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The contribution of mutual recognition to international regulatory co-operation

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THE CONTRIBUTION OF MUTUAL RECOGNITION TO INTERNATIONAL REGULATORY CO-OPERATION

Anabela Correia de Brito*, Céline Kauffmann[+] and Jacques Pelkmans*

JEL Classification: K2, F1, F5, H7

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THE CONTRIBUTION OF MUTUAL RECOGNITION TO INTERNATIONAL REGULATORY CO-OPERATION

By Anabela Correia de Brito*, Céline Kauffmann[+] and Jacques Pelkmans*

ABSTRACT

This study takes stock of the institutional setting, operational modalities, strengths and weaknesses of various forms of mutual recognition when used in different sector and country contexts. It aims to build a greater understanding of the benefits and pitfalls of one of the 11 mechanisms of international regulatory co-operation identified by the OECD Regulatory Policy Committee in OECD (2013), *International Regulatory Co-operation: Addressing Global Challenges*. The paper relies on an empirical stocktaking of mutual recognition agreements (MRAs) among selected OECD countries, the systematic review of mutual recognition clauses in trade agreements, case studies of the specific experience of the EU internal market, the Trans-Tasman arrangement, and the MRA between the US and the EU of 1998, and an extensive review of the literature.

JEL Classification: K2, F1, F5, H7

Key words: international regulatory co-operation, regulatory policy, mutual recognition, trade agreements

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NOTE BY THE SECRETARIAT

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ACRONYMS

ACAA	Agreements on Conformity Assessment and Acceptance of Industrial Products
ACIO	Australian Commerce and Industry Office
APEC	Asia-Pacific Economic Co-operation
APEC EE MRA	Asia-Pacific Economic Co-operation Mutual Recognition Arrangement for Electrical and Electronic Equipment
APEC TEL MRA	Asia-Pacific Economic Co-operation Mutual Recognition Arrangement for Telecommunications Equipment
APLAC	Asia Pacific Laboratory Accreditation Co-operation
B2B	Business to Business
BIPM	Bureau International des Poids et Mesure
CA	Conformity Assessment
CAB	Conformity Assessment Bodies
CAP	Conformity Assessment Procedure
CEN	European Committee for Standardisation
CENELEC	Association of the National Electrotechnical Committees of European Countries
CER	Closer Economic Relations
CETA	Comprehensive Economic and Trade Agreement between Canada and the European Union
CIPM	Comité International des Poids et Mesures
CITEL	Inter-American Telecommunications Commission
CJEU	Court of Justice of the European Union
COAG	Council of Australia Governments
CARIFORUM	The Forum of the Caribbean Group of African, Caribbean and Pacific (ACP) States
CTI	Committee on Trade and Investment
EA	European Co-operation for Accreditation
EC	European Community
EEA	European Economic Area
EFTA	European Free Trade Area
EMA	European Medicinal Agency
EMAS	European Eco-Management and Audit Scheme
EMC	Electro-Magnetic Compatibility
EP	European Parliament
EPA	Economic Partnership Agreement
ETSI	European Telecommunications Standards Institute
EU	European Union
FCC	United States Federal Communications Commission
FDA	United States Food and Drug Administration
FTA	Free Trade Agreement

GATT	General Agreement on Tariffs and Trade
GDP	Gross Domestic Product
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practices
GRP	Good Regulatory Practices
GST	Global System of Trade Preferences among Developing Countries
IAF	International Accreditation Forum
IANZ	International Accreditation New Zealand
IEC	International Electrical Commission
IEC (standards)	International Standards and Conformity Assessment for electrical, electronic and related technologies
IHC	International Conference on Harmonisation of Technical Requirements of Pharmaceutical for Human Use
ILAC	International Laboratory Accreditation and Co-operation
IMO	International Maritime Organisation
IQNet	International Certification Network
IRC	International Regulatory Co-operation
ISO	International Standards from the International Organization for Standardization
IT	Information Technology
ITU	International Telecommunications Union
JAS-ANZ	Joint Accreditation System of Australia and New Zealand
LAIA	Latin American Integration Association Agreement
MLA	Mutual Recognition Arrangement
MR	Mutual Recognition
MRA	Mutual Recognition Agreement
MRATF	Mutual Recognition Arrangement Task Force
MRA-ETR	Mutual Recognition Arrangement for Equivalence of Technical Requirements
MS	Member States
NAFTA	North America Free Trade Agreement
NIST	National Institute for Standards and Technology
NTM	New Transatlantic Marketplace
OAS	Organisation of American States
OECD	Organisation for Economic Co-operation and Development
OSHA	United States Occupational Safety and Health Administration
PECA	Europe Agreement on Conformity Assessment and Acceptance of Industrial Products
PPE	Personal Protective Equipment
QMS	Quality Management System
RAPEX	EU Rapid Alert System
R&TTE	Radio and Telecommunication Equipment
RTA	Regional Trade Agreement
SCSC	Sub-committee on Standards and Investment

SDoC	Supplier Declaration of Conformity
SGP	Singapore
SHEC	Safety, Health, Environment and Consumer Protection
SMEs	Small and Medium Enterprises
SPARTECA	South Pacific Regional Trade and Economic Co-operation Agreement
SPS	Sanitary and Phytosanitary
TABD	Trans-Atlantic Business Dialogue
TBT	Technical Barriers to Trade
TECO	Taipei Economic and Cultural Office
TFEU	Treaty on the Functioning of the European Union
TTIP	Transatlantic Trade and Investment Partnership
TTMRA	Trans-Tasman Mutual Recognition Agreement
USTR	United States Trade Representative
VCCI	The Voluntary Control Council for the Interference by Information Technology Equipment
WTO	World Trade Organization

HIGHLIGHTS

Mutual recognition including the narrower but targeted option of Mutual Recognition Agreements (MRAs), is one of 11 types of international regulatory co-operation (IRC) identified by the OECD (OECD, 2013). Both imply 'hard' law, which means that they are found fairly high on the IRC ladder of increasing ambition, with mutual recognition of rules taking the highest position of the two. However, there are only two examples of such mutual recognition – the EU and Trans-Tasman – and they have been made possible by a uniquely deep form of economic integration and some common institutional framework with responsibilities at high political level. Although the principle of mutual recognition is employed with MRAs too, it is strictly confined to the recognition of technical competence of designated foreign bodies, in the exporting country, in specific product markets, to perform conformity assessment for products to the rules and procedures of the importing country. The latter country neither gives up nor adapts any safety, health, environment and consumer protection objectives, nor does it have to change any existing procedure for conformity assessment.

MRAs have existed for nearly two decades. They have emerged because the less ambitious principle in international trade – namely, 'national treatment'- pre-empts plain forms of discrimination between the regulation of national and foreign goods, but does little or nothing to remove or reduce Technical Barriers to Trade (TBTs). The purpose of a MRA is to facilitate mutual market access by eliminating duplicative testing and certification or inspection. Expectations are that TBTs will be reduced by allowing Conformity Assessment Bodies (CABs) of country B to test/certify goods to requirements of country A before exporting these goods to A. Once arriving in A, the results of the testing and certification in B are recognised and goods may enter without any further testing or time loss. MRAs have become more popular (some 139 have been notified to the WTO) and most of them are initiated by OECD countries. APEC and CITEL have also created voluntary frameworks to stimulate Member Countries to engage in MRAs, in particular in telecoms equipment and, to a lesser extent, in electrical/electronic goods.

The mapping exercise undertaken in support of this work shows that there are currently more than 130 MRAs in the world. One can distinguish between stand-alone MRAs (this work identifies 33 of them) and those incorporated in Regional Trade Agreements (RTAs) (the work considers 99 RTAs); governmental and non-governmental (e.g. between CABs and between accreditation bodies). The governmental MRAs can be either multilateral or bilateral, which in turn can be divided in traditional MRAs (where national regulatory regimes and obligations are different, and remain unchanged) and 'enhanced' MRAs (where regulatory alignment precedes the MRA itself). Bilateral governmental MRAs of the traditional type are most numerous and they are encouraged by the TBT agreement of the WTO.

The paper studies the obligations, incentives and encouragements for mutual recognition obligations in 99 RTAs involving a selected group of OECD countries. Outside of the EU or the Closer Economic Relations (CER), there are no RTAs promoting mutual recognition of rules. Most of them promote the conclusion of MRAs as one amongst several options. Nearly half of them also promote mutual recognition of the results of Conformity Assessment Procedures (CAPs) and many of those require that the reasons for not doing so ought to be explained. Approximately a third promote, usually in broad "best endeavour" language, the recognition of technical regulations as equivalent, often in combination with a requirement to explain the reasons for not granting equivalence. Fewer RTAs require explaining why a country does not want to enter into negotiations aiming at a MRA. Even less common is the encouragement to promote the use of existing regional or international mutual recognition agreements or arrangements on conformity assessment, or, for that matter, a MRA incorporated in the RTA. Less than one third of the RTAs promote the conclusion of voluntary arrangements between CABs of the parties to mutually accept the results of

each other's CAP results. In a number of instances, separate stand-alone MRAs were concluded between RTA partners and some RTAs incorporate MRAs in the agreement.

The landscape of MRAs has drastically changed since the late 1990s. There are far more MRAs; they have become more sophisticated; they may be connected or even incorporated in RTAs; and they have become more targeted in terms of sectors (than in the late 1990s). Most frequently, MRAs are limited to telecoms equipment, Good Manufacturing Practices (GMP) for medicines and electronic goods. The preponderance of telecoms equipment and electronic goods (especially in East Asia) can be explained, on the one hand, by strong incentives to cooperate given compatibility or even interoperability requirements, and, on the other hand, by global value chains in these sectors for which delays and uncertainty about conformity assessment is costly. However, the range of sectors tends to be wider when either the EU or EFTA countries, including Switzerland, are involved. Sectors such as medical devices, pressure equipment (a risky component of many engines), or even machinery are typically derived from the EU New Approach and they only appear with European countries. However, they are not always operational. Recreational craft is only found in US/EU (or EFTA) and Canada/EU (or Switzerland). Special cases include marine equipment (an enhanced MRA between the US and the EU based on aligned rules of the International Maritime Organisation) and aeronautical products (Japan/US). A large number of MRAs rely heavily on international standards where available, and for CABs and their accreditation. CABs have responded pro-actively and formed large voluntary quality networks and based their activities on ISO/IEC standards, which makes them attractive for regulatory authorities to use.

Little is known about the actual implementation and functioning of MRAs because reporting on their use is rare or inexistent. A legal text of a treaty is no guarantee that implementation has been successful. In this respect the experience with the US/EU MRA is instructive because not only was it the first MRA negotiated in the mid-1990s, it is also the one where major public debates, (well documented) business efforts at the highest level and political decision-making can be traced and evaluated, in addition to analytical literature and basic facts about implementation. Despite major efforts up to the highest level of politics, only two of the six sectorial MRAs are operational today, with only one-fifth of the expected trade value covered. In pharma, medical devices and electrical goods, the MRA does not work. The recreational craft annex has not been in operation since 2006.

The report comprises an attempt to analyse and evaluate MRAs as a form of IRC, taking stock of the literature on the subject and using the benefits-costs-challenges framework in OECD (2013). At the outset, MRAs were probably overrated in terms of benefits, without fully realising their costs and challenges. Now that many OECD countries have moved further on the learning curve of MRAs and their alternatives, an application of the OECD analytical framework for IRC may help policy makers both in trade policy and in regulation to better appreciate what MRAs can and cannot bring, what the pitfalls might be and how they might be addressed.

Of the four benefits in OECD (2013), MRAs are undoubtedly driven by economic gains, in particular through increased trade flows. The impact of MRAs on trade made possible by lower costs of market access is found to be positive in the empirical economic literature. Nevertheless, the empirical evidence is not always very powerful. In fact, little is known about cost differentials of conformity assessment with and without a MRA, or, about how frequently companies use these provisions. Moreover, five alternatives to MRAs are used by business, with little data about their use and impacts. This renders any empirical work seeking to isolate the effects of one or the other tool difficult. The weak impact of MRAs on trade can also be explained by the relatively small costs gains, as a share of the total costs of TBTs. Most of the costs of TBTs are caused by regulatory divergence and by definition that is not touched by traditional MRAs. A second type of benefits, through knowledge flow and peer learning, may well be important. This can be true both for the failed MRAs and the successful ones. In the US/EU case, in pharma and medical devices continued regulatory co-operation is the follow-up of the MRA. For the functioning MRAs, these

flows may amount to a capacity building tool. In a dynamic sector like telecoms equipment, it is even indispensable to organise regular peer learning.

There is a range of actual or perceived costs related to MRAs. In particular, MRAs, though narrowly focused and supposedly functioning more or less automatically once in place, are widely regarded as costly for administrations and regulators. These costs consist in time and human resources, often highly specialist ones. The time of administrative maintenance matters after the operationalisation of sectorial MRAs. However, before a MRA has been concluded, there is evidence that MRAs are costly to negotiate – although perhaps less today in the well-known sectors such as telecoms equipment, given worldwide experience. Typically, substantial time (also of higher officials and even ministers) is needed to raise the political capital to support the MRA negotiations, to mobilise the administration, to lobby legislatures and to gather the support from business.

There are also important implementation challenges. This can be a question of 'trust'. The evidence on past MRA experience shows that MRAs require sustained trust in each other regulatory systems, structures and procedures for accreditation and conformity assessment, and a certain level of technological development for a high-quality infrastructure. A lack of trust can be costly, it may undermine the cooperative attitude of partners and derail the MRA scheme. MRAs can also be formulated in such a conditional, if not open-ended, way that implementation can be feared to become difficult. Problems of implementation may be greater once the coverage is larger and more actors are involved. But these aspects may well be less relevant for MRAs as they are well-defined for specific sectors and their operation is both technical and under specialised committees.

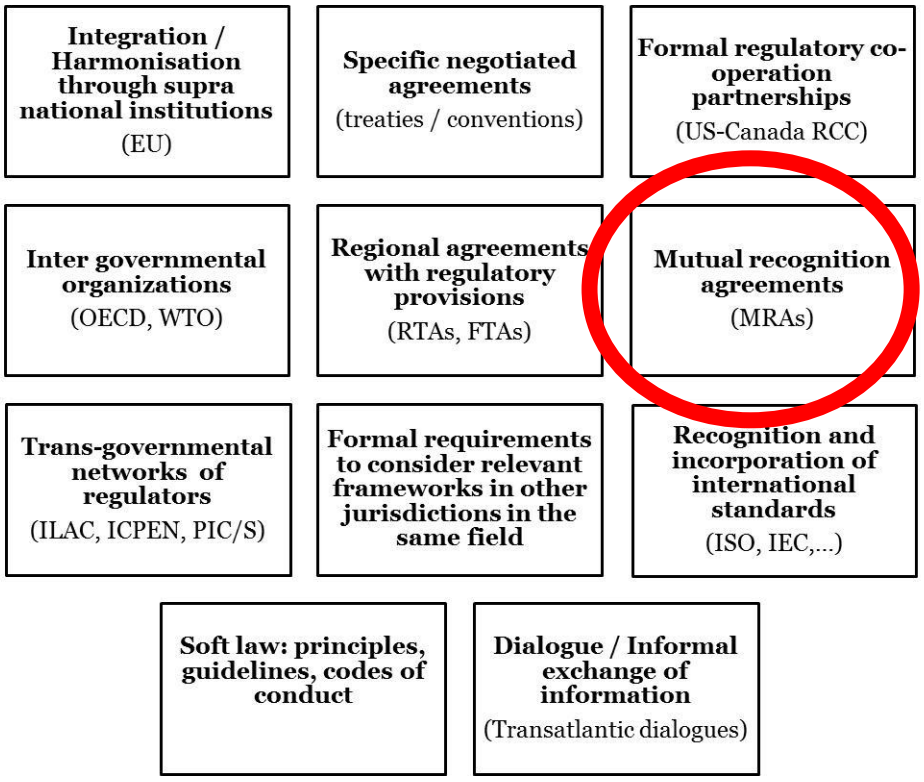
INTRODUCTION: BACKGROUND, OBJECTIVE, STRUCTURE AND METHODOLOGY

Background

OECD (2013) notes the increased internationalisation of regulation for a variety of reasons including expected economic gains, administrative efficiency and improved safety and strengthened environmental sustainability. At the same time, as markets integrate across borders and trade frictions due to tariffs are becoming less of a concern, unnecessary regulatory divergence across jurisdictions is increasingly perceived as imposing trade costs and unduly inhibiting international trade. Attention is growing on the potential of international regulatory cooperation (IRC) to help policy makers maximise welfare and address the potential barriers to economic integration and trade.

OECD (2013) shows that regulatory cooperation can take place through a wide variety of IRC mechanisms. It identifies 11 mechanisms used by countries to support their IRC objectives, including among others joint rule making, recognition of international standards, and mutual recognition (Figure 1). However, despite growing regulatory co-operation and the availability of a menu of different options, the choice among various cooperation approaches is not informed by a clear understanding of benefits, costs and success factors of diverse IRC options. Decision making in this area remains largely driven by political considerations and path dependency, owing to a paucity of evidence on what works and what does not work. Most information on how diverse approaches to IRC perform is anecdotal, not granular enough or purely qualitative.

Figure 1. MRA in the OECD typology of IRC mechanisms



Source: OECD (2013), *International Regulatory Co-operation – Addressing Global Challenges*, OECD Publishing, Paris, http://dx.doi.org/10.1787/97892642004663-en.

In this context and at the request of delegates in the Regulatory Policy Committee, the OECD has started identifying the different forms of IRC and their relative merits and challenges. Among them, OECD (2013) notes that mutual recognition is increasingly used in a range of different sectors and by an increasing number of countries, according to a wide variety of modalities and in combination with a range of other IRC mechanisms. At the same time, experience with this mechanism within the EU and as part of the Trans-Tasman co-operation for instance, has led to identify a number of pre-conditions (close degree of equivalence and reciprocal confidence in the responsible institutions of the respective countries involved) and shortcomings (enforcement issues, inadequacy to address co-operation for occupational activities,…). However, except for a handful of academic papers and some specific country / regional work, a systematic review of the strengths and weaknesses of various forms of mutual recognition across sectors and in specific country context, taking into account the dynamic nature of such arrangements, is still lacking.

Objectives of the study

The present study precisely aims to take stock of the institutional setting, operational modalities, strengths and weaknesses of various forms of mutual recognition when used in various sectors and in different country contexts and to differentiate the various instruments that may be understood under the wide-ranging concept of mutual recognition (see Box 1 for clarifications on terminology). The study investigates the potential of mutual recognition to reconcile the mission of national regulatory authorities to protect safety, health, environment and consumers (SHEC) and the imperative to facilitate or accommodate trade to support the dynamism of economies.

The study is based on concrete examples and the experience of OECD countries to date. It builds on inputs provided by New Zealand, the European Commission, Japan, Mexico and the US. It contributes to work of the OECD Regulatory Policy Committee on IRC by supporting a greater understanding of the benefits and pitfalls of using these mechanisms, and of the opportunities to improve the existing experiences and to extend them to new fields of co-operation. It focuses mainly on experiences of MRAs in industrial goods.

Box 1. On terminology and definitions

Mutual Recognition (MR) is a wide-ranging concept: one can mutually recognise limited or general aspects of a regulatory regime. A very ambitious form is MR of rules or standards. 'Rules' can mean various manifestations of legal obligations. 'Standards' are by definition voluntary; however, in some regimes, adhering to a specific standard may be regarded as fulfilling the relevant regulatory objective of health or safety (etc.). MR will be possible only if the relevant regulatory objectives are regarded as 'equivalent'.

Mutual Recognition Agreements (MRAs) are far more limited and modest. Their purpose is solely to avoid duplicative testing in international trade. Neither the regulatory objectives, nor the technical requirements, nor the conformity assessment procedures are the same or 'equivalent'. What is mutually recognised is (i) the technical competence of specific conformity assessment bodies in the export country to perform conformity assessment at the expected level of the import country, and (ii) the knowledge of these bodies about the technical requirements and conformity assessment procedures in the import country. MRAs thus recognise the competence of designated conformity assessment bodies in export country A to test and issue certificates on the basis of the technical requirements and procedures of import country B, and vice versa, thereby allowing such imports to enter the destination country without further barriers or delays.

MRAs are one of many ways to address technical barriers to trade (TBTs) which arise from divergences in national technical regulations. There are alternatives to MRAs which partly or imperfectly substitute functions of MRAs. The most important example is the **Supplier Declaration of Conformity (SDoC)**. According to Fliess, Gonzales and Schonfield (2008), "by definition, under SDOC the supplier himself (this can be the manufacturer, distributor, importer, assembler, etc) provides written assurance of conformity to all applicable technical regulations of a market. Allowing the supplier himself to declare compliance of a product removes the regulatory need for obtaining certification from a recognised third party, usually located in the export market."

Box 1. On terminology and definitions (*cont.*)

Countries can also conclude '**equivalence agreements**'. In such agreements, the importing country recognises the 'equivalence' of the objectives and conformity assessment of the exporting country in product x to that of its own, although they need not be exactly the same. The discretion is therefore on the importing country (under certain procedures). Indeed, equivalence may well be granted on a case by case basis, just like a 'positive list' approach in trade negotiations. Therefore, mutual recognition is more ambitious : mutual (and not unilateral) recognition is the rule, and procedures to claim exceptions are typically difficult, rendering MR akin to a liberalisation of market access based on a (strict) negative list approach.

Structure and methodology of the study

Following the introduction, Chapter 2 sets out the wide spectrum of 'mutual recognition' approaches. It clarifies and illustrates the ambition and implications of mutual recognition of rules based on the examples of the EU internal market and the experience of the Trans-Tasman arrangement (based on Annexes 1 and 2). Subsequently, the chapter sets out what MRAs are, and their place and role in tackling TBTs. MRAs are considered on a wider spectrum of six categories of alternatives or approaches for obtaining cross-border acceptance of conformity assessment which are to some extent alternatives. A brief account of the experience of the US/EU MRA of 1998, and its application in six goods sectors, is provided (based on a case study in Annex 3).

Chapter 3 provides an extensive empirical stocktaking of MRAs among selected OECD countries (MRAs of the EU with OECD partners included). The chapter classifies them according to their characteristics and proposes a typology differentiating MRAs between governmental and non-governmental ones, as well as bilateral and multilateral ones.

Chapter 4 supplements this stocktaking exercise with a wide-ranging survey of mutual recognition provisions in or connected to Regional Trading Agreements (RTAs). It maps the provisions on mutual recognition and equivalence of standards, technical regulations and conformity assessment procedures of 99 RTAs concluded by 8 OECD economies and notified to the WTO by 30 May 2014. The chapter reviews whether RTAs encourage MRAs or forms of 'equivalence' as a facilitation of market access and a reduction of barriers and the form this takes. In particular, it analyses the extent to which the RTAs promote the recognition of technical regulations as equivalent, the mutual recognition of technical regulations and/or standards, and / or the acceptance of results of conformity assessment procedures, and whether it is done within the RTA or by reference to an outside MRA.

Chapter 5 applies the scheme of benefits and cost of IRC developed in OECD (2013) to analyse the merits and challenges of MRAs and their alternatives. It comprises a survey of the empirical economic literature of the effects of MRAs on trade, building on an earlier OECD effort in this area. Beyond this effect, it identifies the lessons learnt from experience on other benefits and challenges of MRAs.

In conclusion, the paper highlights a number of critical considerations to ensure the success of mutual recognition, including pre-conditions and success factors.

The work is mostly based on desk research, including an extensive literature search, scrutinizing government websites from a number of OECD and some non-OECD countries (tracing MRAs and other relevant agreement and arrangements) as well from the WTO and other international organisations, both public and private, and some so-called 'grey' (not officially published) literature or presentations. Inputs were also provided by representatives to the OECD Regulatory Policy Committee and collected through a few interviews with European Commission officials and other experts.

