/2011, the conformity assessment bodies within the meaning of the CETA Protocol are to be understood as bodies authorised to carry out third-party tasks in the process of assessment and verification of constancy of performance under the Regulation i.e. 'notified bodies'.

- Electrical and electronic equipment, including electrical installations and appliances, and related components;
- Radio and telecommunications terminal equipment;
- Toys;
- Construction products;
- Machinery, including parts, components, including safety components, interchangeable equipment, and assemblies of machines;
- Measuring instruments;
- Hot-water boilers, including related appliances.

CABs that were recognised under the MRA continue to be recognised under the CETA Protocol. The recognition of new CABs follows the procedure as set out in Article 3 of the Protocol. The designation of new CABS is laid out in Article 5 of the Protocol, and requires that the designating party must provide the other side with the information listed in Annex III to the Protocol. This information needs to be provided by the notifying authority of the EU Member State in which the CAB is located to the Standards Council of Canada, and by Canada to the European Commission – in the same way that an EU Member State would.

The Agreement does not require recognition or acceptance of the other Party's technical regulations, nor does it limit a Party's right to set technical regulations or conformity assessment procedures. More information on the CETA Protocol on Conformity Assessment can be found here. The Protocol itself can be consulted here.

The 1998 MRA Sectoral Annex on GMP for pharmaceuticals has been incorporated into CETA under the Protocol on the mutual recognition of the compliance and enforcement programme regarding good manufacturing practices for pharmaceutical products, which can be found here.

JAPAN

1. Signature

Council Decision 2001/747/EC of 27 September 2001 on the conclusion of an Agreement on Mutual Recognition between the European Community and Japan (OJ L 284, 29.10.2001, p.1) as amended by Council Decision 2002/804/EC of 8.10. 2002 (OJ 278, 16.10.2002, p. 23). Entered into force on 1 January 2002 and was the first bilateral agreement on mutual recognition for Japan.

View the text of the Agreement.

Sectoral Annexes	Operational since	Number of CABs
Telecommunications terminal equipment and radio equipment	1 January 2002	8 EU CABs and 2 JP CABs
Electrical products	1 January 2002	0 EU CABs and 0 JP CABs
Good manufacturing practice (GMP) for medicinal products	29 May 2004 (enlargement of scope on 17 July 2018)	Not applicable (the legislation does not refer to CABs)
Good laboratory practice (GLP) for chemicals	1 January 2002	Not applicable (the legislation does not refer to CABs)

See the Commission's website for a complete list of the designated CABs

2. Joint Committee meetings

The last meeting was held on 7 June 2010 by video-conference.

3. State of play

R&TTE: The telecommunications and radio equipment annex of the MRA is functioning well, with 10 CABs currently operating under it. The range of products which need third-party certification has been narrowed, as Japan introduced a system of Supplier's Verification of Conformity (SVC) some time ago for a broad range of products.

The EU adopted new legislation – Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 – on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment, repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62), which has been applied from 13 June 2016. On this date, the old Directive 1999/5/EC was repealed and replaced by Directive 2014/53/EU.

As the new legislation provides new requirements for CABs, the currently designated CABs have been re-designated in accordance with the requirements of the new EU legislation.

From 13 June 2016, CABs notified following the procedures set out in the new Directive were entitled to carry out conformity assessment under the new Directive. The bodies notified under Directive 1999/5/EC were withdrawn from the NANDO data base as of 13 June 2017 (the end of the transitional period specified in Article 48 of Directive 2014/53/EU), and thus, as of that date, were automatically de-notified.

Electrical products: Under the new Low Voltage Equipment Directive 2014/35/EU (OJ L 96, 29.3.2014, p. 357), applied from 20 April 2016, conformity assessment is solely the obligation of the manufacturer. There is therefore no conformity assessment procedure anymore requiring the intervention of a CAB. The new Directive 2014/30/EU on electromagnetic compatibility (recast) (OJ L 96, 29.3.2014, p. 79), applied from 20 April 2016, imposes no third-party certification obligation on manufacturers, though *voluntary* third-party involvement is still envisaged.