MUTUAL RECOGNITION AND MRAS: THE SPECTRUM OF MODALITIES

Introduction

The meaning, properties and limitations of MRAs are much better appreciated when placing MRAs as one option amongst alternative ways to accomplish similar trade facilitation via regulatory co-operation. This chapter surveys the overall spectrum of modalities of 'mutual recognition' (MR), from the wide spectrum of 'mutual recognition' to the narrower (sub)-spectrum of six modes of recognising the test results or other elements of conformity assessment only.

This chapter provides the wide spectrum of 'mutual recognition', including the MRAs. This wider spectrum of 'mutual recognition' incorporates mutual recognition of (different) rules between two or more countries, given certain pre-requisites. Mutual recognition of rules is analysed through the two examples of the EU and the Trans-Tasman Mutual Recognition Arrangement building on Annex 1 and Annex 2. Then MRAs are explained as a response to TBTs caused by differences in national regulations. They are also compared to their five alternatives, including unilateral approaches. The practical experience with MRAs is finally exemplified using the US/EU MRAs concluded in 1998 for six industrial sectors, based on Annex 3.

The wider mutual recognition spectrum

In a general sense, mutual recognition implies that goods or services produced under a regulatory regime or rules in country A enjoy unhindered market access in country B, presumably having different rules. When there is uniformity of safety, health, environment and consumers (SHEC) requirements or when such requirements are similar in A and B, these requirements will not impede market access. However, when SHEC requirements differ, MR may help address the trade frictions that such differences may generate by promoting the notion of "equivalence" of SHEC levels or of relevant aspects/procedures ensuring such equivalence. MR therefore respects the prevailing SHEC levels in the countries A and B. If found or trusted to be 'equivalent', the SHEC objectives are fulfilled and the mission of the regulator is not affected. What might be affected are the often different technical requirements for an 'equivalent' level of 'safety' (etc.) but there is usually no reason why such requirements are critical. Under these conditions, MR might be a practical way to allow unhindered market access without altering national regulation.

Figure 2 provides the wide spectrum of MR modalities in goods sectors. Mutual recognition of rules is the most fundamental option. More precisely, the regulatory objectives or effective results of regulation for goods coming from country A are regarded as 'equivalent' in country B, implicitly or explicitly, and vice versa. Hence, the regulatory requirements, standards and results of conformity assessment applied in A are recognised as yielding functional equivalence for SHEC protection of consumers and workers in B, and vice versa. There are two well-known examples of MR of rules in the OECD: the EU internal market and the Trans-Tasman Mutual Recognition Arrangement. Annexes 1 (on the EU) and 2 (on Trans-Tasman) however show how demanding this MR modality is. Also in neither case is MR a stand-alone approach. In both cases, MR is embedded in a more extensive system of mutual market access, which also makes use of harmonisation and selective centralisation. The EU goes even further than this with the European Commission as a permanent watchdog (the 'guardian of the treaty') and judicially enforced by a supranational EU Court.

Mutual recognition of conformity assessment (procedures/results) is less ambitious: the MR refers solely to the capability of conformity assessment bodies (CABs) in country A to perform testing and certification on selected goods to be exported to country B, against the rules, standards and conformity assessment procedures in B, and vice versa. In this more limited option, there is neither acceptance of

equivalence, nor is it needed. What underlies this MR option is the confidence that the technical infrastructure in A (resp. B) is of sufficiently high quality and that the CABs in A carrying out the conformity assessment are competent to do so and knowledgeable about the requirements in B. In most cases, the CABs in A will be designated only after B has been reassured of their competence. Once designated, goods assessed by CABs in A will enter B's market without further testing or certification in B, which implies lower 'trading costs' for their producers (and vice versa for producers of B). Depending on the intrusiveness of their conformity assessment procedures, which in turn depends on the sector, authorities may require more or less time to build up the confidence that CABs from other countries with developed infrastructures can be trusted to deliver the same quality of conformity assessment as domestic accredited bodies.

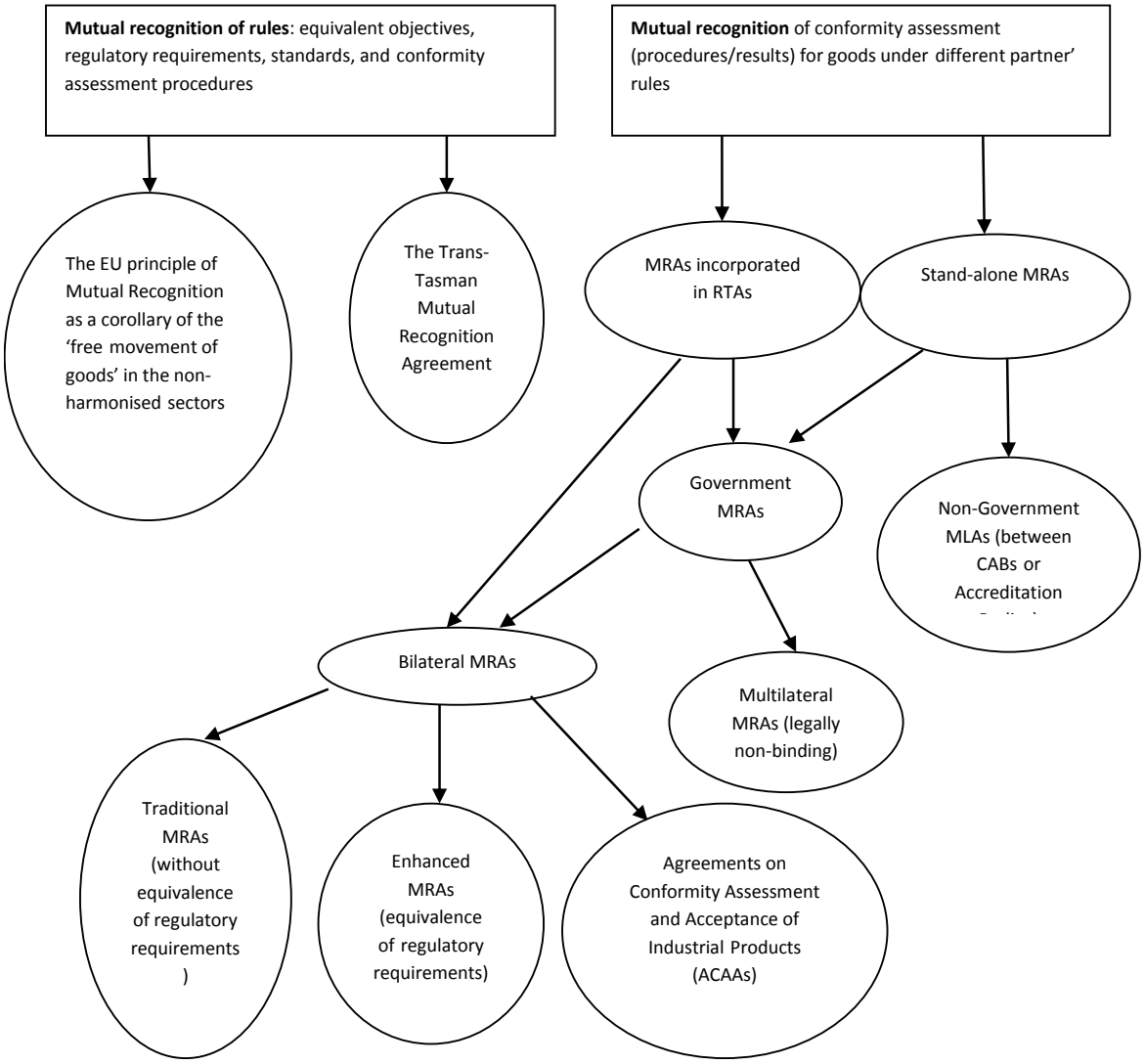
MRAs have become much more common than MR of rules. MRAs have also developed in variety. Most MRAs are 'stand-alone' but increasingly Regional Trade Agreements (RTAs) refer to mutual recognition of conformity assessment in more or less elaborated ways. Stand-alone MRAs have become more varied, too. Traditionally, MRAs are agreements concluded by two or more governmental bodies, with the aim of facilitating the acceptance of the results of conformity assessment procedures undertaken by the other party's or parties' conformity assessment bodies (CABs) in accordance with the importing country regulations. Governmental MRAs can be bilateral or multilateral, cover one single sector or multiple sectors and they can create legally binding obligations for the parties in the agreement or be of a voluntary nature. The scope of government MRAs of conformity assessment is limited to products which are subject to regulation by government authorities and which involve some form of mandatory third-party intervention (conformity assessment) prior to the product allowed to be placed in the market.

Traditional MRAs have been complemented by two kinds of (what the EU calls) 'enhanced' MRAs. Such enhanced MRAs are characterised by prior 'equivalence' achieved via harmonisation or alignment of rules and standards with those of the EU, or by agreed commitments to gradually align domestic rules and standards over time with those of the EU, followed by sectoral MRAs called ACAAs (Agreements on Conformity Assessment and Acceptance of Industrial Products). These enhanced MRAs are discussed in Annex 1 (on the EU) as they typically apply to candidate countries and so-called 'neighbourhood' countries to the South and South-East of the EU.

Another recent development is the emergence of multilateral government "arrangements" in specific sectors. These voluntary arrangements have been initiated by APEC in telecoms equipment and in electric/electronic goods. These 'MRAs' have different stages of ambition and APEC countries can adhere to them stage by stage. Both sectors have powerful incentives to join MRAs given compatibility requirements and interoperability. In East Asia (part of APEC), complicated value chains, spread over a range of countries, can only function efficiently when compatibility requirements and interoperability are guaranteed throughout the region without many interruptions due to conformity assessment of components or otherwise.

A very interesting development is that CABs and national accreditation bodies have organised non-governmental agreements of a multi-lateral nature recognising each other's competence, based on a high quality world (ISO) standard for such bodies. Non-governmental mutual recognition arrangements are typically voluntary agreements, through which the CABs or Accreditation Bodies agree to recognize each other's processes for testing, certification, inspection and/or accreditation, with the aim of facilitating the acceptance of the results of conformity assessment. They do not create obligations for the governments of the parties involved. However, by recognizing the quality of the testing, certification and inspection undertaken by the signatory's CABs and/or recognizing that the CABs accredited by accreditation bodies of parties to the agreement meet certain quality requirements and standards, they can contribute to avoid double testing products in the countries of origin and of destination.

Figure 2. Mutual Recognition: spectrum of modalities



Mutual recognition of rules: ambition and functioning

There are two examples of MR of rules for goods: the EU internal market and the Trans-Tasman Mutual Recognition Arrangement. MR of rules is ambitious and embedded in wider systems with harmonisation and even centralisation options in some instances. In order to appreciate this, the sections below explain briefly what the ambitions of these two practical examples are and how each one of them works.

Mutual Recognition in the EU internal market

The EU is at the origin of 'mutual recognition'. Much of the EU internal market for industrial products (and to some extent for services, too) is governed by mutual recognition. However, the EU does not have internal MRAs. It has concluded MRAs with third countries, be they 'traditional MRAs' (as meant in the TBT Agreement) with countries having different rules and/or conformity assessment procedures, or 'enhanced MRAs', based on commitments to align the relevant rules with those of the EU.

The EU notion of MR is highly formalised in two distinct ways. The basis is the quasi-constitutional obligation of 'free movement' (here, of goods) in the EU internal market. Free movement goes much further than free trade, it is right-of-market-access for all economic agents in the EU be it with derogations for Member States. The second form of MR is a derivative of the Court of Justice of the European Union (CJEU)'s notion of equivalence of objectives, which is often not easy to determine. This "regulatory mutual recognition" combines harmonisation and judicial MR by first enacting a minimum harmonisation directive on the equivalence of objectives: they are set in common and thereby doing away with any uncertainty in this respect. Beyond that, little is harmonised (hence, is subject to MR by implication) and practical certainty for companies is provided via reference to (voluntary) harmonised European standards written such that the SHEC objectives are adhered to. This is called the New Approach, meanwhile renamed as the New Legislative Framework, and it covers a number of fairly large industrial sectors such as machinery, pressure vessels, toys, electrical safety[1], Electro-Magnetic Compatibility (EMC), medical devices, etc.

Annex 1 elaborates on the internal workings of the EU. The implications of MR in the EU are summarised below.

1. In case of judicial MR there is no EU regulation, only national regulation, but there are no longer TBTs either.

2. In case of regulatory MR, there is 'light' harmonisation of objectives only, sometimes complemented with a few basic technical requirements when the complexity of the sector demands such; but the relevant European standards facilitate market access as adherence allows the affixing of a CE mark (indicating conformity with EU requirements). In many instances, the CE mark can be based on a SDoC, backed up by a technical file (authorities can demand this file for verification); in some cases of higher risk, CE marks can only be affixed after 3rd part certification by a so-called Notified Body, accredited via the European Co-operation for Accreditation system (EA).

3. Given 1. and 2., MRAs inside the EU are not necessary. Notified Bodies are CABs which are accredited by the EU's EA system, and the underlying rules, standards and procedures are identical. For the Old Approach regulating higher risks sectors, all detailed specifications tend to be included in directives, and procedures for conformity assessment (including inspection or type approval) are identical. Thus, also here no MRAs are needed inside the EU.

4. With third countries, like the US, Canada, Australia and New Zealand as well as Japan, MRAs have been concluded in the late 1990s (they are discussed in chapters 3 and 4 and Annex 3). For 'associated' or candidate countries expressing a desire to be 'part of the EU internal market', so-called 'enhanced MRAs' have been concluded on a sector by sector basis. This is logical as the regulatory 'acquis' (the rules and market institutions of the EU) is adopted by these countries, and at some point 'free movement' can be applied. For candidate countries, some sectors might be advanced in the "pre-accession process" and an ACAA in sector x or y might ensure market access without further conformity assessment. For neighbourhood countries, there is usually no hard promise of EU membership, or it is impossible as they are not European countries, so that MRAs are unavoidable. However, the EU only accepts such MRAs (also called ACAAs) in sectors where regulations and conformity procedures have been aligned with the EU, and the CABs recognised as Notified Bodies (or otherwise designated).

1. Strictly, the 1973 Low Voltage directive precedes the New Approach but the practical effects are similar.

Mutual recognition under Trans-Tasman

The Trans-Tasman Mutual Recognition Arrangement (TTMRA) is a far-reaching 'arrangement' about reciprocal market access for goods based on mutual recognition of rules, with a 'negative list' approach for derogations. The TTMRA is ambitious but it is not clear whether it can serve as example for other countries for two principal reasons. One is a long list of 'success factors' which is unlikely to be found easily anywhere else in the world economy.[2] These include a sound regulatory infrastructure, sufficient volumes of trade in goods, underlying compatibility of the two regulatory systems, sharing an existing bilateral platform (the CER dating back to 1983), a broad consensus on wider geo-political and macro-economic issues, a similarly high level of economic development, and similarity in cultural and historical background. The other reason is that one should not fall into the trap of focusing solely on MR and ignore the alternatives (to MR) which are also used in the TTMRA, and similarly neglect the unusually strong links with the *intra*-Australian MRA between its states/territories and the federal government (Commonwealth).

Australia and New Zealand have developed exceptionally close relations in many areas and certainly in goods market integration. The TTMRA is a companion of the intra-Australian MRA between the states and territories of Australia together with the federal government. The intra-Australian MRA was driven by an urge for deep structural reforms, in a search for productivity increases after a long period of protectionism and restrictive attitudes inside Australia as well as internationally (but not vis a vis New Zealand). The intra-Australian MRA can only be understood if it is seen as embedded in a wide-ranging attempt to structurally increase Australian productivity via all kinds of reforms, including liberalisation from restrictive regulation, external unilateral tariff reduction, mutual recognition between Australian states in goods markets (with exceptions), centralisation of functions (to pre-empt fragmentation) to the level of the Commonwealth, attempts to radically improve infrastructure for some network industries as a prerequisite for efficiency and further reforms, and regulatory harmonisation in other cases (usually where risks were thought to be higher, including food).

New Zealand has been incorporated fully into the COAG (Council of Australian Governments) for the purpose of the TTMRA. The 'arrangement' might seem non-binding, in fact, however, both countries have enacted laws for the legal implementation and enforcement of the TTMRA and its many consequences.[3] The TTMRA is essentially based on two properties. First, the definition of MR is directly derived from the EU judicial approach in Cassis-de-Dijon formulating the origin principle: 'a good that may be sold in the jurisdiction of any Australian party, may be sold in New Zealand …' (and vice versa). 'Goods need only comply with the standards or regulations applying in the jurisdiction in which they are produced or through which they are imported'. Contrary to the EU, in most cases, the equivalence of SHEC objectives is simply assumed to exist. Second, mutual recognition is embedded in a much wider regulatory regime. In selected instances, harmonisation of laws and even centralisation (a common Agency for food safety) are chosen instead of mutual recognition.

Annex 2 describes the TTMRA in more details. Generally, the Australian Productivity Commission's overall judgment is that MR is a low-cost decentralised means of dealing with inter-jurisdictional differences in laws and regulations, which is working better for goods than for services (see Box 2).

2. However, two cases come close: the US/Canada FTA prior to NAFTA, and the old EFTA before the EEA was negotiated. Strikingly, they did not comprise MR.

3. The TTMRA differs in only a few respects, for example, it can be ended by both parties on relatively short notice and some clauses are different from the MRA.

Box 2. Key points from the draft assessment report on Mutual Recognition Schemes

The Mutual Recognition Agreement (MRA) and Trans-Tasman Mutual Recognition Arrangement (TTMRA) are generally working well. The benefits include making it easier to do business across borders and a wider range of goods and services.

However, the value of the schemes risks slowly being eroded due to regulators not always implementing mutual recognition as required, weak oversight, and an increase in the number of goods and related laws permanently kept outside the scope of the schemes.

There are specific concerns with the operation of mutual recognition of occupations relating to 'shopping and hopping', continuing professional development, background checks and determining occupational equivalence. These issues have the potential to weaken the community's and regulators' trust in the schemes and undermine their legitimacy.

Source: Productivity Commission, Commissioned Study on Mutual Recognition Scheme, Draft report: www.pc.gov.au/inquiries/current/mutual-recognition-schemes.

Mutual Recognition of conformity assessment

TBTs and the place and role of MRAs

For a proper understanding of the role and place of MRAs, it is good to first define what MRAs are and are not, how they can help to address TBTs and what closely related policy alternatives or less/more ambitious approaches exist with similar long-term aims. MRAs are meant to facilitate market access without affecting domestic risk regulation. They are not the only approaches that can help to facilitate market access. They also do not address all forms of TBTs that arise from diverging regulatory requirements. There are three types of TBTs: barriers resulting from (diverging) standards, from (diverging) technical regulations and from various forms of conformity assessment, widely conceived.

Though technical standards are by definition voluntary, adaptation to other standards used in another country may be indispensable commercially or even technically (e.g. in case of incompatibility or a lack of interoperability). This often leads to a call for (more) international standards which is indeed one way to facilitate market access. However, international standards for final goods are not so numerous (for example, compared to European standards, now approaching 25000, or the total of US standards, probably much higher in total) because there is often not enough interest to engage in the costly process of writing them, or, national or regional preferences (or technical traditions) differ. Moreover, if standards at world level relate to products or components – other than for telecoms & radio equipment or electrical and electronic goods and components, for which compatibility and/or interoperability is crucial – they tend to have different 'options' which reduce their global market value (Pelkmans & Costello, 1991). Therefore, the encouragement of adhering to international standards in the WTO TBT agreement is helpful to stimulate national regulators to assume a wider view (or, prevent them from being 'captured' by local 'lobbies'), but frequently such international standards do not exist at the product level or deal with only some aspects of health, safety or the environment.

A lot of international standards are not applicable to final goods but to intermediate industrial processes (e.g. paper and pulp standards), or are measurement standards or testing methods (e.g. standards for proper sound tests of, say, machinery). On the other hand, modern standard writing tries to avoid promulgating so-called 'design standards', which are highly prescriptive and detailed for final goods and, hence, can lead to severe de-facto market access barriers. Insofar as health, safety and environmental aspects are involved, what matters is a maximum residue, a tolerance limit for a risky substance, the avoidance of sharp edges and of e.g. certain chemicals in paint of toys, a minimum of strength of materials,

etc.; these standards are called ‘performance standards’ and they do not impose a particular technology or a prescription of how to design a good in detail but focus on what avoids a lack of safety or health, etc. or what constrains emissions. Performance standards tend not to be de-facto protectionist; it is also easier to agree on them at world level if there is enough commercial interest. Nevertheless, standards in and by themselves are usually not seen as a major TBT, precisely because they are voluntary. Indeed, the large bulk of standards are simply *not* concerned with health, safety or environmental aspects at all and merely facilitate the reduction of redundant variety (which is likely to prevent economies of scale), the transfer of technical information and/or proper testing of certain properties of a good or component.[4]

TBTs are usually associated with differences in national (or regional) technical regulations. Technical regulations impose, prescribe or forbid; they are compulsory, unlike standards. And almost without exception, they are about safety, health and environment aspects of goods, unlike most standards (and unlike most aspects of standards). However, the range of degrees of restrictiveness of technical regulations is very wide. Some regulations reflect a light, almost residual approach solely focused on objectives[5] or can be seemingly non-intrusive, due to strict product liability which is likely to have a deterrent effect on producers, especially in the US. Some regulations, on the other end of the spectrum, are intrusive and, unless such precision and detail is based on international standards (which is rare), such national regulations tend to differ in many ways, causing costly TBTs.

Trends of regulatory reform in the OECD have frequently had the beneficial effect of re-regulating such product laws in ways which also reduce somewhat the actual or potential TBT costs. More often than not, such trends are driven by local desires to reduce the cost burden of regulation, rather than by market access considerations. The general idea behind such reforms is that regulation should be objective-driven, and avoid - unless absolutely indispensable – a myriad of highly detailed technical specifications. For this purpose it can be very helpful to make use of well-written performance standards, as long as such standards clearly support the objective(s) of the regulation. Standards are market driven and even when societal objectives such as safety (etc.) are to be adhered to, tendencies of over-specification and rigidity in allowing variation as well as rendering it cumbersome to enact amendments, would be nipped in the bud. Where regulations are intrusive / restrictive, standards might simply not exist and TBTs can be strict. But even here, regulation has often moved away from command-and-control to incentive driven such as in carbon markets; however, such markets also require standards and rules (and indeed conformity assessment).

For regulation to be properly enforced - thereby ensuring that objectives be achieved and distortions pre-empted by avoiding free riding due to lack of controls - *conformity assessment* is indispensable. But that is also true for standardisation, as supplier companies may wish to employ such formal assurance as a reputation device to sell or maintain a respected position in global value chains, whereas purchasing companies’ wish to have certainty that the component or product is reliably produced according to the standards in the product description. Conformity assessment is a complicated activity. It takes place before a product or component is brought to the market, in contrast to market surveillance which is ex post. It might be executed via inspection, licensing, type approval, testing, certification of products and certification of quality management systems. In turn, testing can be done in-house [with technical facilities

4. At world level it is hard to provide reliable information but at EU level it is possible. Of the nearly 25000 European standards (from CEN, CENELEC and ETSI), less than 4000 are linked to EU regulatory provisions. For example, (voluntary) standards for bed sizes facilitate economies of scale for simple beds and compatible matrasses, but have no relation with regulation.

5. As an example, the 2001 EU product safety directive merely states that (consumer) goods brought to the market have to be ‘safe’ and a rapid alert system (Rapex) deals with cases of ‘serious risk’. The directive can be so ‘light’ because many other specific directives already cover safety aspects.