GMP Medicinal products: A subcommittee was created by JC Decision 2/2002 of 20 June 2002. Mutual visits to exchange information and discuss key elements of the preparatory work under this Annex took place in June and July 2002. Further rounds of mutual visits took place in 2003 and early 2004. The third subcommittee meeting on 18-19 February 2004 confirmed equivalence, except for biological pharmaceuticals, including immunological and stable medicinal products derived from human blood or plasma and sterile medicinal products. The fifth meeting of the sub-committee set up under the Joint Committee of the Agreement on Mutual Recognition between the EU and Japan took place through videoconference on 8 April 2014. It acknowledged that the expansion of the coverage of the Agreement had been identified as a priority and both sides decided to continue their ongoing efforts in this perspective. The sub-committee reviewed the work that had been carried out and confirmed steps to be taken to add Competent Authorities. The sub-committee also identified different categories of products for possible inclusion in the operational scope of the Sectoral Annex on GMP.

In April of 2016, the Sectoral Annex on GMP was amended to include Member States that had joined the EU since 2004. The EU-Japan subcommittee held in June 2018 confirmed the expansion of the coverage of the GMP Annex for additional categories of medicinal products. It resulted in the adoption of Joint Committee Decision no 2/JP/2018 - on 17 July 2018 - which enlarges the scope of the Annex on GMP to chemical pharmaceuticals, homeopathic medicinal products (GMP), vitamins, minerals and herbal medicines (medicines), biological pharmaceuticals including immunologicals and vaccines, active pharmaceutical ingredients, and sterile products.

SWITZERLAND

1. Signature:

Council and Commission Decision 2002/309/EC of 4 April 2002 on the conclusion of an Agreement on Mutual Recognition between the European Community and Switzerland (OJ L 114, 30.04.2002, p.1), signed on 21 June 1999. Entered into force on 1 June 2002.

View the Commission's website for the text of the Agreement.

2. Joint Committee meetings

Last meeting was held on 24 January 2020.

Sectoral Annexes	Operational since
Machinery	1 June 2002
Personal Protective Equipment (PPE)	1 June 2002
Toys	1 June 2002
Medical Devices	1 June 2002
Gas Appliances and Boilers	1 June 2002
Pressure Vessels	1 June 2002
Radio and Telecommunications Terminal Equipment (R&TTE)	1 June 2002
Equipment and Protective Systems intended for use in potentially explosive atmospheres (ATEX)	1 June 2002
Electrical Safety and Electromagnetic Compatibility	1 June 2002
Construction Plant and Equipment	1 June 2002
Measuring Instruments and Pre-packages	1 June 2002

Motor Vehicles	1 June 2002
Agricultural and Forestry tractors	1 June 2002
Good Laboratory Practice (GLP)	1 June 2002
Medicinal products GMP inspection and batch certification	1 June 2002
Construction Products	12 March 2008
Lifts	21 December 2009
Biocidal Products	18 October 2010
Cableway Installations	20 December 2011
Explosives for civil use	17 December 2012

Up to date information on Swiss CABs and EU Notified Bodies operating under each respective sector of the MRA can be found on the Commission's website, as well as in the NANDO database.

3. State of play

"Enhanced" type MRA: Mutual recognition of certificates based on equivalent or common requirements. Gas Appliances and Efficiency Hot Water Boilers are non-equivalent sectors. Pressure Equipment, Construction Plant and Equipment, as well as Non-Automatic Measuring Instruments are non-equivalent, but Switzerland accepts compliance with EU Directives. Measuring Instruments and Pre-packages is equivalent for certain products only.

Sector chapters need to be regularly updated by Joint Committee Decisions to reflect changes in equivalent legislation on both side. The latest is the Decision No 2/2017 of the Committee established under the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment of 22 December 2017 on the amendment of Chapter 2 on Personal protective equipment, Chapter 4 on medical devices, Chapter 5 on gas appliances and boilers and Chapter 19 on Cableway installations (*OJ L 72, 15.3.2018, p. 24–41)*

AUSTRALIA

1. Signature

Council Decision 98/508/EC of 18.6.1998 (OJ L 229, 17. 8.1998, p.1), as amended by Council Decision 2002/800/EC of 8.10.2002 (OJ L 278, 16.10.2002, p.19) and Council Decision 2012/837/EU of 18 July 2011 . (OJ L 359/1 of 29.12.2012, p.1). Entered into force on 1 January 1999.

View the text of the Agreement.

Sectoral Annexes	Operational since	Number of CABs
EMC	1 January 1999	2 AUS and 21 EU. See note below on applicability of this Annex.
Low voltage equipment	1 January 1999	0 AUS and 12 EU
Machinery	1 January 1999	1 AUS and 12 EU
Medical devices	1 January 1999	1 AUS and 4 EU
Pressure equipment	1 January 1999	0 AUS and 6 EU
Radio equipment	1 January 1999	0 AUS and 3 EU
Automotive products	1 January 1999	Not applicable (the legislation does not refer to CABs)
Medicinal Products GMP	1 January 1999 for human and 1 June 2001 for veterinary medicinal products	Not applicable (the legislation does not refer to CABs)

For a complete list of the designated CABs under the MRA with Australia, see the Commission's Website.

2. Joint Committee meeting

The last meeting was held in Canberra, Australia, March 2012.

3. State of play

"Traditional" type MRA: Mutual recognition of conformity assessment certificates without alignment of the relevant requirements.

Amendment: The Amendment to the main text of the MRA to empower the Joint Committee to amend the Sectoral Annexes and otherwise to simplify the operation of the MRA has been ratified (see section 1 above).

This MRA will likely be affected by the outcome of the negotiations on a Free Trade Agreement with Australia.

EMC: The EMC Directive 2004/108/EC of 15 December 2004 (OJ L 390, 31.12.2004, p. 24), amending Directive 89/336/EEC of 3 May 1989 (OJ L 139/19, 23.05.1989, p. 19), removed the need for mandatory third-party certification in the EU. The new Directive 2014/30/EU on electromagnetic compatibility (recast) (OJ L 96,29.3.2014, p. 79), which applies from 20 April 2016, does not imposes third-party certification obligation on manufacturers, though *voluntary* third-party assessment is still possible.

Medical devices: The chapter is not operational with regard to high-risk medical devices (class III). Australia is planning to introduce new legislation on medical devices, based on the recently adopted Regulation (EU) 2017/745 of 5 April 2017 on medical devices (OJ L 117, 5.5.2017, p. 1) and Regulation (EU) 2017/746 of 5 April 2017 on In-Vitro Diagnostic medical devices (OJ L 117, 5.5.2017, p. 176). The date of application of most of the provisions of the EU Regulation on medical devices was recently postponed by one year to May 2021. The EU In-Vitro Diagnostic medical devices Regulation will be applicable as of May 2022.

Electrical products: The EU legislation - Directive 2006/95/EC of 12 December 2006 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits (OJ L 374, 27.12.2006, p. 10), does not require third-party certification. Under the new Low Voltage Equipment Directive 2014/35/EU (OJ L 96, 29.3.2014, p. 357), which applies from 20 April 2016, conformity assessment is solely the obligation of the manufacturer, and therefore there is no conformity assessment procedure which requires or makes possible the intervention of a CAB.

GMP Medicinal Products: At the time of implementing the Sectoral Annex, only Australia had legal requirements for GMP for Active Pharmaceutical Ingredients (API) in place. However, with the adoption of Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 (OJ L 136, 30.4.2004, p. 34) and Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 (OJ L 174, 1.7.2011, p. 74) amending Directive 2001/83/EC as regards GMP for API, the EU explicitly includes API in the scope of Directive 2001/83/EC. Regarding the Australian legislation, the 'equivalence assessment' which was conducted by the European Commission in the context of Article 111b of Directive 2001/83/EC has confirmed that the Australian Therapeutic Goods Act has equivalent legal requirements for GMP for API in place. It is therefore understood that API for medicinal products for human use are within the operational scope of the MRA.