– sometimes having been approved by authorities or certification bodies – as the basis for a supplier-declaration-of-conformity (SDoC)] and via third parties, typically laboratories, testing houses and certification bodies which have been accredited for this purpose. Certification bodies can issue certificates for private standards and for declaring that technical regulations have been adhered to in case of the given product. There are quality and reliability issues in such activities. They are solved differently across countries.[6]

Conformity assessment costs in the export market can be reduced or eliminated, once testing and certification has been done in the country of production, that is, before exporting, even if regulation and perhaps underlying standards differ between the countries, and specific (national) requirements for verification exist. This implies that the certification body in the production country should be trusted to know well the rules and verification requirements in the export market, and is formally accepted as technically competent to execute this conformity assessment. This works both ways between countries A and B, or, inside a group of countries in a regional agreement.

MRAs therefore remove or at least reduce the costs of only one specific form of TBT: given different product/component regulations and conformity assessment procedures or their technical details, between A and B, MRAs avoid (i) double testing, (ii) the uncertainty about a possible rejection due to slight differences in testing or verification, and the costly correction as a result of that, and (iii) the delays in terms of 'time-to-market'. These costs are avoided because a MRA guarantees that a product/component x produced in country A, if certified by an accredited certification body in A which is 'recognised' under the MRA procedures by B because it is trusted to certify x for compliance with technical regulations in B, can enter country B's market without any further testing or verification. And of course, the same goes for B's product/component y, assured to comply with A's technical regulations under the same MRA provisions. All of this trade facilitation occurs without any change in objectives and/or regulatory requirements in either country.

Cross-border acceptance of conformity assessment results: a spectrum of six alternatives

This section contextualises MRAs as one option on a range of alternatives which may deliver automatic or at least less costly market access, while satisfying the importing country's requirement that it gives "(…) adequate confidence of conformity" (Quoted from the legal analysis by Appleton, 2013). There are six alternatives or approaches[7] to obtain acceptance of CA results from country A in country B, which can be depicted under two headings: governmental and private / public co-operation (Figure 3).

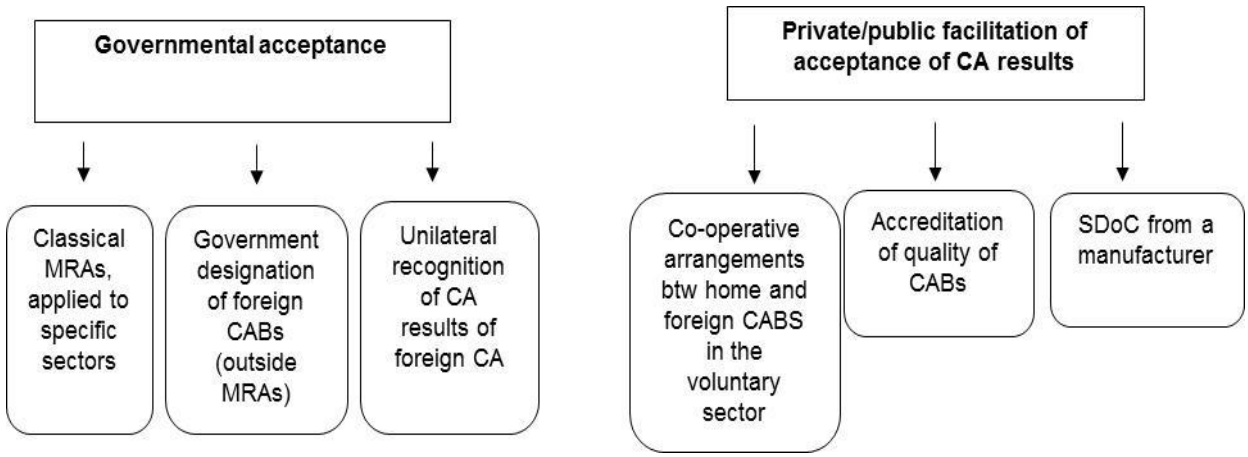
The first category is the classical MRA between governments of A and B. MRAs can have rules of origin (product x needs to originate – with enough value-added - from A or B, resp.), which is restrictive and might therefore cause trade diversion. However, many MRAs have no origin rules and hence product x may originate from a third country C but has to be certified by a designated CAB from A or B. Despite the demanding prerequisites and drawbacks of MRAs (such as fairly heavy administrative costs and a degree

6. In the EU, Reg. 2008/765 and Decision 2008/768 stipulate that accreditation is a not-for-profit activity; competition is ruled out by having only one accreditation body per EU Member State [themselves under peer review in the European co-operation for Accreditation] but they do not compete because accreditation is restricted to the Member State where the certification body is located. Certification bodies, however, can compete throughout the EU internal market, given that they all must be accredited at a high quality/competence level (so, no race to the bottom). Other OECD countries (e.g. the US) do allow more accreditation bodies as long as they are subject to peer review and comply with ISO 17000 series.

7. As identified during the Second Triennial review of the TBT Agreement; see www.wto.org, document G/TBT/9 of 2000.

of rigidity; also, firms are vulnerable to delays; amendments of laws may cause re-designation which is cumbersome), market access is automatic once the system works.

Figure 3. Spectrum of MRAs and alternatives



The second category (co-operative arrangements between CABs in A and B in the voluntary – unregulated - sector) is important for international business, in particular in the context of global value chains. In the study by Fliess & Schonfield (2006), some 160 of the surveyed CA bodies had private agreements with CABs from other countries. These private agreements are not necessarily accreditation agreements (see the third category, below) but usually there is acceptance of one another's test results, and this must be based on de facto recognition of technical competence, possibly with peer review or temporary exchange of staff. Such arrangements can be pairs of CABs but, more often than not, they are becoming part of networks of CABs working on similar (CA quality) ISO standards. Two prominent examples of such networks are the IECEE-CB scheme on safety of electrical and electronic products, and the International Certification Network [IQNet] (Box 3). However, the degree to which they serve as an alternative for MRAs is not clear. For instance, IQNet seems to be more important for local production and the protection of workers and neighbourhoods than directly for products in international trade.

Box 3. The IECEE-CB scheme on safety of electrical and electronic products and the International Certification Network [IQNet]

The IECEE-CB scheme is a multilateral arrangement among 57 participating IEC members, most of which are standardisation bodies; once a CA report is issued by CAB H in country D, it is recognised and accepted in all participating countries by the relevant CABs. Electric/onic products often rely on numerous components from many suppliers and these components ought to be reliable (under certain requirements for quality, durability, etc.) for global value chains. Thus, the IECEE-CB scheme is expected to facilitate international trade.

IQNet has more than 35 member CABs (with many subsidiaries worldwide) and it specialises in certifying quality management systems (beginning with ISO 9001) like in environmental sustainability (ISO 14001; EMAS; ISO 50001) and some other ones such as in IT – ISO 27000, ISO 20000, food safety – ISO 22000 – and industry-specific solutions such as in the oil & gas sector – ISO 29001.

Source: www.iqnet-certification.com and www.iecee.org.

The third category [accreditation for qualifying as a CAB] can be split into private (or voluntary sector) accreditation across borders and accreditation for regulatory purposes. The latter is subsumed in MRAs so the focus will be on the voluntary mutual recognition of accreditation across borders. In principle, this can occur on a case by case basis but nowadays this typically occurs in networks. Three such

networks can be mentioned here: the MRA amongst the metrology institutes of the CIPM (Comité International des Poids et Mesures), the MRA network of the ILAC (International Laboratory Accreditation Co-operation) and the network of IAF (International Accreditation Forum) (see Box 4).

Box 4. Selected examples of accreditation networks: CIPM, ILAC and IAF

The CIPM is now signed by directors of 98 institutes in 54 Member States, also covering a further 153 institutes designated by the signatory bodies. The MRA refers to calibration and measurement certificates issued by national metrology institutes. The signing institutes recognise the calibration and measurement capabilities of the other 94 institutes and their designated entities.

This MRA has laid the basis for a second MRA network by ILAC, the International Laboratory Accreditation Co-operation. ILAC currently has 90 accreditation bodies that are Full Members from 87 countries. It covers accredited testing and calibration laboratories since 2000 and accredited inspection bodies since 2012. The ultimate goal is to achieve that "a product tested or inspected once is accepted everywhere". ILAC seeks to maintain confidence that its laboratories and bodies conform with various ISO/IEC standards and related ILAC guidance documents. This is done by a strict verification procedure and peer review by senior staff of already accredited laboratories. According to ILAC, "regulatory agencies around the world now accept the results from testing and calibration laboratories and inspection bodies that are accredited by accreditation bodies that are signatories to the ILAC Arrangement, without direct government review, including results from facilities in other countries." The recent CETA, chapter 27, is now the most prominent example of this acceptance.

IAF, the International Accreditation Forum, specialises on (the accreditation of CABs for) management systems, products, services and personnel. Its scope is complementing the Arrangement of ILAC. The IAF Multilateral Recognition Agreement (MLA) ensures recognition of equivalence of accreditation of other IAF member bodies to its own. IAF has 74 members.

Source: www.bipm.org/fr/committees/cipm; www.ilac.org/ilacarrangement.html; www.iaf.nu; and www.international.gc.ca/trade-agreements-accords-commerciaux/agr-acc/ceta-aecg/text-texte/27.aspx?lang=eng.

The fourth category is government designation of a recognised CAB in another country but outside a MRA. It is little known whether this is practiced frequently and by what countries. Japan has published reports on this method[8] but it refers only to seven CABs abroad.[9] The reason to choose this option is that the costs and efforts of a formal MRA are avoided, including language barriers; it is simply 'more practical'. However, in the absence of clear processes and rules to designate the CABs, this option may seem arbitrary and may prejudice the CABs which have not been selected.

The fifth category is unilateral recognition of results of foreign conformity assessment as equivalent. This would only be different from the fourth category if the recognition of results is not the consequence of (unilateral) designation of foreign CABs. This method is attractive for countries, such as developing countries, as they can rely on reputation and/or on CABs accredited under ILAC and IAF networks without formal agreements. However, there is no empirical information on its use, let alone, on lessons learnt.

The sixth category is the Supplier's Declaration of Conformity (SDoC). The SDoC needs to be embedded in a system that can give 'adequate confidence' to regulators that conformity is ensured. That may depend on several conditions. Sometimes, SDoCs can be linked to prior harmonisation of the underlying regulations or technical standards referred to, which renders the comparison with MRAs

8. See submission by Japan in 2007, Japan's experience concerning cross-border designation systems, WTO, doc G/TBT/W/277 of July 10.

9. Four in East Asia (Chinese Taipei, China and Hong Kong), two in the EU and one in the US. Only for electrical appliances and materials safety law.

inappropriate. When standards are the same, so must be the testing requirements/methods, as these are normally written into a product standard; when regulations are the same, the mutual recognition of competent CABs and their results should be much easier and no MRAs would seem to be necessary, even when CA procedures differ. Another condition is 'market surveillance' but that is (a) ex post, (b) costly for governments for it to have a serious deterrent effect. A third condition could be product liability, again ex post but it can be designed as having deterrent effects (that is, very costly for firms to get it wrong or to mislead). A fourth condition may be that firms using SDoC must demonstrate the technical competence of their facilities & personnel, for example, via certification by CABs under IAF or IECEE-CB rules. A fifth condition should be that penalties for wrong self-declaration should be high enough.

In a detailed empirical study, Flies, Gonzalez & Schonfeld (2008) have set out how SDoCs are used in actual practice in world trade and whether, in some sectors, one can rigorously derive the net impact on trade, when controlling for several other determinants of trade. They confirm that the dominant motive for companies to prefer SDoCs is time-to-market, [10] even though there may be other minor advantages as well. From a broader public interest view, SDoCs are also beneficial because they are non-discriminatory. However, lower costs and time-to-market benefits may be mitigated by some complications. A SDoC does not always mean that testing requirements are less or fewer; interestingly, a SDoC may also still involve *private* third-party certification for reasons of value-chains or preferences of ultimate consumers in some countries. Moreover, SDoCs are not well-defined in terms of costs because there are many varieties of SDoCs with very different requirements: in Fliess et al. (2008, Annex 4) no less than 18 variants are listed and the authors suggest that an exhaustive list might well include around 50 variants.

Practical MRA experiences: lessons learnt from the EU/US experience of MRA in goods

Little is known at the aggregate level about the practical experience with MRAs. Therefore, a case study has been conducted about the US/EU 1998 MRA in six sectors (Annex 3). This case was selected because (i) fairly detailed literature is available; (ii) this MRA has been used as a model for many subsequent MRAs in the world concluded in the late 1990s, and later. The main lessons from the US/EU MRA experience are summarised.

The US/EU 1998 MRA and its six sectoral annexes have been prepared ever since the late 1980s. The negotiations themselves took four years until formal adoption at the 1998 London EU/US summit. These efforts reflected the lack of experience in drafting MRAs on both sides and the complicated involvement of domestic regulators or regulatory authorities in what began as a trade policy exercise within the framework of EU/US IRC. The MRA has a general set of principles, rules and procedures in a 'chapeau' or umbrella', with six distinct annexes of the sectors telecoms equipment, electromagnetic compatibility (EMC) of equipment and appliances, electrical safety of goods, pharmaceutical GMP, medical devices and recreational craft.

Despite many years of great efforts by negotiators, but also by US and EU business (in the Transatlantic business dialogue) investing deeply in solutions and practical support, only three of the six sector MRAs became operational. In terms of trade values, the three MRAs that worked initially cover

10. What mandatory CAPs (i.e. no SDoC) can mean in business practice, is illustrated in footnote 17 of Fliess et al (2008, p. 15). Mr. Crosby from Lucent technologies explains how it can work in telecoms equipment, a fast-moving sector where new products may not have a very long life and time-to-market is critical for the competitiveness of the business. "…Suppliers obtain permission to bring models in the country of importation, along with technical support personnel, and place the product in queue for testing….[but for certification..] the test results are placed in yet another queue…Since most suppliers are incapable of performing approval activities in ..[many].. countries.. simultaneously, the average delay for marketing products is actually much greater than delays per country ..."

only some one-fifth of the bilateral trade originally foreseen under all six sectorial MRAs. Since 2006, the MRA on recreational craft is no longer operational either due to amendments of the relevant EU directives, adding non-safety features such as emissions and energy efficiency.

MRAs reflect a conscious choice of governments not to engage in regulatory change, and solely focus on reducing transaction costs of market access in case of relatively more regulated products. Both (or more) countries do this not unilaterally but jointly. Lowering transaction costs usually consists of reducing or eliminating duplicative controls/certification and tests, and this, in turn, can be achieved when both governments accept (subject to a safeguard clause only) that the other government has a system which is competent in assuring conformity with the other country's requirements. If this acceptance is lacking and country A in product x insists on direct control, the MRA risks degenerating into a heavy structure for processes that can also be executed *without* a MRA, namely unilaterally.

In the case of the US and the EU, the stark difference between the two in a few sectors can be traced to the combination of the critical difference in the institutional setting (in particular the existence of independent regulatory agencies on one side and not on the other) and the lack of prior exposure to international regulatory debate. In the EU, trade policy and regulatory strategy in the internal market are both in the hands of the Commission. In the US FDA and OSHA enjoy a tradition of far-reaching control and caution that translates in important resources for verification. What for the EU boils down to merely following the spirit of the MRA, may signify regulatory reform and a sense of 'loss' of control for an agency so accustomed to a full say on the matter. This point is raising the critical question of the rationale for an independent agency to condition some of its control to trade policy. The agency might wish to protect its full remit, but also claim that *any* change would possibly jeopardise health and safety.

MRAs are feasible in markets which are less heavily regulated, but ironically, in these cases they are also less needed because alternatives to MRAs (in particular, SDoCs) might serve as a low cost and swift solution. Large US (EU) exporters with a steady customer base (or as part of a value chain) in the EU (US) have for instance a great interest in durable relationships with CABs. The costs of getting to know their products and the associated risks are lower and communication faster and easier when CABs regularly test their product range or new variants. It might also facilitate the planning of testing which may help time-to-market. In other words, for large and regular exporters there are costs of switching CABs and therefore they will favour subcontracting via 'their' CAB. The practical working of the MRA will then be significant only for new entrants or occasional exporters or in cases of overload. New entrants may well be SMEs, so for them and possibly the emergence of 'new' competitive rivalry, the MRA would still fulfil a useful function.

MRAs in heavily regulated markets are only possible once a considerable degree of alignment has taken place. Medicines and high-risk medical devices are heavily regulated and that may well be justified. Between the US and the EU, however, high-risk medical devices were excluded whereas for low-risk medical devices the FDA was simply unwilling to alter its approach (and control) and for pharmaceutical products 'only' GMP was at issue, be it both with pre- and post-approvals, but even that was an 'acceptance' bridge too far. At the same time, at world level cautious attempts were initiated to come to greater harmonisation for pharma and medical devices[11], in which the EU and the US played a leading role. These world fora move extremely slowly and may be read as a sign that underlying regulatory convergence facilitating a MRA is highly ambitious. The experience suggests not so much that it is impossible (e.g. pharma works between EU and Canada since a few years, and for the EU / Israel MRA since 2013) but that

11. The Global Harmonisation Task Force for medical devices, active since the mid-1990s, and the International Conference on Harmonisation of Technical Requirements of Pharmaceuticals for Human use (ICH), founded in 1989.

there are important pre-conditions for the MRAs in such sectors to work, including a minimum level of understanding and agreement between stakeholders beforehand (including regulators) and sufficient time to evaluate and build trust.

MRAs in other heavily regulated sectors such as cars and trucks, chemicals (including pesticides), metrology and tractors would require far-reaching alignment and presumably common alert systems. However, when alignment is lacking, there can be no doubt that the transaction costs of market access are high. No MRAs are known except the partial one on automotive components between the EU and Australia and a number of international initiatives (e.g. in chemicals [OECD] and cars [UN-ECE]).

The merits of the US/EU MRAs are partly found in what they have accomplished and partly in what they have engendered. In an era where the remaining costs of market access are largely attributable to non-tariff (and in particular regulatory) barriers, the US/EU MRA negotiations inevitably led to discussions about the costs and (marginal) benefits of heavier regulation, and about possible alternatives, and not only between regulators. The latter were challenged by trade policy makers, eager to bring results of trade facilitation, and by international business having to deal with duplicative tests and red tape. In the US/EU case the Transatlantic Business Dialogue (TABD) was a unique move. Its strength consisted not only in the fact that CEOs were running these meetings but that they succeeded, time and again, to assume common positions, also on the MRAs. The TABD also managed to involve top political decision makers in an issue as technical as MRAs. As one can observe in the US/EU relations broadly, MRAs have had a crowbar function, as transatlantic co-operation has routinely incorporated regulatory issues ever since.

But the MRAs between the US and the EU have also shown the limitations of this instrument. Despite the unique and powerful TABD, the failures of medical devices, electrical safety and pharma could not be prevented. The US business' hope that procedures of the OSHA and the FDA could be simplified as a corollary of the MRAs was not fulfilled. There was also mistrust. A sectoral committee established under a MRA can only work when the spirit is one of co-operation and willingness to solve problems as they arise. Finally, there are also possible gaps. For example, US independent agencies are under the duty to conduct strict cost-benefit analysis and impact assessment. However, the MRA literature does not report any analysis of the costs and benefits of the FDA and OSHA procedures as compared to the EU approach. Cost- benefit analysis and risk assessment are well accepted approaches in the OECD and they could have been useful in defusing or reducing tensions in the MRA committees.

MRAS OF CONFORMITY ASSESSMENT: CLASSIFICATION AND MAPPING

Introduction

Mutual recognition of conformity assessment can assume various modalities as highlighted in the previous chapter (Figure 2). This chapter provides an overview of the different modalities of governmental and non-governmental mutual recognition agreement / arrangements concluded by selected OECD countries/economies, at the exception of mutual recognition incorporated in RTAs, which is the object of next chapter. The sample includes EU, US, Australia, Mexico, New Zealand and Japan. The data was collected through desk research, a review of the existing literature on MRAs and direct inputs from countries. Since most of the existing MRAs have been concluded by the selected OECD countries, the stocktaking exercise, although not exhaustive, includes a large part of the existing MRAs.

Governmental Mutual Recognition Agreements/Arrangements

Bilateral Governmental Mutual Recognition Agreements/Arrangements

Bilateral governmental MRAs are legally binding treaties between two countries enabling conformity assessment (testing, inspection and certification) of products or of manufacturers of products intended for export to the other party's market, to be undertaken in the country of export, aiming thereby to reduce the costs of technical and/or regulatory barriers to trade between the parties. The regulatory authorities of both parties in the MRA recognise the test reports and certificates issued by conformity assessment bodies deemed by both parties to be competent to assess whether products conform to the standards and regulatory requirements of the other party.

Usually, MRAs of conformity assessment neither require harmonization of each party's standards or technical regulations nor do they require that the parties recognise their regulations as equivalent. However, the European Union distinguishes between 'traditional' and 'enhanced' MRAs. In the former, mutual recognition of conformity assessment is accorded without prior alignment of the relevant requirements (e.g. EU-AUS, EU-Japan, EU-USA and EU-NZL). By contrast, in the 'enhanced' MRAs, mutual recognition is based on equivalence or full alignment of regulatory requirements.[12] The equivalence of regulatory requirements can be determined on basis of adherence to rules or standards developed by an international organization (for example, the Conventions of the International Maritime Organisation, IMO, or the World Forum for Harmonisation of vehicles regulations of the United Nations Economic Commission for Europe) or where the two parties have agreed, through screening of the relevant legislation, that the respective rules are equivalent. So far, few 'enhanced' MRAs have been concluded: the EU-Switzerland MRA is an enhanced MRA (see Annex 1) as the legislation of the Parties in many EU New Approach sectors covered by the agreement is deemed to be equivalent,[13] and the EU-US MRA on maritime equipment, based on global rules of the International Maritime Organisation (See Annex 3). The conclusion of 'traditional' MRAs also implies a sufficient degree of compatibility of the parties CA infrastructures and regulatory objectives and this explains why MRAs have been concluded mainly between developed countries. However, since 'traditional' MRAs do not require parties to accept that their

12. This distinction was first made in a Commission Staff Working document, 'Priorities for Bilateral/Regional Trade Related Activities in the Field of Mutual Recognition Agreements for Industrial Products and Related Technical Dialogue, SEC (2004) 1072, 25 August 2004.

13. Although there are some limited deviations in Switzerland for a few products.

regulations fulfil similar policy objectives in a sufficient way, some sectoral MRAs have encountered problems and the EU has come to prefer 'enhanced' MRAs.[14]

The EU also works with a third type of bilateral MRAs, the so-called Agreements on Conformity Assessment and Acceptance of Industrial Products (ACAAs). The ACAAs are a specific type of MRAs based on the alignment of the legislative system and technical infrastructures of the country concerned with those of the European Union. This type of agreements is concluded between the EU and candidate countries for EU membership, potential future candidate countries and EU neighbouring countries, notably Mediterranean ones, with which the EU concluded Association Agreements. These countries commit themselves to progressively adopt the Community *'acquis'* (of the internal market, including technical regulations and European standards) in a range of sectors, and gradually achieve alignment or uniformity with EU technical regulations, European standardization, metrology, accreditation and conformity assessment procedures. The EU concluded an ACAA with Israel on mutual recognition of OECD principles of good laboratory practices (GLP) for pharmaceutical products.[15]

Bilateral Government MRAs can cover a single product sector or be multi-sectoral agreements. The majority of the MRAs concluded by the EU and EFTA[16] cover several sectors, such as telecommunications terminal equipment, electrical safety (of low voltage equipment), recreational craft, EMC, machinery, pressure equipment, and medical devices. The only exceptions are the very narrow EU-Israel ACAA, EU-Israel MRA, and the EU-US ('enhanced') MRA on Marine Equipment. Churchman (2013) observes that, although some of the sectors included in these agreements are of little importance, some are broad and comprehensive (e.g. machinery). The recently concluded CETA (chapter 27) represents a new model. It has the broadest sector coverage of any MRA, with procedures to further extend it in three years to another six sectors.[17]

Other OECD countries, however, have mainly concluded single sector MRAs on telecommunications or electric and electronic equipment (see Annex D). A likely explanation of the frequency of MRAs in these two sectors in all continents is the need for compatibility and interoperability of equipment in these sectors, and the technical sensitivity of the 'fit' and performance of the components. That is the principal reason why the IEC (and the ITU where relevant) has been able to promulgate international standards relatively early (compared to ISO) and why the stock of IEC (ITU) standards has a high share of product standards (compared to that of ISO, with more testing, measurement and definition standards, and product standards with options). With compatibility and, where relevant, interoperability facilitated by IEC or ITU standards, telecoms and electrical equipment (e.g. appliances, cables, etc.) could more easily become global industries, with complicated value-chains over many countries, in turn, further augmenting the demand for such MRAs. This also helps to explain why such MRAs have come up in East Asia (under APEC) as most of the world's output in such equipment is fabricated there. Recently, China has also begun designating foreign CABs in these sectors.