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, which entered into force on 1 January 2013, replaced the old sectoral annex on GMP by the new one with an updated list of legislation.

NEW ZEALAND

1. Signature

Council Decision 98/509/EC of 18.6.1998 (OJ L 229 of 17.08.1998), as amended by Council Decision 2002/801/EC of 8.10.2002 (OJ L 278, 16.10.2002, p.20) and Council Decision 2012/828/EU of 22.12.2012 (OJ L356, p.1). Entered into force on 1 January 1999.

View the text of the Agreement.

Sectoral Annexes	Operational since	Number of CABs
EMC	1 January 1999	1 NZ and 17 EU. See note below on applicability of this Annex.
Low voltage equipment	1 January 1999	0 NZ and 16 EU
Machinery	1 January 1999	0 NZ and 10 EU
Medical devices	1 January 1999	0 NZ and 3 EU
Pressure equipment	1 January 1999	0 NZ and 7 EU
Radio equipment	1 January 1999	0 NZ and 4 EU
Medicinal Products GMP	1 January 1999 for human and 1 June 2002 for veterinary medicinal products	Not applicable (the legislation does not refer to CABs)

For a complete list of the designated CABs under the MRA with New Zealand, see the Commission's Website.

2. Joint Committee meeting

The last Joint Committee meeting was held in Wellington, NZ in October 2002.

3. State of play

"Traditional" type MRA: Mutual recognition of conformity assessment certificates without alignment of the relevant requirements.

Amendment: The Amendment to the main text of the MRA to empower the Joint Committee to amend the Sectoral Annexes and otherwise to simplify the operation of the MRA has been ratified (see section 1 above). This MRA will likely be affected by the outcome of the negotiations on a Free Trade Agreement with New Zealand.

EMC: The revision of the EMC Directive (2004/108/EC) of 15 December 2004 (OJ L 390, 31.12.2004, p. 24) removed the mandatory third-party certification in the EU. The new Directive 2014/30/EU on electromagnetic compatibility (recast) (OJ L 96, 29.3.2014, p. 79), which applies from 20 April 2016, does not impose third-party certification obligation on manufacturers, though *voluntary* third-party assessment is still possible.

Electrical products: The EU legislation - Directive 2006/95/EC of 12 December 2006 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits (OJ L 374, 27.12.2006, p. 10), does not require third-party assessment. Under the new Low Voltage Equipment Directive 2014/35/EU (OJ L 96, 29.3.2014, p. 357), which applies from 20 April 2016, conformity assessment is solely the obligation of the manufacturer. Therefore, there is no conformity assessment procedure that requires or makes possible the intervention of a CAB.

Medical devices: New Zealand is planning to introduce new legislation on medical devices, based on the recently adopted EU Regulation (EU) 2017/745 of 5 April 2017 on medical devices (OJ L 117, 5.5.2017, p. 1) and Regulation (EU) 2017/746 of 5 April 2017 on In-Vitro Diagnostic medical devices (OJ L 117, 5.5.2017, p. 176). The date of application of most of the provisions of the EU Regulation on medical devices was recently postponed by one year to May 2021. The EU In-Vitro Diagnostic medical devices Regulation will be applicable as of May 2022.

ISRAEL

A. Agreement on mutual recognition of OECD principles of good laboratory practice (GLP)

1. Signature

Council Decision 99/662/EC of 19 July 1999 (OJ L 263, 9.10.1999, p.7).

The Agreement on mutual recognition of OECD principles of good laboratory practice (GLP) and compliance monitoring programmes between the European Community and the State of Israel allows Israel to use the OECD guidelines for Good Laboratory Practice.

View the text of the Agreement.

B. Protocol to the Euro-Mediterranean Agreement establishing an association between the European Communities and their Member States, of the one part, and the State of Israel, of the other part, on Conformity Assessment and Acceptance of Industrial Products (CAA)

View the text of the Agreement.