14. Information provided to the authors during a personal interview with Commission officials. See also SEC (2004) 1072, op. cit.

15. The EU is considering concluding ACAAs with Israel in pressure equipment, medical devices, and, eventually, machinery and cosmetics. Negotiations are in course with the former Yugoslav Republic of Macedonia to conclude an ACAA. The EU is also considering concluding ACAAs with Algeria, Egypt, Jordan, Lebanon, Morocco, and Palestine. For further details see European Commission MRAs Newsletter N. 8, April 2014.

16. The EFTA MRAs are built on the model of the European Union MRAs.

17. www.international.gc.ca/trade-agreements-accords-commerciaux/agr-acc/ceta-aecg/text-texte/27.aspx?lang=eng.

In the Multi-sector MRAs the different annexes are considered an integral part of the MRA. This means that, for an amendment of an annex, the Parties have to follow the normal procedure for the revision of a Treaty. Therefore, it is not often done. As a consequence, many of the annexes of the EU MRAs are presently outdated. To facilitate the revision of annexes, the European Union, when amending the EU-AUS and EU-NZL agreements, has decided to confer to the annexes of the MRAs with New Zealand and Australia a status of 'less-than-a-treaty'.[18] The amended agreements also aim to clarify other operational aspects of the agreements, and to clarify the scope of the Sectoral Annexes for Medical Devices. For example, Class III medical devices are excluded from the MRAs until acceptable confidence building activities are undertaken.

The Multi-sector agreements consist first of all of a framework agreement, which sets out the rights and obligations of the parties, establishing the administrative mechanisms for implementation of the agreement and the principles of technical competence and systems under which CABs may be designated for the purposes of the MRA. These MRAs also contain a series of annexes – one for each product sector covered by the agreement – defining the exact scope and coverage of the annex, determining with more precision the requirements for the designation of CABs in the specific sector and setting out any additional provisions relating to the operation of the MRA for the sector in question. Because the essence of a MRA of conformity assessment is the confidence of each Party in the technical competence of the CABs designated under a MRA, the agreements, usually, also establish the system/procedure to be used to designate CABs under each of the annexes. Moreover, the MRAs stipulate that regulatory authorities of both parties maintain market surveillance programs to ensure that products continue to meet health and safety legal requirements. They typically contain provisions, too, for challenging the competence of particular CABs, based on unsatisfactory outcomes of such market surveillance activities, and for such bodies to be suspended until their competences are re-established to the satisfaction of both parties, or to be withdrawn. In the case of the CETA, heavy and time consuming designation procedures and the need for confidence-building measures are largely avoided due to the strict accreditation approach.

Some of the MRAs provide for a transition period after the date of signing it (e.g. EU-US, EU-CAN, CAN-MEX, US-MEX MRAs), during which a number of confidence building activities should take place. In certain cases the implementation of the MRAs is phased: a first phase for the mutual recognition by both parties of testing laboratories, and, only in the second phase, the parties start to accept the conformity assessment results of the recognised CABs. This is the case, for instance, of the CAN-ISR MRAs on telecommunications equipment.

Some of these Agreements include rules of origin restrictions. This was the case for the EU-Australia and the EU-New Zealand MRAs in their original version. However, these two MRAs have recently been amended in order to introduce greater flexibility and, among other changes, the rules of origin provisions were removed from the MRAs.[19] These rules impede products with origin from other countries from benefitting of the MRA. This could be of particular importance for developing countries. In their study Chen and Mattoo (2008) find that MRAs tend to be trade promoting unless they contain restrictive rules of origin. With origin rules, trade between developed countries may still benefit but market access for

18. See www.tga.gov.au/about/international-eu-mra-amendments.htm#.VAPTBREcTMw. The full text of the amending agreements can be found at www.austlii.edu.au/au/other/dfat/treaties/ATS/2013/2.html and http://eur-lex.europa.eu/legal-content/en/txt/?qid=1400578778307&uri=celex:22012a1222(01).

19. See European Commission: DG Enterprise and Industry http://ec.europa.eu/enterprise/policies/single-market-goods/international-aspects/mutual-recognition-agreement/australia/index_en.htm and http://ec.europa.eu/enterprise/policies/single-market-goods/international-aspects/mutual-recognition-agreement/new-zealand/index_en.htm

developing countries to the MRA countries is likely to deteriorate in a relative sense, causing adverse trade flow effects. However, the great majority of the analysed MRAs do not contain rules of origin.

A large number of MRAs relies on the use of ISO/IEC standards and guides for the accreditation of the designated CABs. Some MRAs, although not based on harmonization or equivalence of the mandatory requirements of the Parties, incentivize them to use international standards as a basis for their technical regulations (e.g. MEX-Canada, Mex-USA, CAN-IRS, US-Israel MRAs). The harmonization of the parties' designation and conformity assessment procedures, and accreditation system/procedures is also promoted in a series of MRAs (e.g. the US-IRS, MEX-CAN, AUS-SGP). Some Agreements go even further by stipulating that, where both parties agree that their respective standards and/or technical regulations are harmonised or equivalent, a Party shall be able to assess compliance with its own mandatory requirements and this shall be deemed acceptable by the other Party (e.g. AUS-SGP and NZL-SGP MRAs).

The Parties in the MRAs assume the commitment to exchange information concerning the implementation and application of the legislative, regulatory and administrative relevant provisions, and to notify to the other party new provisions at least 60 days before their entry into force, except when urgent action is required. Similarly, the parties shall notify the other Party of any changes of its designating authorities and conformity assessment bodies.

In order to increase the Parties' confidence in the mutual recognition process and the legitimacy and sustainability of the agreement, some MRAs, apart from providing for a confidence building period, also promote the exchange of information, training of the designated CABs on the requirements of the other party legislation, the participation of the designated CABs in coordination meetings and the realization of joint inspections. Exceptionally, the authorities of one of the parties can conduct inspections at the premises of a manufacturer located in the territory of the other party, with the previous agreement of the manufacturer (e.g. CAN-AUS MRA).

Most MRAs set up a Committee that is responsible for monitoring and the implementation of the MRA and its amendment. In the case of Multi-sectorial MRAs, the Committee (usually, designated Joint-Committee) can designate sectorial-committees or working groups responsible for monitoring the implementation of the respective sectorial annexes (e.g. EU MRAs, CAN-CHE MRA). The committee adopts its decisions and recommendations by consensus. Any matter related to the interpretation, operation and implementation of the MRA should be discussed in the Committees. In the rare cases when no Committee is established under the MRA (e.g. CAN-ISR MRA), disputes shall be settled through consultations between the designating authorities or regulatory authorities. In the case of MRAs incorporated in RTAs, the disputes related to the implementation of the MRAs should be solved by the TBT Joint Committee (e.g. Korea-Singapore) or the Sub-Committee on Mutual Recognition (e.g. JPN-Philippines, Japan-Singapore MRAs). None of the sampled stand-alone MRAs provides for a more formal mechanism for the resolution of disputes between the parties. Some MRAs contain provisions on product liability (e.g. CAN-CHE). If one of the parties intends to take a legal action connected with conformity assessment performed by a CAB of the other Party, it should notify the other Party, and Parties should cooperate in the investigation and facilitate access to relevant documents.

If one of the parties does not comply with its obligations under the agreement, for instance if it refuses to accept a test report issue by a CAB of the other Party, it has to provide a written notice to the other Party, and explain its reasons. The same happens when one of the Parties intends to suspend a CAB designated by the designating authority of the other Party.

Multilateral Government Mutual Recognition Arrangements (voluntary)

Multilateral or Regional Government Mutual Recognition Arrangements (MLAs) are non-binding arrangements concluded by inter-governmental forums that provide for the mutual acceptance of the results of testing and certification undertaken by CABs located in the exporting country in assessing the conformity of equipment to the technical regulations of the importing countries.

APEC is an inter-governmental forum (established in 1989) with the aim of facilitating trade and investment among its twenty-one member's economies[20] in the Asia-Pacific region. APEC is based on voluntarism and it uses no treaties. In some respects, it is reminiscent of the OECD, but one crucial difference is that APEC has explicit long-term trade liberalisation goals (e.g. the Bogor strategy). APEC's commitments are non-binding and decisions are taken by consensus in meetings of governments, ministers and senior officials. To facilitate its work, several committees, subcommittees and working groups have been created. The APEC Committee on Trade and Investment (CTI) is responsible for coordinating the work on trade and investment liberalization and facilitation. In 1994, it set up a Sub-committee on Standards and Conformance (SCSC), which has attempted to promote the harmonization of standards and conformity assessment procedures in the region, with a view to reduce technical barriers to trade, decrease transaction costs for market access and increase trade flows. An APEC Telecommunications and Information Working Group (APECTEL) was also created to promote the development of the telecommunications and information infrastructures in the region.

In the late 1990s, the APEC ministers responsible for the telecommunications sector decided to conclude a mutual recognition arrangement for testing and approval of telecommunications equipment. The APEC TEL MLA came into effect in June 1999. One year later, the SCSC also concluded a mutual recognition arrangement on Electrical and Electronic Equipment (APEC EE MRA). In response to an APEC Leaders declaration to further reduce transaction costs made on 31 October 2010, an APEC mutual recognition arrangement for equivalence of technical requirements was endorsed as well. A Mutual Recognition Arrangements Task Force (MRATF) was created for this purpose.

The APEC Mutual Recognition Arrangement for Conformity Assessment of Telecommunications Equipment (hereafter TEL APEC MRA) is a government-to-government arrangement that comes into effect when two or more economies agree to implement it. It provides for the mutual recognition of results of testing and equipment certification procedures undertaken by CABs located in the exporting country in assessing conformity of equipment to technical regulations of the importing countries. The APEC TEL MRA includes all equipment subject to telecommunications regulations, including wireline and wireless, territorial and satellite equipment. As mentioned above, the implementation of the APEC TEL MRA between two or more APEC economies/countries is not automatic. APEC economies interested in implementing the APEC TEL MRA between them, should declare their will to implement it by, for example, an exchange of diplomatic letters. The APEC TEL MRA has two phases of implementation.

- Phase 1 is for mutual acceptance of test data; and
- Phase 2 for the mutual acceptance of equipment approvals.

20. The following economies/countries are APEC members: Australia, Brunei Darussalam, Canada, Chile, People's Republic of China, Chinese Taipei, Hong Kong, Indonesia, Japan, Republic of Korea, Malaysia, Mexico, New Zealand, Papua New Guinea, Peru, Philippines, Russia, Singapore, Thailand, United States of America, Vietnam.

The APEC TEL meets twice a year to discuss issues related to the implementation and operation of the MRA. The MRA Task Force participates in these meetings. According to the MRA Task Force report the implementation of the agreement have been quite successful.[21]

The Mutual Recognition Arrangement for Equivalence of Technical Requirements (thereafter MRA-ETR), builds on the APEC TEL MRA. It aims to facilitate the mutual recognition of equivalent *regulations* of the APEC members in the telecommunications sector. Like the other two APEC MRAs, the arrangement is a voluntary economy-to-economy MRA. If one APEC member wants to implement the MRA-ETR, it should notify the APEC TEL WG Chair. When doing that, the APEC member is not accepting the relevant telecommunications regulations of the other members as equivalent. It is only agreeing to consider requests for recognition of equivalence of technical regulations from APEC members participating in the MRA. It also assumes the obligation to answer and to provide a justification in case of a refusal of a request. The arrangement also lays down the procedure to be followed, to make a request of equivalence of technical regulations in the telecommunications sector.

Another mutual recognition Arrangement concluded by APEC is the APEC Electrical and Electronic Equipment Mutual Recognition Arrangement (hereafter APEC EE MRA). It provides for product development, testing, certification, inspection and approvals in accordance with the regulations of the importing country to be obtained in the exporting country through designated CABs. The APEC EE MRA applies to both pre and post-market, where test reports or certifications are used as the basis for regulatory compliance for electrical and electronic equipment. Like the APEC TEL MRA, the implementation of the APEC EE MRA is not automatic. The APEC EE MRA has three parts reflecting different levels of participation and ambition:[22]

- Part I is about information exchange: during this phase the APEC members should exchange, in standardized format, information about their mandatory requirements on electrical and electronic products in order to allow the other APEC members who may export electrical and electronic equipment to that economy, to become aware of the requirements that equipment has to comply with. At present, 17 APEC members participate in Part I of the MRA.[23]

- Part II is on the acceptance of test reports: it commits APEC members to mutually accept test reports produced by testing facilities designated by the participating economies in accordance with the designation requirements of the EE MRA. The designation requirements defined in the MRA are in accordance with the relevant ISO/IEC standards and do not require re-testing. Only 5 APEC economies have implemented Part II of the MRA (Australia, Brunei Darussalam, Malaysia, New Zealand and Singapore).

- Part III is on the acceptance of certification: it commits each participating importing economy to accept product certification (including batch testing) produced by certification bodies designated by participating exporting economies in accordance with the designation requirements defined in the MRA. These requirements are in accordance with the relevant ISO/IEC Guide. Part III has

21. See APEC TEL MRA Task Force, ‘ Fostering International Trade: Ten Years of MRA Success’, 2009: www.ida.gov.sg/~/media/Files/Archive/Policies%20and%20Regulation/Policies_and_Regulation_Level2/20060602142302/APEC_MRA.pdf

22. See www.apec.org.Groups/Committee-on-Trade-and-Investment/Sub-Committee-on-Standards and Conformance/apec_eemra.aspx

23. Australia, Brunei Darussalam, Chile, China, Hong Kong, Indonesia, Japan, Korea, Malaysia, New Zealand, Papua New Guinea, Peru, Philippines, Russia, Singapore, Chinese Taipei, Thailand, Vietnam.

only been implemented by 4 APEC members (Australia, Brunei Darussalam, New Zealand and Singapore).

A Joint Regulatory Advisory Committee on Electrical and Electronic Equipment was set up to promote regulatory dialogue and co-operation between the APEC members regulators. However, the implementation of the APEC EE MRA has not been so successful as the implementation of the APEC TEL MRA. One observes that neither the USA nor Canada are in any of the three phases of this MRA. This may well have similar reasons as the difficulties in the electrical goods sector in the MRAs between the US and the EU (see case study, Annex F) and that between Canada and the EU.

The Organisation of American States (OAS) is another such inter-governmental forum, composed of 35 independent states of America. The OAS General Assembly, following the Declaration of Santiago in the second Summit of the Americas, which includes a Plan Action for Telecommunications decided to establish the Inter-American Telecommunications Commission (CITEL). CITEL it was established in 1994 to promote sustainable development of the telecommunications sector, and to pursue consistent regulatory approaches among its OAS member countries, mainly by promote greater commonality in the certification process. Today, members of CITEL comprises all OAS Member States and more than 100 Associated members from the telecommunications, internet, electronic media industry and others. In 1999, it endorsed the Inter-America Mutual Recognition Agreement for Conformity Assessment of Telecommunications Equipment. The CITEL MRA, like the APEC TEL MRA, is a voluntary inter-governmental framework agreement that comes into effect when two or more economies agree on its implementation. It provides for the mutual recognition, by the importing Parties, of CABs as well as mutual acceptance of the results of testing and equipment certification undertaken by those bodies to conformity of equipment to the importing Parties' own technical regulations. Its implementation also has two different phases: the first one for the acceptance of test data, and the second one for the acceptance of equipment approvals.

Non-governmental Mutual Recognition Arrangements

There are two types of non-governmental mutual recognition arrangements: mutual recognition arrangements among conformity assessment bodies and mutual recognition arrangements concluded between national, regional, or international accreditation bodies. Table 1 gives some examples of these types of co-operative non-governmental arrangements.

Table 1. Illustrative list of co-operative non-governmental MRA in place in Japan, Mexico and New Zealand

JAPAN
Mutual Recognition Arrangement between the Interchange Association and the Association of East Asian Relations for the Co-operation on Mutual Recognition (http://koryu.or.jp)
MEXICO
Mutual Recognition Agreement between the Mexican Association for Standardization and Certification of the Electrical Sector AC and the Colombia Institute for Standards and Certification for mutual recognition of activities of each party evaluation and certification of products
Mutual Recognition Agreement of Laboratory test results of Electronic Products; Parties Intertek Testing Services (ITS) of Mexico, Intertek Testing Services NA Inc. USA, Intertek Testing Services NA Ltd. Canada
Mutual Recognition Agreement for acceptance of test results concluded between the Mexican Association of Standardization and Certification , CA (ANCE) and the Canadian Standards Association (CSA)

Mutual Recognition Agreement between the Mexican Chamber of Electronics, Telecommunications and Informatics (CANIETI) and Tuv Rheinland of North America (TUV)
Mutual Recognition Agreement for the acceptance of results regarding conformity assessment in electrical and electronic products entered into by UL de Mexico, SA de CV, and UL International Demko A/S and Underwriters Laboratories Inc.
Mutual Recognition Agreement between the Mexican Association for Standardization and Certification, CA (ANCE) and the Norwegian Institute for Testing and Certification of Electric Equipment (NEMKO).
Mutual Recognition Agreement between the Mexican Association for Standardization and Certification, CA (ANCE) and members of the International Certification Network IQNet
Mutual Recognition Agreement between Intertek Testing Services (ITS) of Mexico and Intertek Testing Services NA Inc. USA, Intertek Testing Services NA Ltd Canada, Intertek Testing Services AB Sweden SEMKO, Intertek Testing and Certification Ltd. UK and Intertek Testing Services Hong Kong LTD
Mutual Recognition Agreement for the acceptance of results regarding to conformity assessment concluded between the Testing Laboratory Services Technical Analysis, SA de CV and Testing Laboratories of TUV SUD PSB Pte Ltd.
Mutual Recognition Agreement between the Mexican Association of Standardization and Certification, CA (ANCE) and KEMA Quality, B.V. Holland
Mutual Recognition Agreement between the Mexican Chamber of Electronics and Telecommunications Information Technology (CANIETI) and the Centre Testing International Co-operation (CTi) of China, for the acceptance of test results of product safety branch electrical-electronics
Mutual Recognition Agreement between Mexico Labotec, SC (LABOTEC) and TUV Rheinland of North America (TUV), on laboratory product safety test results in the electrical and electronic branches
Mutual Recognition Agreement between the Mexican Chamber of Electronics and Telecommunications Information Technology (CANIETI) and Nemko Usa, Inc. (Nemko), on laboratory test results of product safety in the electrical and electronics branches
Mutual Recognition Agreement between Intertek Testing Services Mexico, SA de C.V. (Intertek ETL Semko Mexico) and Intertek Testing Services NA Inc. (Intertek), located in the United States on results of conformity assessment in electric-electronics industry
Renewal of Mutual Recognition Agreement held between the agency Technical Analysis Services SA de C.V. (SEATSA) located in Mexico, and Test Laboratories group of TUV SUD PSB Pte Ltd located in Singapore and the People's Republic of China, for the acceptance of results of conformity assessment in electronic-electronics industry
Mutual Recognition Agreement between Intertek Testing Service Mexico, SA de C.V. (Intertek ETL Semko Mexico) located in Mexico, Thailand and Intertek Testing Services Limited (Intertek) located in Thailand, for the acceptance of results regarding conformity assessment in electrical and electronic products
Extension to the Mutual Recognition Agreement held between the Association of Standardization and Certification, CA (ANCE) and different certification bodies and their respective laboratories, members of the IECEE CB-Scheme association in the inspection and/or monitoring in the factory and/or warehouse, only for participants in the IECEE CB-FCS members (Full Certification Scheme)
Extension to Mutual Recognition Agreement held between the Colombia Institute for Technical Standards and Certification (ICONTEC) and the Association of Standardization and Certification, CA (ANCE), on test results for electrical products and gas
Extension to Mutual Recognition Agreement held between the Association of Standardization and Certification, CA (ANCE) and DEKRA Certification B.V. Holland, for the laboratory test results for electrical appliances and products
Mutual Recognition Agreement between the National Chamber of Electronics and Telecommunications Information Technology (Canieti) and SGS-CSTC Standards Technical Services Co. Ltd, Guangzhou Branch (SGS-CSTC GZ) on test results lab safety
Mutual Recognition Agreement between Factual Services, SC (FACTUAL) located in Mexico, and TUV Rheinland of North America Inc. (TUV) located in the United States of America, for the acceptance of results of conformity assessment in electrical and electronic products

Mutual Recognition Agreement between Standard Technology Union Co., Ltd (STU) and the Association of Standardisation and Certification, CA (ANCE), to conduct assessments of products in accordance with national and international standards
Mutual Recognition Agreement between SGS-CSTC Standards Technical Services Co., Ltd Guangzhou Branch Testing Center (SGS-GZ-) and the Association of Standardisation and Certification, CA (ANCE), to conduct safety assessments of products in accordance with national and international standards
Mutual Recognition Agreement between Vkan Certification & Testing, Co., Ltd (CVC) and the Association of Standardisation and Certification, CA (ANCE), to conduct safety assessments of products in accordance with national and international standards
Mutual Recognition Agreement between Electrosuisse and the Association of Standardisation and Certification, CA (ANCE), to conduct safety assessments of products in accordance with national and international standards
Mutual Recognition Agreement between TUV Rheinland de Mexico, SA de C.V. and TUV Rheinland of North America, Inc., to perform safety assessments of products in accordance with national and international standards
Mutual Recognition Agreement held between the Agency Services Technical Analysis, SA de C.V. (SEATSA) and testing laboratories Group TUV SUD PSB Pte Ltd., for the acceptance of results regarding to conformity assessment in the electrical-electronics branch and to add testing laboratories TUV SUD Asia Ltd. Taiwan Branch of TUV SUD PSB Pte Ltd.
NEW ZEALAND
Arrangement between the International Electrical Commission (IEC) and the International Laboratory Accreditation and Co-operation (ILAC)
The Joint Accreditation System of Australia and New Zealand (JAS-ANZ), a Trans-Tasman body set up by the JAS-ANZ Treaties are member and signatories to the International Accreditation Forum (IAF) MLA
The International Accreditation New Zealand (IANZ) and the Joint Accreditation System of Australia and New Zealand (JAS-ANZ) are members and signatories of the International Laboratory Accreditation Co-operation MRA
IANZ and JAS-ANZ are members of the Asia Pacific Laboratory Accreditation Co-operation MRA (APLAC)
New Zealand's Measurement Standards Laboratory is member and signatory of the MRA of the Comité International des Poids et Mesures
Trading Standards (Ministry of Business, Innovation and Employment) represents New Zealand in the International Organisation of Legal Metrology MRA

Source: Based on lists provided directly by countries.

Mutual recognition arrangements between conformity assessment bodies are arrangements between CABs located in different countries through which they recognise the quality of each other's processes for testing, certification and/or inspection. Mutual recognition arrangements between accreditation bodies are arrangements concluded by national or regional accreditation bodies or international accreditation organizations representing national and regional accreditation bodies, through which they mutually recognize that the CABs accredited by them or by its members have a pre-specified degree of quality and use similar quality standards to accredit their respective CABs.

These are voluntary agreements, and do not create obligations for the governments of the respective parties involved. However, by recognizing the quality of the testing, certification and inspection undertaken by the signatory CABs and/or recognizing that the CABs accredited by accreditation bodies which are parties to the agreement, meet high minimum quality requirements and standards, they also contribute to avoid double testing of products in the countries of origin and of destination.