1. Signature

Council Decision 2013/1/EU of 20 November 2012 (OJ L1 of 4.1.2013, p.1).

2. Sectoral Annexes

Sectoral Annexes	Operational since
Good manufacturing practice (GMP) for medicinal products	19 January 2013

There are no CABs, since GMP does not rely on them.

2. Joint Committee meeting.

There is no Joint Committee under this ACAA.

3. State of play.

The ACAA has entered into force in January 2013. The Parties have exchanged information on contact points, responsible authorities and scope of recognition, as provided for in the text.

The agreement covers **pharmaceutical products**, and more specifically mutual recognition of the Good Manufacturing Practices (GMP) certificates for active pharmaceutical substances, chemical medicinal products, biological pharmaceuticals, immunologicals, radio-pharmaceuticals, and herbal medicinal products. It also includes batch release testing and waiving.

Medicinal products derived from human blood and plasma, investigational medicinal products, medicinal gases and veterinary immunological products are excluded from the scope of the Annex.

Active pharmaceutical substances fall within the scope of the Agreement. In addition, the "equivalence assessment" conducted by the European Commission in the context of Article 111b of Directive 2001/83/EC has confirmed that Israel has equivalent legal requirements for GMP for active pharmaceutical substances and, on 1st July 2015, the Commission took a decision to list Israel as an equivalent third country. Therefore, the obligation of providing written conformation on the GMP compliance of an active pharmaceutical substance does not apply to active substances imported from Israel.

Overview of ACAAs currently under consideration

1. Introduction

This text provides an overview of all the ACAAs (Agreements on Conformity Assessment and Acceptance of Industrial Products) currently under consideration between non-EU countries and the Union.

2. Agreements with countries encompassed by Stabilisation and Association Process

	Legal Basis	Status
Albania ACAA	A commitment to an agreement of this type is included in the Stabilisation and Association Agreement with Albania.	Albania has not requested the start of negotiations.
Bosnia & Herzegovina ACAA	A commitment to an agreement of this type is included in the Stabilisation and Association Agreement with Bosnia & Herzegovina.	Bosnia & Herzegovina has not requested the start of negotiations.
North Macedonia ACAA	A commitment to an agreement is included in the Stabilisation and Association Agreement with North Macedonia.	The possibility of negotiating an ACAA has been discussed informally, but the official negotiations have not been launched.
Montenegro ACAA	A commitment to an agreement of this type is included in the Stabilisation and Association Agreement with Montenegro.	Preliminary discussions were held with Montenegro in March 2010, but Montenegro has not yet requested the start of negotiations.
Serbia ACAA	A commitment to an agreement of this type is included in the Stabilisation and Association Agreement with Serbia.	Serbia has not requested the start of negotiations.
Turkey		The Customs Union with Turkey includes the elements of an ACAA and goes beyond them, since Turkey has the obligation to align with EU technical legislation in the areas covered by the Customs Union. The proposed modernisation and extension of the Customs Union aims at further improving Turkey's alignment.

3. Agreements with European neighbourhood countries

a) Eastern Partner countries

	Legal Basis	Status
Georgia	The possibility of an agreement of this type is included in the Deep and Comprehensive Free Trade Agreement ("DCFTA")	Georgia has not requested the start of negotiations.
Moldova	A commitment to an agreement of this type is included in the DCFTA.	Moldova has asked for the starting of the negotiations. However, the opening of the negotiations is dependent on transposition of relevant EU legislation and its efficient implementation to be ascertained by the EU side.
Ukraine	A commitment to an agreement of this type is included in the DCFTA.	Ukraine has asked for the starting of the negotiations. However, the opening of the negotiations is dependent on transposition of relevant EU legislation and its efficient implementation to be ascertained by the EU side. A pre-assessment mission is planned for 2020.