There is a multitude of mutual recognition arrangements between CABs. Fliess & Schonfield (2006) mentions that some 160 of the CA bodies having answered the questionnaire had private agreements with CABs from other countries. These Non-governmental arrangements between CABs can be bilateral or multilateral. Several non-governmental mutual recognition arrangements are concluded between national or regional accreditation bodies or by international accreditation organizations (see previous chapter).

Conclusion

Many government and non-government agreements/arrangements aiming to facilitate the acceptance of conformity assessment results have been concluded in the last two decades. Practically all the countries under consideration have concluded bilateral governmental MRAs. Only two MRAs have been concluded with developing countries (Philippines, Thailand with Japan), probably because MRAs require sustained trust in each other regulatory systems, structures and procedures for accreditation and conformity assessment, and a certain level of technological development for a high-quality infrastructure. Some international inter-governmental organizations also conclude voluntary framework arrangements with the objective to reduce trade costs and increase trade flows between their country/economy members (CITEL and APEC MRAs).

The great majority of the concluded MRAs are in the sectors of telecommunications equipment and electric and electronic equipment. That may be because in these two sectors and in all continents, there is the need for compatibility and interoperability of equipment in these sectors, and the technical sensitivity of the 'fit' and performance of components. It also explains why the demand for the development international standards (IEC) started so early as compared with ISO standards. With the compatibility and, where relevant, interoperability facilitated by IEC or ITU standards, telecoms and electric/onic equipment (e.g. appliances, cables, electronic devices, etc.) could more easily become global industries, with complicated value-chains over many countries, in turn, further augmenting the demand for such MRAs.

It is, however, difficult to determine whether the conclusion of government MRAs in these two sectors (and others) effectively led to a reduction of conformity costs and an increase of trade flows. As reported in the WTO case study to clarify the effectiveness of the MRAs (WTO, 2007a), many countries do not have a register of the number of certificates/testing reports issued under MRAs. Moreover, impact assessments prior to negotiation of an MRA are not systematically always carried out or do not include a comparison with other mechanisms aimed to avoid double testing. Typically, at the time the EU started to negotiate and conclude MRAs with its main trading Partners, in the 1990s, the obligation to carry out a regulatory impact assessment to analysis the cost/benefits of its future proposals and investigate different policy options was not yet introduced.

Nevertheless, some experiences have shown that the conclusion of MRAs in certain sectors is more successful than in others. For instance, all the EU MRAs concluded in the area of Telecommunications seem to be functioning satisfactorily.[24] Also, the APEC TEL MRA is reported as being a successful experience. In other sectors, such as medical devices and electrical safety, the EU experience has not been very successful. The conclusion of MRAs in these sectors was mainly promoted by the EU. Several factors have contributed to their failure, one of which is the significant differences in the regulatory and accreditation system of the parties involved. For these reasons, the European Commission has declared that it will give preference to the conclusion of MRAs based on alignment, that is, a far-reaching degree of equivalence between the mandatory requirements of the parties.

24. See European Commission MRAs Newsletter N.8, April 2008.

Apart from the conclusion of a series of governmental MRAs between developed countries, there has been a multiplication of co-operative arrangements between CABs and national and regional accreditation bodies and the international organizations representing them. Today CABs and Accreditation bodies from different countries are connected at international level in global networks of CABs and Accreditation Organisations. These CABs work on the basis of the same (CA quality) ISO standards, which facilitates the acceptance of their conformity assessment results by other CABs. Many of these CABs belong to CAB networks having developed schemes for mutual acceptance of their CABs' CA results. This is the case of the IECEE-CB scheme on safety of electrical and electronic products, and the International Certification Network [IQNet].

Most of these CABs have been accredited by national accreditation bodies, in accordance with a series of ISO quality standards, which are members of regional and/or international accreditation organisations, such as ILAC, IAF and CIPM. These international organisations only accept as members accreditation bodies meeting certain quality requirements and standards. They have concluded arrangements for mutual recognition of the accreditation of their members by other members or for mutual acceptance of the CA results conducted by CABs accredited by their members. Although these arrangements are voluntary, and do not create obligations for the respective governments of the parties, they help to avoid double testing. Moreover, in some governmental MRAs, one of the criteria that should be taken into account in the designation authorities in the designation of the CABs is, precisely, whether the CABs participate in appropriate proficiency testing programmes and other comparative reviews, such as non-governmental mutual recognition arrangements, so that confidence in their technical competence is maintained (e.g. Australia-Singapore MRA).

MUTUAL RECOGNITION AND EQUIVALENCE IN REGIONAL TRADE AGREEMENTS

Introduction

An increasing number of bilateral and plurilateral free trade agreements and customs unions agreements have been concluded between WTO members. As of May 2014, there were 253 Regional Trade Agreements (RTAs) in force that had been notified to the WTO, covering both goods and services.[25] As underlined in OECD (2013), these RTAs increasingly involve provisions relevant to regulatory cooperation and the removal of technical barriers to trade. Some of them do it by reference to the WTO discipline on technical barriers to trade (TBT); others go beyond and contain more stringent disciplines than the ones in the WTO TBT Agreement (these RTAs are WTO TBT-plus Agreements).[26]

Table 2 provides an overview of the tools relevant to regulatory cooperation promoted in the WTO TBT Agreement to reduce or eliminate TBTs. The WTO TBT Agreement recognizes that the removal or reduction of technical barriers to trade can be achieved, mainly, through harmonization of technical regulations and standards, equivalence of technical regulations and the acceptance or recognition of conformity assessment procedures.

Table 2. IRC provisions in the WTO TBT Agreement

Harmonisation of technical regulations	WTO member should use existing international standards as the basis of their technical regulations, except when the use of those international standards is an ineffective or inappropriate way for the legitimate objectives to be pursued (Article 2.4).
Harmonisation of standards	WTO members shall fully participate in the preparation of international standards by international standardization bodies, and promoting the use of the Code of Good Practice for the Preparation, Adoption and Standards (the so-called Code of Good Practice) by central, local and regional government standardization bodies and national or regional non-governmental standardization bodies (Article 4.1). WTO members should also refrain from adopting measures that, directly or indirectly, require or encourage such standardization bodies to act in a manner inconsistent with the 'Code of Good Practice.'
Equivalence of technical regulations	WTO members are encouraged to accept as equivalent the technical regulations of other countries, provided that these regulations, even if different from their own, adequately fulfil the same objective of their own regulations (Article 2.7).
Acceptance of the results of conformity assessment procedures	WTO agreement promotes the acceptance of the results of conformity assessment procedures undertaken by CABs of other Members, provided that those procedures, even if different from their own, offer equivalent assurance of conformity with the applicable technical regulations and standards as their own procedures (Article 6.1).
Negotiation and conclusion of MRAs	WTO members are also encouraged to negotiate and conclude MRAs in order to avoid duplicative tests and reduce the costs of conformity assessment (Article 6.3)
Transparency and information exchange	The WTO TBT Agreement acknowledges the importance of transparency and information exchange for the elimination of TBTs

25. See http://rtais.wto.org/UI/publicsummarytable.aspx.

26. Lesser (2007), and Piermartini and Budetta (2009), among others, provide overviews of the TBT provisions in RTAs.

Countries, such as the United States, Canada and Australia, have a single model of RTAs. TBT reduction in their RTAs is mainly promoted by the acceptance of technical regulations as equivalent, the alignment towards international standards and/or the recognition of conformity assessment results through a broad range of mechanisms, including the conclusion of MRAs. By contrast, the European Union does not maintain a single model of RTAs. EU RTAs can be classified in three categories: (i) The Stabilization and Association Agreements (with actual or potential candidate countries or neighbour countries) where harmonization towards EU regulations, standards and conformity assessment procedures is sought; (ii) the Economic Partnership Agreements (with third countries with which the EU seeks a closer political and economic partnership); and (iii) modern WTO-plus RTAs with third countries (e.g. EU-South Korea RTA).

This chapter examines the extent to which mutual recognition (MR) is promoted in RTAs. It maps the provisions on mutual recognition and equivalence of standards, technical regulations and conformity assessment procedures of 99 RTAs concluded by 8 OECD economies and notified to the WTO by 30 May 2014. It investigates whether these provisions go beyond the WTO TBT agreement provisions and which modalities of (mutual) recognition are promoted by the Parties. It analyses first the extent to which the RTAs promote the recognition of technical regulations as equivalent. The chapter then examines whether the agreements require or promote mutual recognition of technical regulations and/or standards. Then, it provides an overview of the RTA provisions aimed at facilitating the acceptance of results of conformity assessment procedures. Finally, it examines whether RTAs promote mutual recognition agreements or integrate them into a MRA.

The comparative analysis focuses on a review of the legal text of the agreements. This approach presents some limitations. From the analysis of the relevant legal provisions, it is not always easy to ascertain the degree of commitment of the parties; it also may be unclear whether the relevant provisions have been effectively implemented or not. However, an empirical investigation of the state of implementation of the relevant TBT provisions in our sample of RTAs is outside the scope of this study.

An overview of mutual recognition and equivalence provisions in a sample of RTAs

The sample includes 99 RTAs concluded by Australia, Canada, the European Union, Republic of Korea, Japan, Mexico, New Zealand and United States notified and published in the WTO RTAs database by 30 May 2014. Because mutual recognition of conformity assessment results requires trust in each other technical infrastructures, regulatory procedures, institutions and accreditation procedures, it is more likely to take place among developed countries with similar technological levels. Consequently, in the sample, all RTAs are concluded by OECD economies. Among the 99 RTAs analysed, 78 have a TBT chapter or, at least, some provision(s) related to TBTs. In the large majority of the agreements with a TBT chapter, the parties reaffirm their rights and obligations under the WTO TBT Agreement.

RTAs are examined for the following 11 aspects. Table 3 presents the shares of RTAs for each one of these 11 aspects. Table 4 shows the results per country.

- the agreement requires or promotes to recognize technical regulations as equivalent;
- the agreement requires to explain the reasons for not recognizing the other Party's technical regulations as equivalent;
- the agreement requires or promotes MR of technical regulations or standards;
- the agreement requires or promotes MR of the results of conformity assessment procedures;

- the agreement requires that the reasons for non-recognition of conformity assessment results are explained;
- the agreement includes or not, a MRA for conformity assessment;
- the agreement requires or promotes the conclusion of a MRA;
- the agreement requires the Parties to explain the reasons for a refusal to enter into negotiations or to conclude MRAs;
- the agreement is accompanied by a separate MRA;
- the agreement requires or promotes the use of existing regional and international MRAs for conformity assessment;
- the agreement requires or promotes the conclusion of voluntary arrangements between the CABs located in the territories of the Parties to mutually accept the results of their assessment procedures.

Table 3. Overview of MRA aspects in RTAs in the sample

As a percentage of total RTAs

The MRA aspects under consideration	Share of RTAs
TBT Provisions	78.8%
Agreements that require or promote the recognition of technical regulations as equivalent	33.3%
Agreements that require explaining the reasons for not recognising other Party's technical regulations as equivalent	27.3%
Agreements that require or promote MR of technical regulations or standards	0%
Agreements that require or promote MR of the results of conformity assessment procedures	41.4%
Agreements that require explaining the reasons for non-recognition of conformity assessment results	28.3%
Agreements that require or promote the conclusion of MRAs	56.6%
Agreements that require the Parties to explain the reasons for a refusal to enter into negotiation or to conclude MRAs	20.2%
Agreements that include a MRA for conformity assessment	6.1%
Agreements that require or promote the use of existing regional and international MRAs for conformity assessment	10.1%
Agreements that require or promote the conclusion of voluntary arrangements between CABs located in the territory of the Parties to mutually accept the results of their assessment procedures	25.3%

Equivalence and mutual recognition of technical regulations

The WTO TBT agreement in its Article 2.7 encourages its members to accept as equivalent the technical regulations of other countries, provided that these regulations, even if different from their own, adequately fulfil the same objective of their own regulations.

A third of the 99 RTAs included in the sample encourage the Parties to give positive consideration to accepting as equivalent technical regulations of the other Party, even if these regulations differ from their own, provided that these regulations adequately fulfil the same objectives. The acceptance of the other party's technical regulations as equivalent is mainly promoted in RTAs concluded by Australia and New Zealand (Table 4). However, in certain RTAs the Parties recognise that it may be necessary to develop common views, methods and procedures to facilitate the use of equivalency (e.g. Canada- Panama and Canada-Peru FTAs).

By contrast, Japan, Korea and the EU RTAs rarely promote equivalence of technical regulations as a mechanism to reduce TBTs (Table 4). In the EU agreements, harmonization of technical regulations and standards is the preferred approach to reduce TBTs. Only three EU RTAs – the EU-Chile and EU-Colombia and Peru RTAs – provide that the Parties should mutually cooperate for identifying the mechanisms more appropriate to combat TBTs in the different sectors, including, among others, equivalence of technical regulations.

Most of the agreements that promote the recognition of technical regulations require an explanation for a refusal of the equivalence of technical regulations of the other party. The exceptions are the Singapore - Australia, Thailand - Australia, EU - Chile, EU - Colombia/Peru, Mexico - Uruguay and New Zealand - Singapore RTAs. The textual analysis of the RTA provisions, without any additional information on the implementation of the RTAs, is insufficient to ascertain the exact level of commitment envisaged by the parties. However, one can assume that, when RTAs require the parties to explain the reasons for not recognizing the other party's technical regulations as equivalent, it reflects a higher level of commitment from the parties.

The New Zealand-Singapore RTA promotes MR of equivalence of mandatory requirements and standards. MR of equivalence of technical requirements means that, 'each Party accepts the mandatory requirements of the other party as producing outcomes equivalent to those produced by its own requirements' (Article 35 (a) of the New Zealand-Singapore Free Trade Agreement). In theory MR of equivalence of technical regulations differs from the MR of technical regulations to the extent that the former requires that technical regulations of the parties, although, different, fulfil adequately the same objectives. Instead, MR of technical regulations may not require that the regulations are equivalent. However, in practice, Parties will not mutually recognize regulations, different from their own, if they do not guarantee the same level of protection and similar outcomes.

Recognition of the results of conformity assessment procedures

41.4% of the sampled RTAs require or promote the (mutual) recognition of the results of conformity assessment procedures. Table 4 shows that recognition of conformity assessment results is promoted, to a greater or less extent, by all sampled countries, except by the EU. Some RTAs do not have an explicit provision encouraging the parties to accept the conformity assessment results, but they require the parties to explain the reasons for not recognizing them (e.g. Australia-Chile, Australia-US, Canada-Peru and Japan-Peru). Only 28.3% of the RTAs require the parties to explain the reasons for a refusal to accept the results of conformity assessment procedures performed by the CABs of the other party.

In conformity with Article 6.1.1 of the WTO TBT Agreement, several RTAs recognise that prior to the acceptance of the results of conformity assessment procedures performed by the other party's CABs, the parties may consult on such matters and on the technical competence of the conformity assessment bodies involved. This is the case in the Australia-Thailand Free Trade Agreement, the North America Free Trade Agreement (NAFTA), the Japan-Malaysia Agreement for an Economic Partnership, Japan-Swiss Confederation Agreement on Free Trade and Economic Partnership and the Trans-Pacific Economic Partnership Agreement. The FTA between Korea and the EFTA countries, NAFTA and the Korea-Chile Free Trade Agreement, for instance, encourage the parties to cooperate in promoting the mutual acceptance of conformity assessment results performed by CABs having been accredited on basis of relevant ISO and IEC guides. And the Agreement on Comprehensive Economic Partnership among Japan and Members States of ASEAN incentivizes the parties to cooperate and establish a programme in mutually agreed areas to facilitate the acceptance of the conformity assessment results.

Beyond this confidence-enhancement tool, the majority of sampled RTAs promote the use of mechanisms facilitating the acceptance of conformity assessment results and the exchange information in order to identify the most appropriate mechanism for different sectors. The mechanisms are consistent with the indicative list of approaches developed by the WTO TBT Committee and include, among others, the conclusion of MRAs for conformity assessment, the supplier's declaration of conformity (SDoC), the conclusion of voluntary arrangements between CABs located in the territories of the parties to accept the results of each other's conformity assessment, unilateral recognition of conformity assessment results, designation of conformity assessment bodies located in the territory of the importing country and the adoption of accreditation procedures for qualifying conformity assessment bodies located in the territory of the other party.

The conclusion of voluntary arrangements between CABs to accept the results of each other's conformity assessment is promoted by 25.3% of the RTAs under examination. This approach is mainly mentioned in the United States and New Zealand Agreements (Table 4).

Some RTAs also promote the use of existing MRAs and MLAs concluded by international and regional organizations. This approach is usually promoted in the RTAs concluded by APEC members, such as the Thailand and Australia, and the US and Singapore, where the parties agree to take the necessary steps to implement the different phases of the APEC Telecommunications equipment Mutual Recognition Arrangement and/or the APEC Electrical and Electronic Mutual Recognition Arrangements.

Table 4. Overview of the equivalence and mutual recognition provisions in RTAs per country

Countries	Number of RTAs	TBT Chapter /provi-sions	Require or promote to recognise technical regulations as equivalent	Require to explain the reasons for not recogni-sing other Party's technical regulations as equivalent	Require or promote MR of technical regulations or standards	Require or promote MR of the results of CAPs	Require explaining the reasons for non-recog-nition of conformity assess-ment results	Require or promote the conclusion of MRAs	Require the Parties to explain the reasons for a refusal to enter into negotiation or to conclude MRAs	Include a MRA for conform-ity assess-ment	Require or promote the use of existing regional and internatio nal MRAs for conform-ity assess-ment	Require or promote the conclusion of voluntary arrangements between CABs located in the territory of the Parties to mutually accept the results of each other assessment procedures
Australia	8	6 (75%)	6 (75%)	4 (50%)	0	6 (75%)	4 (50%)	5 (62.5%)	2 (25%)	0	3 (37.5%)	4 (50%)
Canada[1]	9	7 (77.8%)	4 (44.4%)	4 (44.4%)	0	4 (44.4%)	3 (33.3%)	4 (44.4%)	2 (22.2%)	0	0	2 (22.2%)
EU[2]	33	22[3] (66.7%)	2 (6.1%)	0	0	1 (3%)	0	14 (42.4%)	0	0	0	3 (9.1%)
Japan	13	11 (84.6%)	2 (15.4%)	2 (15.4%)	0	6 (46.2%)	3 (23.1%)	6 (46.2%)	0	3 (23.1%)	0	0
Korea	11	10 (91%)	2 (18.2%)	2 (18.2%)	0	5 (45.5%)	2 (18.2%)	8 (72.7%)	1 (9.1%)	1 (9.1%)	3 (27.3%)	4 (36.4%)
Mexico	12	10 (83.3%)	6 (50%)	5 (41.7%)	0	5 (41.7%)	3 (25%)	6 (50%)	2 (16.7%)	0	0	0
New Zealand	9	8 (88.9%)	8 (88.9%)	7 (77.8%)	0	8 (88.9%)	7 (77.8%)	7 (77.8%)	5 (55.6%)	2 (22.2%)	4 (44.4%)	6 (66.7%)
United States	14	12 (85.7%)	7 (50%)	7 (50%)	0	11 (78.6%)	9 (64.3%)	12 (85.7%)	9 (64.3%)	0	2 (14.3%)	10 (71.4%)

1. CETA is not included in the sample of Table 4 as it was published only recently. It has a strong chapter on the mutual acceptance of the results of conformity assessment.

2. The RTAs concluded between the EU and EFTA countries as well as Switzerland are not included in the sampled RTAs.

3. A great part of the RTAs concluded by the EU are Association Agreements concluded with EU neighbouring countries. Most of them only have one or a few provisions, stipulating that the Parties agree to cooperate with a view to EU counterparties progressively achieving conformity with EU technical regulations, European standardization, metrology, accreditation and conformity assessment procedures. Since these agreements envisage the harmonization of these countries laws, standards and conformity assessment systems and procedures with the EU ones, and some of them promote the conclusion of sectoral Agreements on Conformity Assessment and Acceptance of Industrial Products (ACAAs), they are considered as having a TBT chapter.

Mutual Recognition Agreements (MRAs)

The conclusion of MRAs is promoted in more than half (56%) of the sampled RTAs. However, the negotiation and conclusion of MRAs is usually mentioned only as one of several mechanisms for the parties to facilitate the acceptance of CA results and avoid duplicating tests. Furthermore, only 20.2% of the RTAs requires the parties to explain reasons to decline an invitation from the other party to negotiate and conclude an agreement accepting on its territory the results of conformity assessment procedures conducted by CABs in the other Party's territory (Table 4).

The conclusion of MRAs is mainly promoted in RTAs concluded by the United States, New Zealand, the Republic of Korea and Australia (Table 4). In the six RTAs in which Japan agrees to promote the conclusion of MRAs, a stronger commitment is defined than those assumed in many of the other RTAs. Indeed, two RTAs with Japan include MRAs, and one other sets a timeline for the possible conclusion of MRAs in specified sectors. EU Economic Partnership Agreements do not promote the conclusion of MRAs, with the exceptions of the EU-Colombia/ Peru, the EU-Korea and the EU-Chile RTAs. However, in most of the Association Agreements concluded between the EU and the Mediterranean, East European and Western Balkans countries the future conclusion of Agreements on Conformity Assessment and Acceptance of industrial products (ACAAs) is envisaged, in sectors to be determined, once the EU partners' relevant sectoral and horizontal legislation, institutions and standards have been sufficiently aligned with those of the EU. So far, however, the EU only concluded such an agreement in good manufacturing practices for pharmaceutical products with Israel.

In some RTAs the parties assume a strong commitment by establishing a timeline for the negotiation and conclusion of MRAs and/or specify the sectors that future MRAs should cover. This is the case of the RTA concluded between Japan and India. According to the agreement, the parties shall, through the Sub-Committee on TBTs, discuss the feasibility of MRAs in such sectors as electrical products, telecommunications terminal equipment and radio equipment as well as other sectors that may be mutually agreed by the Parties. The Sub-Committee shall meet within three months from the date of entry into force of the agreement, in order to discuss the feasibility of MRAs in these sectors. If the Sub-Committee concludes that the MRAs are feasible, the parties shall endeavour to conclude the MRAs within a reasonable period of time, normally not exceeding three years from the date of such conclusion. Also in the Korea-India Free Trade Agreement, the parties agree to undertake consultations no later than one year from the date of entry into force of the agreement, with a view to negotiate and conclude MRAs for conformity assessment of telecommunications equipment and electrical and electronic equipment as well as other sectors that the parties may agree to include.

Moreover, some of the parties on the sampled RTAs have concluded separate MRAs. Table 5 gives some examples of the stand-alone MRAs concluded between the RTAs parties.

Six of the RTAs incorporate a MRA(s): Japan-Philippines, Japan-Singapore, Japan-Thailand, Korea-Singapore, New-Zealand China and New-Zealand Singapore Free Trade Agreements.

The Japan-Philippines and the Japan-Thailand RTAs include in their respective Annexes 4, a MRA for the recognition of conformity assessment results of electrical products. These two agreements are very similar to the stand-alone MRAs described in the chapter on MRAs of conformity assessment. The main text of the agreement contains the general rules establishing the mechanisms for implementation of the agreement and the principles under which CABs may be designated, suspended or withdrawn as well as market surveillance programmes. The annexes define the exact scope of coverage of the agreement and additional provisions related to the designation of the CABs. The Japan-Singapore RTA contains two MRAs: one in telecommunications terminal equipment and radio equipment and the other in electrical products.

The Korea-Singapore RTA includes a MRA for conformity assessment of Electrical and Electronic Equipment in its Annex 8B. Its structure is similar to the two Japan RTAs mentioned above, however, it contains more detailed provisions. Another MRA of conformity assessment of electrical and electronic equipment is integrated in Annex 14 of the New Zealand-China FTA. It applies to electric and electronic products that are subject to the China Compulsory Certification System and to the requirements of New Zealand SDoCs for such products. Annex 4.1 of the Free Trade Agreement concluded between Singapore and New Zealand also includes a MRA of conformity assessment of electrical and electronic equipment.

Table 5. Stand-alone bilateral MRAs concluded between the parties in the sampled RTAs

Countries	Date of entry into force	Sectors covered
Australia-Singapore	2002	• Medicinal Products • GMP Inspections • Electrical and Electronic Equipment • Telecommunications Equipment
Canada-Israel	18 Jan 2013	• Telecommunications Equipment
Canada-EFTA	2001	• Information Technology Equipment • Radio Transmitters • Electromagnetic Compatibility • Recreational Craft • Good Manufacturing Practices for Medicinal Products • Electrical Safety • Telecommunications Terminal Equipment
North America Free Trade Agreement (Canada-Mexico MRA)	01 Jan 2012	• Telecommunications Equipment
Canada-Switzerland	1998	• Pharmaceuticals • Medicinal Equipment • Telecommunications Equipment
EU-Israel	2000	• OECD principles of good laboratory practice • Compliance monitoring programmes between the EU and the State of Israel
EU-Israel	2013	• Good Manufacturing Practice for Pharmaceutical Products
North America Free Trade Agreement (US-Mexico MRA)	10 June 2011	• Telecommunications Equipment

Conclusions

All of the sampled countries promote, in one way or another, unilateral recognition of technical regulations as well as unilateral or mutual recognition of the results of conformity assessment procedures as part of their RTAs.

The only exception is the EU, which favours the harmonization of its trade partner's legislation and regulatory, standardization, accreditation and metrology structures and systems towards the EU 'acquis'.[27] However, one should note that, with exception of the so-called EU WTO-Plus RTAs (notably the ones concluded with South Korea and Singapore), the large majority of EU RTAs has been concluded with European and North African EU neighbourhood countries and with selected developing countries. Hence, it is less surprising that the EU and its neighbourhood partners have agreed to go for the harmonization approach, and the conclusion of ACAAs.

Very few RTAs integrate a MRA in its annexes. The large majority of MRAs integrated in RTAs are on electrical and electronic sector. Globally, with the exception of Japan, the countries considered in the sample have a preference to conclude stand-alone MRAs.

The acceptance of technical regulations as equivalent is mainly promoted in the Australian and New Zealand RTAs (6 out of 8 RTAs and 7 out of 9 RTAs, respectively), and to a lesser extent by other countries. However, for a country to accept the other party's technical regulations as equivalent, prior consultations and negotiations are promoted in certain RTAs in order to build confidence.

27. This is an important change from the 1990s, formalized in a 2004 working paper: SEC (2004) 1072.

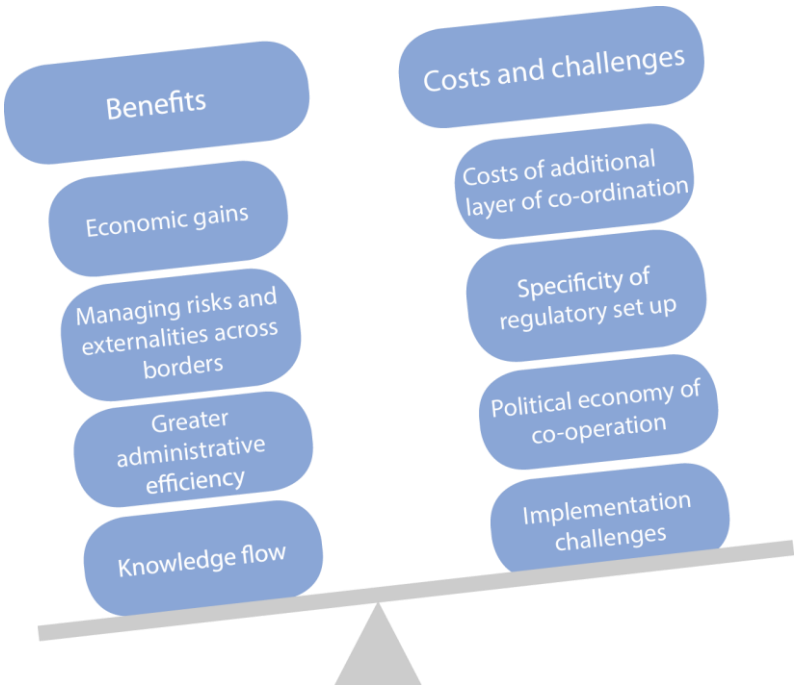
BENEFITS, COSTS AND CHALLENGES OF MRAS

Introduction

OECD (2013) identifies the benefits, costs and challenges of alternative international regulatory co-operation (IRC) approaches using a simple classification (Figure 4). This chapter applies the OECD's analytical framework on benefits, costs and challenges of IRC to MRAs. This is relevant because although, as previous chapters show, there are now many sectorial MRAs in the world, the original expectations about benefits and costs of MRAs have altered over time, given the various experiences. Of the 11 forms of IRC identified in OECD (2013), MRAs are one of four forms employing hard law, mutually obliging both (or more) governments. MRAs are therefore purposefully modest but firm in ambition and focus solely on getting duplicative conformity assessment out of the way in specific sectors where TBTs are a serious cost. Initially, MRAs were probably overrated in terms of benefits, without fully realising their costs and challenges. Now that many OECD countries have moved further on the learning curve of MRAs and their alternatives, an application of the OECD analytical framework for IRC may help both regulatory and trade policy makers to better appreciate what MRAs can and cannot bring, what the pitfalls might be and how they might be addressed.

Insofar as possible – given scarce data about the actual implementation of MRAs throughout the OECD and the few detailed studies or reports on them -, this chapter discusses the four types of benefits and then the four types of costs and challenges that MRAs may generate.

Figure 4. Schematic approach to benefits, costs and challenges of IRC



Source: OECD (2013), International Regulatory Co-operation: Addressing Global Challenges, OECD Publishing, Paris. http://dx.doi.org/10.1787/9789264200463-en.

Trade effects of MRAs: lessons from the literature

A near-exhaustive survey of the empirical economic literature on the impact of MRAs and their alternatives on trade flows was carried out by Vancauteren for the OECD in 2009. A summary of the literature at that point in time is provided in Table 6. The main conclusion of the literature at that time

is the empirical support for the intuitive inference that MRAs and their alternatives tend to have a positive impact on trade flows. But a closer inspection brings up several difficulties in interpreting the studies, as they differ in technical methodologies, in terms of the sectors studied, the countries studied, whether they are a part of RTAs or 'stand-alone', and what type of data could be used.

Table 6. Literature survey: trade impact of MRAs and alternatives*

Type of study	MRAs	alternatives	Comments
Qualitative studies (interviews, surveys, questionnaires, case-studies) 17 studies (9 on MRAs; 8 on alternatives; 3 of the 17 are on both)	Of 9 studies on MRAs, 6 report an unambiguously positive effect on trade; 3 report minor or no effect	Of 10 studies (8 only on alternatives), only one has 'no effect'; all other ones report positive effect	comment 1: 3 MRA studies with minor or no effect can be explained by (a) a lack of implementation; (b) rules of origin; (c) [for developing countries] inadequate technical infrastructure comment 2 : 1 study on alternatives reports 'no effect', is on Cambodia, seeking international accreditation of CA bodies, based on ASEAN's CA model; but Cambodia's infrastructure is tiny and weak
Econometric studies 6 studies (3 on MRAs and 3 on alternatives)	2 of 3 MRA studies report positive effect on trade; one shows no effect (not even in four different model specifications)	All 3 studies on alternatives report positive effects; all 3 study SDoCs; 2 of them in combination with private mutual recognition between CABs	comment 3 : the MRA study with 'no effect' is the Australian/EU MRA in 4 sectors; however, this study was executed only 2–3 years after the MRA went into force, this may have been too short; there is also the issue of bilateral trade (in these 4 sectors) being rather small comment 4: SDoC studies tend to rely on the EU New Approach, as tantamount to a general application of SDoC, which is indeed often the case; nevertheless, in the New Approach, there is underlying harmonisation of regulations and reference to European standards, thereby rendering a proper comparison with MRAs inappropriate. This must imply that a careful econometric procedure has to be applied which can separate the 'pure SDoC effect' from the effect on trade from harmonisation of rules (ort standards). The only serious attempt in this respect is found in Fliess, Gonzalez & Schonfeld (2008) [see text]

*. Until mid-2009 only.

The alternatives to MRAs in facilitating acceptance of tests and/or certificates from foreign CABs include: (i) co-operative arrangements between domestic and foreign CABs in the voluntary sector; (ii) the use of accreditation to qualify (foreign) CABs; (iii) government designation; (iv) unilateral recognition of results from (designated) foreign CABs; (v) SDoCs as evidence of compliance.

Source: Based on Vancauteren (2009); comments from the authors.

Table 6 and the comments show that MRAs have a positive effect on trade, once the fundamentals are fulfilled (e.g. sound technical infrastructure; it is actually implemented; and there is enough trade as well as some time to adjust). A positive effect on trade might also be true for the alternatives, but here one has to be very careful not to mix up harmonisation effects (e.g. in the New Approach) with SDoCs effects on trade. A large number of the sectors and submarkets falling under the New Approach can indeed rely on SDoCs. However, in the New Approach, SDoCs are (self)declarations of conformity to harmonised rules (in directives, mostly), with reference to European standards. It would be a mistake to compare this approach with MRAs, which leave the regulation of the partner countries unchanged. In the presence of extensive underlying harmonisation and a common conformity assessment system, it is much more likely that domestic regulators feel re-

assured that MRAs can work. The US/EU marine equipment MRA of 2004 provides a rare example outside of the EU of such underlying harmonisation, since it relies on global IMO rules which are essentially identical over the world (Annex 3).

The study by Fliess et al. (2008), based on three sectorial cases falling under the EU New Approach, studies the effects of SDoCs against 3rd party certification inside the EU, while controlling for the harmonisation of SDoCs as a corollary of the New Approach in these sectors. However, the underlying regulations and European standards are also harmonised by the New Approach and it is difficult to control for that as well: the case of machinery turns out to be ambiguous in their empirics and precisely in that sector, a two-decades long programme of drafting European standards is part and parcel of the New Approach (more than 800 such standards have meanwhile been endorsed). Nevertheless, the care taken by the authors of controlling for these aspects of harmonisation and the appropriate econometric methodology render their conclusions far more robust than any other attempt. They find that (a) trade is facilitated and increases in two of the three sector studies – with machinery being ambiguous - due to SDoCs (instead of earlier 3rd party certification), (b) besides intra-EU trade increases, larger increases of extra-EU imports can be attributed to the introduction of SDoCs, in particular for developing countries, (c) existing traders benefit much more (i.e. new entry is barely encouraged only because of SDoCs) as variable costs fall.

Other alternatives are hardly studied. Arrangements between CABs in different countries have been included in a few studies but together with SDoCs which, again, makes it harder to disentangle the effects. Some of the qualitative studies provide considerable support to the positive effects. Only one study (outside of the Cambodia case) focuses on accreditation of CABs, yielding a positive effect on trade, but this is a special – though significant – case on the global metrology institutes network (of 48 countries) under the international BIPM. The option of government designation of foreign CABs may overlap with the option of unilateral recognition of results of foreign CABs in the case of Japan. In two submissions to the WTO TBT committee, Japan has advocated the (Japanese) government designation of specific foreign CABs for a few sectors, the results of which are then (unilaterally) recognized. Japan claims that this method avoids the considerable costs of setting up and maintaining MRAs. It applies the method for materials under the materials safety law and for certain electrical products. But only 7 foreign CABs have been recognized, in 3 continents. Unlike under a MRA, it is not clear why one CAB is selected and not another. Hong Kong has unilaterally recognized all CABs accredited by APEC countries for telecoms equipment under the APEC TEL MRA. In this context, one expects that trade is positively influenced. Unilateral recognition in such a way is cheap – once there is trust – and avoids any restrictive effect of origin. In this respect, the case of telecoms equipment is unique because it often relies on international standards (ITU and IEC) which facilitates a mere focus on CABs.

Conformity with ISO 9000 (a quality-management system, with traceability) might be seen as a (partial) alternative for MRAs, as a help to support the credibility of SDoCs. Concentrating on harmonisation of standards (i.e. acceptance of e.g. European standards or relying on world product standards where available), Shepherd (2007) finds for textiles, clothing and footwear, that standards can be a factor reducing export variety while increasing trade, but reference to international standards reduces the loss of variety. Although reference to international standards is not in the list of five direct alternatives to MRAs, it is relevant as the TBT Agreement would lead one to expect WTO partners to facilitate market access based on international standards, and this may play a positive role for conformity assessment. The issue is also relevant for the question of whether regional agreements may include MRAs, having positive effects on intra-group trade whilst having negative effects on developing countries if the MRAs have restrictive rules of origin.

Chen & Mattoo (2008) show econometrically that both harmonisation of regulations (in the EU) and MRAs promote trade but that restrictive origin rules in MRAs (a problem that cannot exist for harmonisation) tend to cause a decline of exports of ‘excluded’ countries, mainly developing ones. However, it is good to note that, in the stocktaking of MRAs undertaken in support of this work, there are not so many MRAs with origin rules. A somewhat similar work, limited to medical devices and

telecoms equipment, by Baller (2007) studies the effects (of MRAs) on the initial decision to export as well as on existing exporters. The study finds that the initial decision to export is positively influenced by MRAs and this may be pro-competitive as entry might well occur. For existing exporters, MRAs have little to no effect in the telecoms sector but a strong positive effect in medical devices. This finding is the opposite of what Fliess et al. (2008) find for SDoCs.

The harvest of new studies is rather small. Orefice, Piermartini & Rocha (2012) exploit the database from the comprehensive survey of RTAs by Piermartini & Budetta (2009). Their results show that when RTAs comprise commitments to address TBTs, trade tends to increase by 7% on this account only. Both harmonisation and MRAs have a positive and significant effect on trade. However, harmonisation of standards or regulations tends to be more trade enhancing than mutual recognition. Zooming in on conformity assessment only, MRAs tend to be more trade enhancing than harmonizing the CA procedures of partner countries. The trade enhancing effect on intra-RTA activity addressing TBTs is stronger in heavily regulated sectors.

A study of the impact of harmonisation to international standards, in the electric/onic goods sector, by Reyes (2012) can be regarded as offering an alternative explanation to Chen & Mattoo (2008). Although the study does not include MRAs as such, Reyes' conclusions give food for thought on the impact on trade. In a Melitz-type model of heterogeneous firms, and based on individual (US) firm level data, he finds that EU harmonisation to international standards has caused two effects: on the one hand, it promotes new entry (into the business of exporting these products to the EU) helping to increase (US) exports, on the other hand, market shares of existing exporters tend to decrease. The pro-competitive impact of harmonisation therefore has two opposing effects. Overall, Reyes finds that the entry effect in enlarging exports to the EU dominates the profit and market share reduction effect for developed countries – hence, a net increase of their exports to the EU –, whereas it is the other way around for developing countries. This conclusion implies that the Chen & Mattoo results are challenged, at least in this very large sector which is important for many developing countries and emerging economies: rather than origin rules, it is the pro-competitive dynamics of exports which are harder for developing countries to keep up with. Whether this is different for MRAs is still unclear.

Finally, a study by Disdier, Fontagné and Cadot (2012) also considers harmonisation of regulations. Its relevance for the present study is found in the preference of the EU for the combination of MRAs and alignment with its regulatory regime for products suffering from TBTs in trade. The authors show that EU association agreements with Mediterranean countries might prompt 'premature harmonisation', not expressing their comparative advantage at today's level of development. It is shown that this is costly for them. Disdier et al. (2012) find that hub-and-spoke patterns are reinforced by inhibiting South-South trade for such countries, trade which has become highly dynamic nowadays. Manufacturers from such countries are forced to position themselves in high-quality segments where they cannot grow as they otherwise could. The authors also include a dummy variable for harmonisation of CAPs which yields a strong negative effect on trade with Southern partners (a tariff equivalent of no less than 38% with Southern trade partners).

Benefits of MRAs

Of the four benefits specified in Figure 5, the expectation of reaping '*economic gains'* is a prominent driver for MRAs. Although, as highlighted above, the literature indicates an increase in (sectorial) trade following MRAs and provides qualitative evidence from business that transaction costs are reduced, the empirical evidence is not very powerful. The main reason for this is likely the lack of data directly measuring the costs of duplicative conformity assessment in every subsector before the MRA and the costs of single conformity assessment once the MRA works.

It is, however, unlikely that the costs prevented by a MRA are large because of their limits. They typically lower costs related to only one element of TBTs, namely, testing and certification. In sectors where TBTs tend to be high – the heavily regulated sectors such as chemicals, automotive, pharmaceuticals, metrology - MRAs are hardly possible and very few have emerged.[28] In these sectors, other forms of IRC are sought to lower the costs of market access, such as worldwide harmonisation fora in medical devices, pharma and cars, as well as private multilateral arrangements in metrology. In (sub)sectors with lower risk, where MRAs have been agreed, TBTs tend to be lower and the economic impact of MRAs is therefore bound to be more limited.

The reduction of the costs of TBTs has been studied by Francois et al. (2013) and Fontagne et al. (2013). While the degree of sector aggregation is too high to be meaningful for a comparison with MRAs, these studies provide insights into the order of magnitude of the likely effects. In Francois et al. (2013), the average trade cost estimates from NTBs (basically, TBTs) is 21.5% for US goods exports to the EU and 25.4% for EU goods exports to the US.[29] These reflect *both* regulatory divergence and explicit TBTs. Duplicative testing and certification, no matter how irritating for industry, would probably represent no more than a few percentage points of this trade cost - most of it is bound to be a function of regulatory divergence and the compliance costs in production (rather than testing and certification).

A sectoral breakdown in Ecorys (2009), which has served as the basis for Francois et al. (2013), provides selected cost estimates for TBTs relevant for MRAs. For US pharma exports to the EU, TBT costs would be 15.3% and for EU exports 9.5%; duplicative pre-and post-approval GMP inspections are only one relatively small part of these TBTs, the largest element being market approval of the medicine (even if that is only once-off). For electric/ronic goods these cost estimates are respectively 6.5% and 6.5%, fairly low percentages because the absolute costs can be spread over very large trade volumes. For EU exporters, the extra OSHA certification is only one element of these costs, hence, cannot be much more than 2% or so. In ICT/telecoms equipment, the trade costs are higher, namely, 19.1% and 22.9%. However, these costs have remained *even though* a well-functioning MRA was in effect.[30] This may demonstrate that what matters most for TBT costs is regulatory diversity, *not* duplicative conformity assessment. However, (lost) time-to-market is not included in these TBT estimates, which constitutes a major cost as shown in Fliess et al. (2008).

The second type of benefit in Figure 5 is progress in *managing risks and externalities across borders*. This can be important for certain forms of IRC (such as the Montreal Protocol banning products damaging ozone layers) but existing MRAs do not have much, if indeed anything, to do with managing global goods and risks.

A third type of benefit is *greater administrative efficiency*. These would rarely be other than "collateral gains" (OECD, 2013) in the case of MRAs. In principle, MRAs might be seen as a form of simplification, but that is eventually true more for firms than for the governments concerned. However, MRAs probably lead in the medium run, when regulators or supervisors have become familiar with the designated CABs and their performance, to less testing and certification activities

28. In pharmaceuticals, MRAs do exist but only for GMP in the production of medicines, not for the approval of the medicines themselves; moreover, some MRAs in pharma do not work (e.g. US/EU). In operation are Canada /EU and Japan/EU, and possibly Israel/EU (only agreed in January 2013).

29. Compare with non-agricultural goods in Fontagne et al. (2013): 42.8% for US exports to the EU, and 32.3% for EU exports to the US. The non-trivial difference between these estimates may be caused by Fontagne et al. using only a gravity approach, whereas Francois et al. rely first on Ecorys (2009) elaborate business and experts' survey, and based on that mass of data, employ a complementary gravity approach.

30. Details about the composing elements of the TBTs in these sectors show that regulatory diversity is often due to a *series* of laws with disparate effects, not one or two laws, indicating that the TBT costs are mainly derived from these aspects. See Ecorys (2009).

directly by regulatory agencies, less resources spent on inspection and, possibly, faster customs lanes for MRA goods. However, there is no empirical evidence on this. The notion of 'work sharing' between administrations, also brought up in the analytical framework, would not seem to be applicable to MRAs, except in one case: Australia and New Zealand share the burden of the MRAs with the EU and with Singapore (electric/onic goods).

A fourth type of benefit consists of *knowledge flow and peer learning*. This is an important benefit that applies both to failed MRAs and effectively operating ones, as the US/EU case study clarifies. In the latter, the MRAs in electrical goods, pharma and medical devices failed. All three had lengthy transitional periods during which intense exchange of information took place and applications for designation of CABs or 'equivalence' of regulatory systems were made and assessed; moreover, sectorial committees repeatedly met on substance and training seminars were held on several occasions; in a few cases, on-site visits were organised too. Following these experiences, several attempts have been made to facilitate progress by adopting general principles of regulatory co-operation, in part also applicable to medical devices and pharma[31]. In addition, the talks in the world fora on medical devices and medicines continue.[32]

For the three MRAs which are operational, the situation is less clear. For recreational craft, the annex is no longer in use since 2006, meaning that the subcommittee does not meet anymore and hence knowledge flows are no longer encouraged by this sectorial MRA. For EMC, the EU allows SDoCs but the US still requires third party certification; the subcommittee should still be active, if only because of the many CABs designated once[33] and because revisions of laws may require administrative re-designations. In telecoms equipment, there are 30 US and EU CABs designated and the MRA works well. The subcommittee is presumably active as the US regularly requests re-assessment of CABs. As this is a dynamic sector, knowledge flow is likely a regular element of the co-operation.

It might well be correct that, for countries with weaker technical capacities, these knowledge flows serve as a 'capacity building tool', possibly even in networks of regulators and specialised authorities. For the EU and the US, this would presumably not apply anymore, although it might have helped some of the new EU Member States in the early years after accession to the EU.

Costs and challenges of MRAs

There is a range of actual or perceived costs related to MRAs for the public authorities. Three types are discussed. Two of them, mentioned in OECD (2013), are 'increased administrative costs' and 'costs of additional layer of coordination on economic activity'. Both play a role for MRAs. MRAs, though narrowly focused and supposedly functioning more or less automatically once in place, are widely regarded as costly for administrations and regulators. This has been noted by the European Commission,[34] by US regulators (Shaffer, 2002) and by Japan, which gave the public costs of MRAs as the principal reason for adopting a substitute (the unilateral designation approach as highlighted in Chapter 2). These costs consist in time and human resources, often highly specialist ones. The time of administrative maintenance matters after the operationalisation of sectorial MRAs. However, before a

31. For both, the April 2012 Commission MRA Newsletter states that 'regulatory co-operation and information exchange exists.

32. For instance, in 2007 the FDA and the EMA (European Medicinal Agency in London, for approval of most medicines in the EU) agreed to jointly approve 'orphan medicines' in order to guarantee higher turnover which makes these orphan drugs cheaper, whilst stimulating R & D for a larger market.

33. In this market, there is also a demand for voluntary third party certification within Europe, which can be valid for access to the US market

34. European Commission (2004) [SEC(2004)1072] says : "The routine maintenance costs of this type of MRA is not small." (p. 4)

MRA has been concluded, substantial time (also of higher officials and even ministers) is spent on investing in and raising the political capital to support the MRA negotiations, to mobilise the administration, to lobby legislatures and to gather the support from business.