b) Euromed countries or economies

	Legal Basis	Status
Algeria ACAA	An action plan to facilitate the free movement of industrial products between the EU and the Euro-Med partners was outlined in the Palermo Action Plan, agreed by Euro-Med Ministers on 7 July 2003.	• Under consideration. • Priority sectors identified by Algeria: Construction products, low voltage equipment. • Algeria has started its preparatory work for an ACAA with the support of technical assistance. • Some legislation has been received for screening. Technical assistance is on-going

Egypt ACAA	An action plan to facilitate the free movement of industrial products between the EU and the Euro-Med partners was outlined in the Palermo Action Plan, agreed by Euro-Med Ministers on 7 July 2003.	• Under consideration. • Priority sectors identified by Egypt: gas appliances, toys. Egypt is currently reflecting on adding new sectors (more important from the point of view of export potential). • Egypt has started the preparations for an ACAA with the support of technical assistance (Trade and Domestic Market Enhancement Programme and three twinning projects). • Some legislation has been sent to DG GROW for screening.
Israel ACAA	An action plan to facilitate the free movement of industrial products between the EU and the Euro-Med partners was outlined in the Palermo Action Plan, agreed by Euro-Med Ministers on 7 July 2003.	• Entered into force: An ACAA on pharmaceutical products has entered into force on 19.01.2013 (see previous section on Israel).
Jordan ACAA	An action plan to facilitate the free movement of industrial products between the EU and the Euro-Med partners was outlined in the Palermo Action Plan, agreed by Euro-Med Ministers on 7 July 2003.	• Under consideration. • Priority sectors identified by Jordan: electrical equipment, toys, gas appliances. • Alignment of horizontal and sectoral legislation is ongoing. • The upgrading of quality infrastructure is ongoing with the help of technical assistance.
Lebanon ACAA	An action plan to facilitate the free movement of industrial products between the EU and the Euro-Med partners was outlined in the Palermo Action Plan, agreed by Euro-Med Ministers on 7 July 2003.	• Under consideration. • Priority sectors identified by Lebanon: electrical products, pressure equipment, construction products. • The upgrading of the quality infrastructure is ongoing.

Morocco ACAA	An action plan to facilitate the free movement of industrial products between the EU and the Euro-Med partners was outlined in the Palermo Action Plan, agreed by Euro-Med Ministers on 7 July 2003.	• Under consideration. • Priority sectors identified by Morocco: electrical products, toys, machinery, gas appliances, energy efficiency, eco design. • A Joint Declaration has been signed in November 2012 by VP Tajani and Minister Amara to speed up the preparatory work. • Screening of horizontal and sectoral legislation is on-going as well as upgrading of the infrastructure with the help of technical assistance.
Palestine ACAA[4]	An action plan to facilitate the free movement of industrial products between the EU and the Euro-Med partners was outlined in the Palermo Action Plan, agreed by Euro-Med Ministers on 7 July 2003.	• Under consideration. • Priority sectors: Construction products, pharmaceuticals. • The re-organisation and upgrading of the quality infrastructure started with the help of the technical assistance.

[4] This designation shall not be construed as recognition of a State of Palestine and is without prejudice to the individual positions of Member States on this issue.

Syria ACAA	An action plan to facilitate the free movement of industrial products between the EU and the Euro-Med partners was outlined in the Palermo Action Plan, agreed by Euro-Med Ministers on 7 July 2003.	• An ACAA is not presently considered, as the Association Agreement has not yet entered into force. • Priority sector: electrical products. • A technical assistance project aimed at the re-organisation and upgrading of the quality has been finalised in 2010. Activities in the area have stalled due to the political situation.
Tunisia ACAA	An action plan to facilitate the free movement of industrial products between the EU and the Euro-Med partners was outlined in the Palermo Action Plan, agreed by Euro-Med Ministers on 7 July 2003.	• Under consideration • Priority sector: electrical products, construction products**.** • Tunisia is advanced in the preparations. • DCFTA negotiations were launched in October 2015 and are ongoing. • Tunisia ceased to make standards mandatory on 30th June 2017. • Some legislation was prepared in view of aligning with the EU acquis. • A study has been launched to evaluate the state of play of the preparation, as well as a gap analysis and impact analysis.