A very different but crucial kind of cost is that of reducing 'regulatory sovereignty' (OECD, 2013). As 'sovereignty' suggests an absolute insistence of countries being totally free to decide whatever one might want to regulate and how, this term might be less appropriate for today's profound economic and regulatory interdependence, and certainly in the case of MRAs. The chapter on Mutual recognition and MRAs and Table 3 have shown that the WTO in general and the TBT Agreement in particular already imply a range of obligations, and indeed some prohibitions. Furthermore, there is a host of other considerations which limit 'sovereignty' in regulatory trade affairs, from the Codex Alimentarius to OECD decisions, codes and pledges, from ICAO (for aircraft safety) or the IMO (for ships) to the Montreal protocol, etc. The US/EU MRA rightly speaks of not affecting or limit the parties' "regulatory authority" in terms of regulatory objectives or the authority of a regulator (Art. 15) which would seem to be a more practical notion (than sovereignty) fitting MRAs well.

The problem emerges in MRAs when alignment or regulatory convergence is absent or when a process to accomplish such alignment is not credible. In such circumstances, the ideal of MRAs accommodating different regulatory regimes via recognised conformity assessment on both sides turns out to be difficult to realise. Frictions may lead to assertions that regulatory autonomy is undermined, or that solutions in the proposed MRA are insufficiently tailored to local needs, or that values or sensitive objectives require stringent controls that are hard to accommodate in a MRA. In OECD (2013), this problem is developed in several ways, such as problems of accountability (when IRC may remove decisions even further away from voters) and transparency. In MRAs, transparency is a problem because the empirical reporting by almost all OECD countries on MRAs is poor. What public reporting there is, is often rather formalistic, without the actual functioning in markets, the actual views of stakeholders (especially business, having daily experience), let alone impact assessments of some kind. Accountability would seem to be a lesser problem for MRAs, for the simple reason that, by the very nature of MRAs, regulatory objectives and institutions of a signatory are not affected. In other words, the 'preferences of the regulated' (OECD, 2013) are not at issue at all.

Another type of concern is *regulatory specificity and a possible lack of flexibility*. "Differences between countries in their regulatory procedures and/or legal systems or traditions may significantly complicate efforts to overcome regulatory divergence. In some cases, regulatory paths are already deeply entrenched making rapprochement difficult" (OECD, 2013). Lack of regulatory flexibility can show up in many forms and areas, from e.g. the legal protection of confidential information (especially when based on case law) to ownership rules or (as sometimes still in the EU) the existence of harmonised rules which are based on sensitive compromises or too much detail, which may be politically impossible to question. In the OECD survey two forms are specified: lack of regulatory flexibility in general and legal obstacles to information sharing. For MRAs, the first one matters. Good regulatory practices and principles may defuse tensions and help to employ an analytical approach, e.g. via cost/benefit analysis and a good account of experiences elsewhere. However, in actual practice, it also and perhaps mainly hinges on trust. Given trust, the preparedness of regulators to seek or investigate or experiment with other options will be far greater. Of course, this risks being a circular reasoning, because that trust can only slowly emerge and one has to invest in it over the medium term.

A third class of concerns relates to the *political economy of co-operation*. The OECD survey specifies three elements: unequal distribution of costs and benefits, reduced regulatory competition and (a fear of) lower quality of regulation. The first one matters for MRAs in two ways: one is for MRAs with multiple sectors as noted in the US/EU case study, the second one may cause problems if a single sector MRA has extremely unbalanced trade flows, expected to get further out of balance (a possible candidate here might be the New Zealand/China MRA in electric/tronic goods essentially based on Chinese standards, although these are largely based on international standards). Reduced

regulatory competition might be an issue if there is a kind of 'trading up',[35] as cost-driven competition may be throttled. In economics, this problem is called "raising rivals' costs" by augmenting regulatory SHEC requirements or demanding standards, as these cost-raising elements reduce the scope of competing on low-costs varieties. If this occurs, it is not easy to attribute that to MRAs as the requirements are not set by the MRA; only the competence for conformity. Another instance of reduced regulatory competition might be envisaged if IRC would be captured by specific interests. Again, that is unlikely to be possible under MRAs. On the contrary, Devereaux et al., op. cit., report that the electrical goods industry in the US was against the MRA, as they felt the status quo with OSHA certification at the workplace served as a kind of protection against competitive foreign firms. Since this sectorial MRA failed, this protection would still seem to work.

Finally, there are *implementation challenges*. MRAs can be formulated in the treaty in such a conditional, if not open-ended, way that implementation can be feared to become difficult. This happened with pharma and medical devices in the US/EU MRAs. What the OECD (2013) quotes in this respect [rule process legitimacy, monitoring quality, enforcement quality and enforcement legitimacy] may all matter in MRAs. However, in close co-operation such as with MRAs, one should expect parties to assume a co-operative attitude and committees to anticipate practical problems or resolve them ad hoc. Letting the process slip out of hand without co-operative action is at odds with the spirit of MRAs. Problems of implementation may be greater once the coverage is larger and more actors are involved. But these aspects may well be less relevant for MRAs as they are well-defined for specific sectors and their operation is both technical and under specialised committees.

Opportunities and success factors for MRAs and their alternatives

OECD (2013) identifies opportunities and success factors for successful IRC. They are applied to the case of MRAs below:

a) regulatory domains which are essentially science-driven and /or based on irrefutable facts

b) issue-areas with strong commercial / economic motivations e.g. trade and investment

c) issue-areas where governments can benefit from sharing information on, say, health and safety aspects – this can be linked to MRAs or indeed precede the conclusion of MRAs

d) areas with regulatory problems similar to those counterpart governments have to cope with

e) areas where two or more countries share similar objectives of regulation and/or standards

f) identify countries where social, economic, political and technological conditions are similar

g) fields where regulatory rapprochement would permit sharing of inspection, testing and certification services

h) fields where regulatory authorities in potentially participating countries have confidence in the technical and regulatory skills of counterparts, and/or where regulators trust each other

i) the existence of bilateral or multi/pluri-lateral frameworks on the regulatory subject in question.

35. The title of a book by David Vogel (1995), showing that food requirements and environmental requirements between the US and the EU have not been subject to a 'race-to-the-bottom' as feared by NGOs and others, but, instead, by upward harmonisation, a race-to-the-top. Vogel (2012) shows that, more recently, the EU has been more 'precautionary' than the US and this has led in some instances to stalemates (agree not to agree). Nevertheless, 'trading up' still occurs frequently.

These aspects do not guarantee in any way that efforts to conclude MRAs will be successful but they might be helpful to underpin a first selection of more credible and realistic plans. Subsequently, following OECD (2013), a checklist of critical considerations for successful MRAs could include:

a) Even when the regulatory context is similar between 2 or more countries and there is mutual respect between regulators, these might be necessary but not sufficient conditions. For example, as the US/EU case study suggests, one may have to move from mutual respect to 'mutual trust' between regulatory authorities in some instances, and thus may well require a long period of lighter co-operation and detailed exchange before the MRA becomes functional in order to build trust.

b) It is indispensable to distinguish relatively new regulatory areas from well-established ones; in the latter case, regulatory positions may have 'hardened' and this might increase actual or perceived adjustment costs; in new areas one might attempt to come to common standards (e.g. compatibility of infrastructure and components in electric vehicles) which may subsequently facilitate MRAs or even SDoC recognition.

c) MRAs may be much easier when high-level political commitment ensures leadership and oversight, as illustrated in the US/EU case study (Annex 3). However, such leadership has to be sustained as the technical implementation might falter if the leadership is short-lived.

d) The systematic application of regulatory policy principles as embodied in the *2012 Recommendation of the Council on Regulatory Policy and Governance* (OECD, 2012) may help to discipline negotiations on MRAs.

e) The systematic application of regulatory policy principles would also imply the use of costs/benefit analysis and impact assessment (with alternative options). MRAs would benefit from a detached impact assessment, justifying limited and targeted reforms *without* having to be interpreted as a trade policy concession, but rather as a measure towards 'better regulation' for all.

f) Building trust between regulators is a slow process. It is illustrated by the OECD case study on chemical safety. In some areas, there is now much more international consultation or exchange, cooperation should move faster, but one must allow considerable time for it.

Finally, the experience with MRAs gathered for this work provides important lessons on the critical components of a successful MRA - in particular beyond its signature. They include:

a) Transition periods and confidence-building mechanisms allow time for different jurisdictions to get better acquainted with their respective institutional settings, promote trust in each other's regulatory systems and smooth frictions that may arise from misunderstanding before the agreement enters into force.

b) MRAs are facilitated by regulatory alignment. The strong anchorage to an international standard for instance has proved an important way to promote this alignment.

c) A commitment to exchange information concerning the implementation and application of the legislative, regulatory and administrative relevant provisions, as well as on changes in the institutional setting, and regulations is a critical condition of success over time.

d) A monitoring mechanism allows understanding the use of the MRA and corrective action if needed.

e) Specifying the dispute settlement mechanisms may diffuse tensions early on when one of the parties may be perceived as not complying with its obligations under the agreement.

CONCLUSION AND RECOMMENDATIONS

MRAs are feasible when regulatory divergences are not too high

On the one hand, in sectors where regulatory divergences are costly, governments might consider negotiating MRAs. They could do this when a conscious choice has been made not to change or reform domestic regulation in efforts of harmonisation. On the other hand, the higher TBT costs for access to export markets, the more difficult it is likely to be to negotiate and implement an effective MRA. This may be so because the sector is heavily regulated by both (or more) countries, perhaps also by independent regulatory agencies, and regulatory diversity is large. In this regard, experience so far suggests that, in heavily regulated sectors, MRAs may not exist at all or only very partially (hence, avoiding these problems) and just for some pairs of countries (e.g. pharma GMP; low-risk medical devices).

MRAs are valuable for a few sectors with global value chains

In sectors where regulatory divergences are a major trade irritant, such as telecoms equipment and electronic goods, MRAs have improved effective market access without problems for the regulators. However, in electronic goods, controls on the workplace have been imposed in some countries, slimming down the economic gains from a MRA. The gains for telecoms equipment probably relate to compatibility, certainty and the pre-emption of delays in complicated global value chains, when intermediates as well as final goods move back and forth over frontiers. For instance, empirical estimates of the costs of US/EU TBTs in telecoms *with* a functioning MRA are much higher than the costs of TBTs in electronic goods *without* such a MRA. This suggests that regulatory diversity rather than conformity assessment determines the costs of TBTs. Yet, the MRA is still worthwhile inside value-chains. Thus, when value-chains in these sectors matter to a country or its business, a MRA may matter for reason of seamlessness across borders and speed.

Before beginning with MRAs, explicitly consider factors shaping MRA opportunities

It is sound strategy to first consider where opportunities for concluding MRAs can be signalled. A checklist of nine such factors should yield a high enough score. Building on OECD (1994 and 2013), factors signalling opportunities include:

1. regulatory domains which are science-driven,
2. strong commercial/trade motivations,
3. areas where regulators may benefit from sharing information and knowledge on safety, health, environment and consumer protection aspects,
4. areas where regulators in potential partner countries struggle with similar problems,
5. domains with similar objectives for safety, health, environment and consumer protection and/or similar standards,
6. countries where economic, social, political, technological conditions are assessed as comparable,
7. regulatory domains where, upon regulatory rapprochement, sharing of testing, certification, inspection would be acceptable,
8. domains for which regulatory authorities have ex ante confidence in the regulatory/technical skills in each other,
9. domains for which some bi-or multilateral frameworks exist, including international standards.

Also consider alternatives to MRAs

Countries need to consider explicitly whether or not, and when, alternatives to MRAs are as attractive or otherwise more convenient to business, or at times to government itself. One element has become more and more acceptable to governments inside and outside the OECD: reliance on the mutual recognition or effective co-operation between CABs in the home and foreign countries, based on accreditation, in turn based on ISO standards for accreditation and peer review in global quality networks. This renders the designation process over time much lighter. This has been pushed to its logical conclusion in chapter 27 of CETA (the Canada/EU FTA, not yet ratified) on the mutual acceptance of results of conformity assessment in a large number of sectors. This new model of a MRA is based on accreditation of CABs following world accreditation standards. The EU and Canada have very similar rules for accreditation, given their reliance on strict world standards, so there is no need for cumbersome and time-consuming designation procedures. Supplier Declarations of Conformity have also gradually become routine. In case MRAs are seen as overly costly for the government, one way to reduce those costs is unilateral government designation of CABs outside MRAs.

Effective MRAs can result from proven 'success factors'

Selecting sectors other than the three most frequently chosen (telecoms equipment, electronic goods, GMP of medicines production) is not necessarily unproductive but one would want to verify how high the expected private gains in pre-empting duplicative conformity assessment really are and whether both sectorial regulatory authorities can reach a consensus on 'what it will take' in practical terms, before starting genuine negotiations. Moreover, 'new' sectors or the application of new technology should be easier than sectors where the regulatory path is entrenched. In case of multiple sector MRAs, high-level political commitment is critical for oversight and leadership. However, implementation issues need to be resolved upfront, largely, because political leadership cannot be expected for such technical issues of specialists. MRAs are likely to require resources, not least because it may require on-site visits, regular consultations with stakeholders, in-depth understanding of the other party's rules and CAPs, building political coalitions to pass the MRA in the legislature and allaying fears that MRAs might negatively affect consumers or workers. Although MRAs leave domestic regulation unaffected, there is still a need for the two or more countries' regulators / authorities to learn to work together in a spirit of genuine co-operation.

Trust is key: partners can invest in trust and 'earn' it

Trust is perhaps not negotiable but much can be done to earn trust, including a co-operative attitude in committees and the allowance of time to build up trust between regulators and/or CABs. In any event, when countries begin to explore the idea of MRAs, regulatory authorities from both sides should already have mutual respect, but investment in the co-operation ought to lift this to mutual trust. MRAs are functional and not adversarial; all the SHEC regulation and CAPs on both sides are retained fully. What matters in each country is that the SHEC responsibilities of regulators can be pursued as before and that the MRA merely allows foreign suppliers to smoothly enter the market, with regulators having 'adequate confidence' (WTO) that the partner CABs act as if they were domestic ones. There is one category of MRAs where this problem is much easier to tackle: 'enhanced' MRAs. These exist mainly between the EU and EU candidate or 'neighbourhood' countries, with one exception: the EU/US marine equipment MRA based on worldwide (IMO) regulatory requirements. It might be possible to identify a few other such sectors where worldwide harmonisation has progressed far enough.

Annex 1

The intra-European Union system of removing and pre-empting Technical Barriers to Trade

Why does the EU matter for understanding Mutual Recognition Agreements (MRAs)?

The EU system of removing existing and pre-empting new TBTs internally amongst its 28 Member States is a radical and highly ambitious approach for providing market access. Since MRAs and their quasi-alternatives are typically more modest and/or selective, one can take the view that the EU example is irrelevant for the analysis of and drawing lessons from MRA experiences. This view is largely correct, but not entirely. There are two reasons why an EU chapter is of interest in this report. First, on the systemic level, it is crucial to appreciate the fundamentals of the EU internal market and the political, legal and institutional choices the Union has made. One element of these fundamentals is 'mutual recognition'. This systemic explanation of market access within the framework of the internal market clarifies why MRAs do not exist inside the EU.

Second, the dynamics of European integration have generated a process of EU enlargement, from the founding Six (in 1957) to the present 28 members, with a few candidate countries preparing for EU membership nowadays and some other ones having expressed an interest in becoming a candidate country. The core of the enlargement process (other than some political fundamentals) is the step-by-step access to the internal market. Focusing on the internal market for industrial goods, a transition instrument was designed starting from the preparation of the Eastern enlargement (from 1995 onwards). This instrument was called Protocol to the Europe Agreements on Conformity Assessment (PECA),[36] and has later been complemented by Agreement on Conformity Assessment and Acceptance of Industrial Products (ACAA) for 'neighbourhood' countries to the South-East and South of the EU. Both are specific types of MRAs. Moreover, there is the special case of Switzerland, with which the EU has an external MRA in a range of industrial goods, but which is, for all market and practical purposes, deeply integrated in the EU internal goods market via regulation, standards and conformity assessment.[37]

Fundamentals of intra-EU market access

In the MRA literature, the EU is often presented as having opted for far-reaching harmonisation and mutual recognition, so that national treatment is the rare exception via derogations (e.g. Nicolaidis, 1997; Schmidt, 2007; Shaffer and Nicolaidis, 2005). In contrast, outside the EU, MRAs are

36. Association agreements for the eight Central European countries which became EU member in 2004 and 2007, plus for Malta and Cyprus[a,b] (also EU members since 2004).

    a. Note by Turkey:

    The information in this document with reference to "Cyprus" relates to the southern part of the Island. There is no single authority representing both Turkish and Greek Cypriot people on the Island. Turkey recognises the Turkish Republic of Northern Cyprus (TRNC). Until a lasting and equitable solution is found within the context of the United Nations, Turkey shall preserve its position concerning the "Cyprus issue".

    b. Note by all the European Union Member States of the OECD and the European Union:

    The Republic of Cyprus is recognised by all members of the United Nations with the exception of Turkey. The information in this document relates to the area under the effective control of the Government of the Republic of Cyprus.

37. Not to be confused with the other three EFTA countries (Norway, Iceland and Liechtenstein) which are in the EEA (European Economic Area) since the mid-1990s, and are fully part of the EU industrial goods market in every respect, including conformity assessment and mutual recognition. For details on the EEA arrangements, see Pelkmans and Boehler (2013). That Switzerland is a special case is the ultimate result of the Swiss voters rejecting the EEA model for them in a referendum in 1992.

usually based on national treatment. Even the derogations have been reduced in the EU over time, mainly by harmonisation. Although these stylized facts are correct, it is nevertheless a misleading picture of market access inside the EU internal goods market. The driving factor of EU internal market integration is "free movement", an extremely powerful principle that does not exist in bilateral or intra-regional trade anywhere.[38] Free movement is not 'free trade' – the absence of tariffs and quotas at the border – but far more radical: it is a *right* of market access to other EU national markets for all economic agents, including consumers, unless the treaty allows Member States to invoke derogation. This fundamental right of market access has been vigorously protected by the Court of Justice of the European Union (CJEU). Developing CJEU case law as well as mutual recognition and common EU regulation have gradually removed practically all derogations in industrial goods markets. It is the radical, uncompromising principle of 'free movement' which has served as a strong incentive to decide on harmonisation, even though common EU regulation involves concessions[39] or national regulatory reforms. The overwhelming majority of EU regulations in goods markets finds its root in market failures which, in a single market with free movement, must be overcome at the EU level.

Thus, when contrasting the intra-EU approach to removing TBTs with that of MRAs, the latter emerge in response to a great reticence or plain unwillingness to engage in harmonisation or mutual recognition of rules. But the deeper explanation is actually that, without 'free movement' or weaker obligations to provide market access, MRA partner countries are under no pressure, expectations or obligation whatsoever to provide market access, unless they themselves see benefits, and even then under restrictive conditions that they negotiate. Indeed, MRAs are negotiated precisely because they tend to have no consequences for regulatory adaptation at home. However, this 'given constraint' limits the options considerably and, hence, the potential benefits of MRAs or their quasi-alternatives.

In the EU internal market for industrial goods, given the overriding importance of 'free movement', the regulatory part of removing TBTs begins with three treaty provisions: a general prohibition of TBTs (art. 34, TFEU),[40] a derogation for Member States[41] essentially for TBTs based on safety, health, environment and consumer protection (SHEC) provisions overcoming market failures, and a harmonisation provision in Art. 114, TFEU.[42]

The history of the EU internal goods market can be stylized for present purposes as follows. First, the TBT prohibition became very general after the strict and narrow interpretation of Art. 34 was rejected by the CJEU in Dassonville in 1973 and replaced by the phrase: what are forbidden are national "(…) trading rules capable of hindering, directly or indirectly, actually or potentially, intra-Community trade". Thus, the pressure on Member States to either justify existing TBTs under the derogation (which was not always easy or even possible) or jointly act via harmonisation became much stronger. Later on, the pressure was augmented by CJEU rulings emphasizing that, even when

38. ASEAN has based its emerging ASEAN single market of the AEC (ASEAN Economic Community) on notions such as 'free flow' (here, of industrial goods) but this wording has no connection with or similar meaning as free movement. For a detailed analysis of the AEC, see Pelkmans (2015).

39. Since 1985, such decision-making in Council is subject to qualified majority voting, i.e. in the rare cases that consensus cannot be reached, a Member States (or more than one) can be overruled. Moreover, today, the European Parliament is also EU legislator and it works with a simple majority.

40. The original text from the Rome treaty of 1957 has remained unchanged: "all measures with an equivalent effect to quantitative restrictions" are prohibited; ever since the Dassonville case (C-8/74), this is interpreted as all regulatory barriers (like TBTs are). For details, see Pelkmans (2012), Barnard (2007), etc.

41. In fact, a derogation from free movement for national measures (like TBTs) can be invoked on the basis of Art. 36 TFEU or on the basis of some specific CJEU case law. For details, see Pelkmans, op. cit, and still greater detail in Barnard, op. cit.

42. EU harmonisation in the EU is always disciplined by the 'necessity' for the internal market and by 'proportionality' of the rules, for the objectives stated.

derogations invoked by Member States were valid in principle, TBTs had to be 'proportional' and not restrict intra-EU trade more than necessary. Proportionality can serve as a tough discipline on domestic regulators, so that targeted regulatory reform in a product market may well be the result, thereby also reducing TBT barriers. In other words, these developments structurally narrowed down the derogation for Member States from free movement of goods.

The Cassis-de-Dijon ruling (C-120/78) introducing 'mutual recognition' (without mentioning the term) further strengthened the disciplines on the derogation for national TBTs. The first element of Cassis-de-Dijon is nothing else than the origin principle: "Member States must allow a product lawfully produced and marketed in another Member State into their own market (…)". The second element is built up from the derogation (Member State can block or condition imports only if 'justified';[43] largely this is about SHEC risk regulation). The Court asks the question whether the protection against these risks is actually affected by the imports from another Member State. Answering this question depends on the SHEC objective in the other Member State, and not on the technical specifications of the rules. If exporting Member State A has slightly different technical rules and controls than importing Member State B, but an *equivalent* level of safety (etc.), the CJEU rules that TBTs are prohibited. For the CJEU, the SHEC objectives matter, because they matter for the safety and health of consumers and workers; however, the technicalities do not matter in their own right. These amounts to a major further limitation of the regulatory discretion of Member State in the internal goods market: Member States can rule, even in detail, on goods but cannot create TBTs (at borders) unless there is a lack of SHEC equivalence in objectives between A and B.

Following all these limitations of the derogations, the incentives to harmonise had become much greater. Therefore, the next stage of the 'deepening' of goods market integration was to reform the EU by facilitating harmonisation and, wherever possible, to build on the mutual recognition doctrine of the CJEU. Until the early 1980s, harmonisation of national rules by the EU legislator (in those days, still the Council of ministers) was characterized by a reticence to accept domestic regulatory reform in order to remove or pre-empt TBTs inside the EU. This reticence was accommodated by the veto system: in Council, unanimity was required. This system created inefficiencies as one or two blocking Member States could frustrate the process for years or impose problematic exceptions or unjustified specifications. As a result, harmonisation became a system of incredible detailed rules on relatively narrow issues,[44] with rigidities for later amendments, no reference to standards, all testing specifications in directives themselves, and occasionally various options for technical solutions that would only apply within a Member State, but leaving intra-EU trade free. This system generated little internal market but was a very costly form of regulation.

Subsequent treaty changes and reforms of the EU regulatory strategy have radically overhauled this so-called Old approach. The veto system was replaced by qualified majority voting which almost immediately altered the conduct of Member States in the Council, now seeking better regulatory quality. The so-called New approach was built up, inspired by mutual recognition. The essence of the New approach is to first ask whether the Member State can agree on common SHEC objectives, based on qualified majority voting. In Europe, SHEC objectives are, more often than not, similar or 'equivalent'. Directives define the common SHEC objective(s) and add procedures (and safeguards) but refrain from technical specifications. In a mutual recognition approach, the technical specifications matter far less for free movement (and the burden of proof for any remaining TBT would be on the Member State). The European standardisation bodies (CEN, CENELEC and ETSI), with which a Memorandum of Understanding exists for this purpose, receive mandates from the European Commission on the technical specifications. Once European standards have been written which support these SHEC objectives, these EN standards are published by the Commission in the EU Official Journal. This means that any producer or supplier (also from 3rd countries) using the standards

43. The justifications are derived from aspects mentioned in Art. 36 or from case law based on Art. 34.

44. Say, a directive only for the mirrors of cars, or, 23 directives on all varieties of tractors, etc.

in the production process enjoys a 'presumption of conformity' with EU rules, hence, enjoys free movement.

The reference to standards in the New approach constitutes a major improvement compared to the Old approach for several reasons. First, by definition, standards are voluntary and therefore other technical specifications (say, due to innovation or new materials) remain possible, of course subject to a possible challenge of conformity, to be tested by an EU designated (and accredited) Notified Body. Second, the European standards tend to be performance standards and are not prescriptive, very much unlike the former Old approach directives.[45] Third, neither specification nor testing requirements in standards are easily influenced by national bureaucratic interventions, perhaps due to lobbies or political sensitivities, as they are written by technical experts from all over Europe and subject to public inquiry. Fourth, European standards, in particular for electric/tronic goods but even to some extent for non-electrical goods, are often based on world (ISO & IEC) standards for testing and/or specifications.

What about marking, conformity assessment and accreditation?

With a surge of harmonisation, and later more and more EU regulation,[46] TBTs caused by different rules, enforceable at intra-EU borders, reduced to very few indeed. Moreover, during the seven years EC-1992 process (1985–1992) deepening the internal market, the customs controls at intra-EU borders were removed, further incentivising the removal of TBTs. Furthermore, the practical functioning of 'mutual recognition' in all cases where no EU regulation exists, was disciplined by enacting a crucial EU procedural regulation,[47] reversing the burden-of-proof away from companies to Member States. In other words, if a Member State wants to invoke a derogation instead of allowing mutual recognition as would be expected, it has to show the risks, give the company adequate hearing (with technical documents on testing, etc.), meanwhile allow the product on the market and decide within 20 days. If imports are blocked, it has to inform the Commission at once, further disciplining the use of such a TBT. A first report[48] on the functioning of this regulation shows that it works well, with a few minor exceptions.

This leaves one category of TBTs, directly relevant for MRAs outside the EU, related to Conformity Assessment (CA). Can governments, companies or citizens/consumers trust that products are actually faithfully follow EU regulation and the standards referred to when this is relevant? Of course this query applies to all EU risk regulation, old or new. But in the Old approach – typically applied in heavily regulated markets such as cars, tractors, motor bikes, pharmaceuticals, chemicals, metrology and a few other ones – strict conformity assessment by (national) inspections or (public) type approval agencies was incorporated. Nowadays this has been improved by introducing a number of flexibilities which go beyond the scope of the present report. In the New approach, the solutions were initially two. One is CE marking placed on the product itself. The CE mark means that the company states that the product conforms to all relevant EU rules (including standards where relevant). CE marking may be backed up by a SDoC or by third-party certification; the latter can be

45. For example, a directive on the 'roll-over characteristics of hill-farming tractors' had almost 20 technical drawings, a four-page specification of an algorithm calculating the probability of 'rolling-over', etc.

46. Harmonisation in the EU was originally meant to merely 'approximate' (or bring 'into harmony') the laws of Member States, so as prevent or remove regulatory barriers. This was done with the help of 'directives', leaving some freedom as to details or legal specification for Member States. However, nowadays, the internal market witnesses a rapid increase of 'regulations' which have 'direct effect' on economic agents, without going through Member State legislative processes (as directives do). See Pelkmans and Correia de Brito (2012) for details and data. See also COM (2014) 25 of 22 Jan 2014.

47. Reg. 764/2008

48. COM (2012) 292 of 15 June 2012, First report on the application of Reg. 764/2008.

voluntarily done [say, by SMEs not disposing of testing facilities] or is compulsory for certain products, seen as potentially more risky, in which case it is done by EU-designated 'Notified Bodies'. Behind this CE marking, the so-called Global Approach of testing and certification was initiated, specifying a number of testing modules, dependent on the nature of the product and the risks involved. This meant that TBT barriers arising from national differences in CA and CA procedures were removed. For the higher risk products, the Notified Bodies (testing & certification bodies) were first designated by Member States, on the basis of technical competence, and then listed by the Commission. Given that the Notified Bodies are regarded as high quality, they were allowed to compete over the entire internal market without a fear of a race-to-the-bottom. Therefore, the internal market, with EU-wide Conformity Assessment system, in combination with common EU rules, common EU SHEC objectives, European standards (where relevant) and mutual recognition, all based on uncompromising 'free movement', can dispense with any form of MRAs. Second, a system of ex-post market surveillance emerged and gradually improved over time. Although EU countries also exercise market surveillance to type-approved products such as motor bikes and tractors (Pelkmans and Correia de Brito, 2011), the main idea is to verify whether producers/suppliers have correctly affixed a CE mark on SDoC based products and whether typical consumer products (including unregulated ones) turn out to be risky.[49]

However, conformity assessment as a system came to be regarded as insufficient and incomplete. One among several problems was that the quality criteria for Member States to designate Notified Bodies and to monitor their competence for the relevant regulations and submarkets were too vague or implicit. At times, domestic 'favours' took the form of designation of Bodies which were either not sufficiently technically competent or had no experience in (some of) the submarkets indicated. These and other problems have been addressed in the New Legislative Framework of 2008, and later, by introducing clear quality criteria for Notified Bodies, one accreditation body per Member State[50] and an EU-wide independent accreditation system, called EA (European co-operation for Accreditation),[51] organising peer review of these Bodies based on the ISO/IEC 17000 series of standards. Since then the number of Notified Bodies has reduced considerably, as they now focus on what they can do best, otherwise risking not to get accredited. There were also complaints about market surveillance, both by consumer organisations and by business. Market surveillance is costly and Member States are not spending enough on this activity (despite the obligation to do so in Reg. 765/2008). Companies in submarkets with many SDoC based products complain of free riders and charlatans selling via the internet, thereby snatching market share away from bona-fide firms. Also customs at the EU outside border need to have the resources to execute adequate verifications, and there are doubts whether this is actually possible with today's resources. In the Product Safety and Market Surveillance package of 2013 the Commission has proposed improvements, including a regulation on market surveillance and a multi-annual plan.[52]

How the EU pre-empts new TBTs from arising

EU Member States still regulate many product-related laws in areas where the EU has not harmonized. According to Correia de Brito and Pelkmans (2012), a rule of thumb is that some 20-

49. For the latter, the General Product Safety directive 2001/95 (at present, under revision) applies, with an alert system in case of serious risks, which may lead to a ban of the good.

50. The principles of accreditation in the EU following Reg. 765/2008 and Decision 768/2008 are: one body per Member State, accreditation is a not-for-profit public sector activity (without competition with other such bodies) and stakeholder representation is assured.

51. See www.european-accreditation.org.

52. See COM (2013) 74 of 13 March 2013 and a host of related documents and proposals – see http://ec.europa.eu/enterprise/policies/single-market-for-goods/internal-market-for-products under the heading 'market surveillance'. For additional details, see The 'Blue Guide' on the implementation of EU product rules (http://ec.europa.eu/DocsRoom/documents/12661).

plus% of intra EU goods trade falls under mutual recognition – areas in which the EU does not regulate - although there is no recent verification of this estimate.[53] Between 2005 and 2010 inclusive, Member States together prepared some 700 – 800 laws annually on goods with technical aspects. Note that so many laws only cover a relatively modest part of the goods spectrum as Member States are not allowed to regulate where EU harmonisation has been adopted. With such a regulatory activity, there is a risk, if not a certainty, that new TBTs would come into being. If the birth rate of new TBTs would be high enough, it would make defeat the purpose of the internal goods market. Under dir. 98/34 (dating back to 1983) a notification system has been set up. It shows that, over the last two decades, more than 12000 such national laws have been notified.

The notification system is more strict and disciplined than that of the TBT notifications of the WTO. Reasons include: (i) it is an infringement of EU law if notification is 'forgotten'; (ii) stronger, non-notified proposals for national law are not enforceable (null and void) once they become law; (iii) the Commission and Member States can comment or issue detailed opinions on notified proposals and these may serve as a warning for a Member State that its drafting implies one or more nascent TBTs (implying that either a mutual recognition or equivalence clause is required or that the proposal is flawed under free movement)[54]; (iv) if the Commission and/or the Member States issue a detailed opinion the Member State in question should take it in consideration and modify the draft proposal accordingly (v) the scope covers all Member State proposals on goods not covered by harmonisation, without exceptions. As Correia de Brito and Pelkmans (2012) shows in an empirical analysis of 22 years of working with 98/34, the discipline has been successful: hundreds of national draft laws have been criticized as threatening to cause new TBTs and many more have been given critical notes or advice to bring in equivalence.

Aligning with the internal market without TBTs: PECA, ACAA and special cases

The EU does make use of MRAs as a transition regime for candidate countries and for other countries gradually aligning their rules, standards and conformity assessment to the EU internal market regime. Since the EU and the eight Central European countries interested in joining the EU began preparing for accession (the so-called pre-accession programmes) in 1995, a transition period was envisaged for the gradual alignment of their legislation with the EU internal market regime. It was hard to foresee how long this period would be, and ratification of the Accession treaties by all EU Member States is always subject to a risk of rejection by one or more Member States.[55] This duration and lingering uncertainty would be a great disadvantage for sectors with laws already aligned with EU law and with the technical infrastructure implying the technical competence and quality as required by the EU. EU companies also ran a risk that candidate countries might not accept their products without further testing (although in actual practice this risk was much smaller). Therefore, PECAs were negotiated in sectors where a candidate country would be considered 'ready' to credibly apply testing and certification of products based on EU rules. PECAs consisted of a MRA framework agreement and sectoral annexes. The basic difference with MRAs is that the relevant underlying regulations are 'aligned' with those of the EU, in the framework of preparing for EU membership. Once candidate countries had aligned such regulations properly, the annexes can establish mutual recognition of conformity assessment per sector, after verifying (or helping to ensure) that the technical infrastructure [standards, accreditation, CA and market surveillance] is sufficient for this purpose. This requires the recognition by the EU of the Notified Bodies in candidate countries. The PECAs provided for mutual

53. Note that another 15% - 20% simply is not regulated.

54. More precisely, there are 'comments' (advisory and a call for clarification) and 'detailed opinions' which are de facto expressing an expectation of a later TBT (which might eventually provoke an infringement procedure by the Commission or even before the CJEU).

55. In the end, Hungary, Poland, Czech Republic, Slovakia, Slovenia, Estonia, Lithuania and Latvia became EU member on 1 May 2004; Romania and Bulgaria followed in 2007.

acceptance of industrial products without further testing or other CA processes. One interesting feature is that, whereas PECAs with Hungary and the Czech Republic had origin rules, other PECAs did not.

A variant of PECAs is currently emerging with ACAAs negotiated with 'neighbourhood countries'.[56] The basic conditions are the same as in PECAs: prior full alignment of the country's regulations and standards with those of the EU and the upgrading of the technical infrastructure to EU equivalent level, including recognition of their Notified Bodies. In many of these countries, this is a considerable ambition in the short to medium run, except for Israel. Not surprisingly, the first ACAA has been agreed with Israel on (Good Manufacturing Practices in) pharmaceutical products in 2013. Some other countries are preparing for an ACAA in electrical products, construction materials, toys, gas appliances and pressure equipment (an intermediate product in engines, etc.).

There are two special cases which are worth mentioning specifically. One is Turkey, a candidate country since 1999. However, before becoming a candidate country, the EU and Turkey concluded a customs union in 1995. The follow-up Decision 2/97 of the EU / Turkey Association Council is highly ambitious, with little known but highly elaborate technical annexes on the full removal of TBTs over time (with language directly taken from the treaty on what now are Arts 34 -36, TFEU, discussed above). Indeed, it is expected that this should even lead to the application of mutual recognition between the EU and Turkey. The technical annexes specify at length what (hundreds of) directives need to be fully adopted by Turkey.[57] Turkey has become a full member of CEN/CENELEC. The country is held to fully align the requirements of its technical infrastructure, including also metrology and market surveillance, with that of the EU. It is therefore misleading to check the progress in the official enlargement negotiations, which are hardly progressing (Boehler, Pelkmans and Selcuki, 2012); the aspects relevant for market access in industrial goods are all linked to the customs union. In Decision 1/2006 of the Association Council, designation of Turkish Notified Bodies is provided as well as the acceptance of test reports and certificates issued by such bodies. In its wake, the EU and Turkey have signed statements that specific Turkish regulations are equivalent to the EU. The Turkish Accreditation Agency is a member of EA. Turkey is therefore on the way of approaching the situation of the three EFTA countries in the EEA (which are fully integrated in the internal goods market) and MRAs are not necessary.

The case of Switzerland is a curious one (Pelkmans and Boehler 2013). Although it is not in the EEA by its own desire (after first having negotiated the EEA with other EFTA partners and the EU), the country is keen to achieve a situation as close as possible to that of its EFTA partners. Many Swiss SMEs and multinationals depend critically on the EU. Yet, formally, it is a third country (but not a candidate) and it needs to negotiate on each and every issue, as the horizontal EEA is ruled out. What Switzerland and the EU have done, is to agree on a series of bilateral agreements on all kinds of legislation. With respect to industrial goods, a framework MRA was concluded in 2002[58] with some twenty annexes on product sectors, including e.g. machinery, medical devices, several other New Approach sectors, Good Laboratory and Good Manufacturing Practices, construction products, etc. Given the EEA example, the Swiss have aligned the relevant legislation. Its technical infrastructure is world standard and its standardisation bodies are long-standing members of CEN, CENELEC and ETSI. The Swiss Accreditation Service is a member of the EA. A parallel but identical MRA has been concluded with its three EFTA partners in the EEA. One can safely conclude that the EU – Swiss MRA is the widest and most ambitious one in the world, based on alignment with EU rules.

56. Algeria, Egypt, Israel, Jordan, Lebanon, Morocco, Palestinian Authority, Tunesia; South East European countries: Armenia, Azerbaijan, Belarus, Georgia, Moldova and Ukraine.

57. However, many of these directives have meanwhile been revised or turned into EU Regulations, with some amendments. The 1997 Decision needs to be revised and modernised.

58. Official Journal EU of 30 April 2002, L 114.

In conclusion, the EU has concluded temporary MRAs with candidate countries, and is, early, in the process of concluding MRAs with 'neighbourhood' countries. Both are what the EU calls 'enhanced MRAs'; that is, based on full alignment with EU rules and requirements for the technical infrastructure. In contrast, with other third countries, the EU has concluded what it calls 'traditional MRAs', that is, without alignment. The two special cases are Turkey (within the framework of the customs union, Turkey is approaching 'free movement' but the exact status of this progress is hard to assess) and Switzerland (where legally one can speak of a MRA because the free movement clauses are lacking, but in practice the extensive alignment and excellent technical infrastructure, as well the application of much of internal market law inside Switzerland, result in a de facto situation which is hardly different from the EEA in industrial goods.

Annex 2

Australian and Trans-Tasman experience with mutual recognition

Introduction

There are two MRAs in Australasia (one an intra-Australia MRA and one involving Australia and New Zealand).[59] One is the Australian 'Intergovernmental Agreement on Mutual Recognition' (usually abbreviated as MRA) for the states and territories of Australia together with the Australian Commonwealth (basically, the federal government); the other is the 'Intergovernmental Arrangement Relating to Trans-Tasman Mutual Recognition' (TTMRA). Both are very similar though not identical. The principal reason why their abbreviations are misleading in the context of the present report is that the two agreements are not focused on conformity assessment, but on mutual recognition of regulations and standards for goods (including conformity assessment) in a horizontal fashion.[60] In this respect, they are reminiscent of the EU internal market for goods. However, both context and their mechanisms differ from the EU. Australasia has shown convincingly that mutual recognition (in goods) can be successfully pursued in ways to some extent different from those of the EU. At the same time, it should be acknowledged that it will be exceedingly difficult for other countries to imitate this model of mutual recognition, due to the context as well as its ambition.

Why mutual recognition in Australasia is 'out of the box'

In the literature, a host of factors has been suggested as being 'behind' the TTMRA (and, a fortiori, for the Australian MRA).[61] A non-exhaustive list includes the following: (i) some of the success factors of MRAs in the narrow sense of conformity assessment only, as listed above, apply here, to begin with [a sound regulatory infrastructure, sufficient volume of trade in goods, underlying compatibility in the regulatory systems of the partners]; (ii) the sharing of an existing bilateral platform, in this case the Closer Economic Relations (CER) agreement from 1983; (iii) the countries enjoying a consensus on wider geopolitical and macro-economic issues; (iv) similar high level of economic development; (v) similarity in cultural and historical background, including the shared common law heritage. In addition, both countries use internationals standards whenever available, unless plainly unsuitable. As emphasized time and again by New Zealand and Australia themselves, there is a high level of mutual trust, a critical condition for mutual recognition (although perhaps not sufficient in and by itself). This long list of favourable factors already makes the relationship between the two neighbours rather special.

Still, one might ask the question whether the two other instances (except for the EU) of closely related developed countries deepening their market integration in goods are really so different from Australasia. One is the European Free Trade Area (EFTA). EFTA never went beyond a classical FTA, until the EU in the late 1980s offered it to 'join' its deeper internal market, but on the terms and laws of the EU: either as full EU members (and Austria, Sweden and Finland did join in 1995) or in the European Economic Area (as Norway, Iceland and Liechtenstein did) which meant that the internal market for goods (and services, capital, but with agriculture and fisheries kept outside) would fully apply.[62] When Switzerland voted against the EEA in 1992, it nevertheless negotiated a chain of bilaterals with the EU having the practical effect of very deep goods market integration. This suggests

59. The two MRAs and a Users' Guide to both can be found at www.coag.gov.au.

60. The MRAs also cover the mobility of workers in registered occupations, which is not discussed here.

61. E.g. Australian Productivity Commission (2009), Churchman (2013), WTO 's triennial review (2003).

62. For details on the EEA and many illustrations in annexes, see Pelkmans and Boehler (2013).

two inferences. One is that EFTA, which fulfilled almost the same conditions as Australasia,[63] did not desire to 'deepen' market integration by introducing mutual recognition in any significant way. One suspects therefore that the favourable factors mentioned above for Australia and Trans-Tasman are important but not the full explanation. Economic dominance may also play a role - possibly explaining that smaller neighbours (enjoying the above factors) have strong incentives to align with or mutually recognise rules of the larger partner as it yields effective access to a significant market.

The other case is that of North America. Before NAFTA, there was a brief episode of the bilateral FTA between the US and Canada. This bilateral (largely taken over by NAFTA) was a modern FTA with attention for TBTs and other regulatory aspects. The favourable factors between Canada and the US were similar to those prevailing in Australasia. Moreover, their mutual goods trade (even before the FTA) was absolutely and relatively the largest for both countries. Yet, no mutual recognition was even attempted and almost no regulatory co-operation, let alone harmonisation, was included (although the US and Canada have had many joint private standard committees for decades). The NAFTA treaty in its wake is extremely elaborate (unlike the TTMRA) but contains virtually no regulatory co-operation. The recent bilateral Regulatory Co-operation Councils between Canada and the US and Mexico and the US have been established outside of NAFTA. The factual economic dominance of the US has made no difference apparently. Again, one is left to wonder why more or less similar factors in Australasia have generated mutual recognition in a broad, horizontal fashion.

One has to appreciate two peculiarities of mutual recognition in Australasia which have been given little explicit attention and which might well explain the depth of the agreements and their functioning. These peculiarities set it apart from any other bilateral or regional attempt to provide effective market access without TBTs. The first peculiarity is that the Australian MRA is *inside* a country, even if a federal one. It is known that internal markets of federal countries can suffer from internal barriers and inconsistencies in regulations, be it in different degrees.[64] Therefore, in order to understand the Australian MRA, one has to appreciate the internal market predicament of Australia some 25 years ago. As a simplification, this predicament will be stylized into three elements, based on Walsh (2012) and on Australian Productivity Commission (2009).

First, Australia had long practiced interventionist and protectionist policies, both inside the country between states and territories and externally vis a vis third countries. In part, it could lean on resources exports to maintain a high degree of prosperity. By the late 1970s, early 1980s, however, these policies began to lead to a steady relative decline of Australian GDP per capita. As a result, a call for higher productivity was heard with ever greater insistence. The first response consisted of a hoped-for productivity shock provoked by a sharp U-turn in external protection, even including unilateral tariff reductions. The upshot was that high-cost inefficient business, especially in manufacturing, insisted on drastic domestic reforms, which would enable them to adjust and show higher productivity. Up until today, Australia has pursued a long-term reform agenda, with a view on productivity and prosperity. When in 1990 intra-Australian mutual recognition came up as a new idea, it was regarded as a sequel of these productivity-driven reforms, but now jointly with all the states.

63. It is harder with six or more countries to come to agreement. Moreover, intra-EFTA trade before 1995 was not made easy due to the spread of the small EFTA countries all over Europe, and the stylized fact that, for each EFTA country, commerce with the EU 'next door' was always far more important.

64. In a special study (Anderson, ed., 2012) the internal markets of four federations are compared, together with that of the EU. The chapters on Canada (by Dymond & Moreau), Switzerland (by Cottier & Oesch) and Australia (by Walsh) show how these countries struggle with TBTs and other regulatory barriers inside their internal market, because their constitutional/supreme courts protect autonomous regulatory powers of states/provinces/cantons and because decentralised federalism is strongly supported by voters. The US (by Weiler) tends to show much deeper market integration given the interstate commerce clause (and acceptance of a more centralised federation, with common regulation), whereas the EU (by Pelkmans), at least in goods, is probably more similar to the US than to the other three.

Second, not unlike Canada (see Courchene, 1986; Pelkmans and Vanheukelen, 1988; Dymond and Moreau, 2013), the fragmentation of the intra-Australian internal goods market became a much more sensitive issue for companies seeking to become internationally competitive or at least more productive; they felt that regulatory inconsistencies or TBTs led to waste of compliance costs which made no sense inside a single country. Hence, this was again linked to productivity, and *not* based on what e.g. in the EU would be 'free movement' or in the US the inter-state commerce clause. When Australian states in 1990 committed to co-operative reform programmes, they "(...) all (…) emphasized that there was more economic integration between nations in the EU than between the states in a single Australian nation" (Walsh, 2012).

Third, given a relatively decentralised form of federalism, Australian states as well as the Commonwealth prefer co-operative modes based on voluntarism, even when in actual practice consensus is usually reached sooner or later, and when these joint decisions are legislated in all states or, sometimes, at federal level. For all these reasons, the MRA is called 'intergovernmental' (i.e. between Australian states and territories). However, it is actively combined with harmonisation or uniformity questions. Different mechanisms, reflecting sensitivities in such a federation, are applied in order to do justice to local autonomy, yet having the effect of agreed bottom-up centralisation.[65] As the MRA is seen as a productivity-driven agreement, it should be assessed together with a series of other reforms which were more centralising in rail, road transport, electricity, food standards, state-owned enterprises and competition-related reforms. Moreover, (central) 'reward' payments were made to states achieving certain benchmarks in reforms. Finally, huge, rolling-over programmes of regulatory reform have been pursued, leading to both greater uniformity and less interventionist regulation, in turn rendering the MRA easier to operate. Taken all these aspects together over more than two decades, it is difficult to compare the mutual recognition approach *inside* Australia with mutual recognition *among* countries. And the latter is already very rare, outside the EU.

The second peculiarity is found in the practical operation of the TTMRA. New Zealand and Australia have concluded an 'arrangement', strictly spoken not an 'agreement'.[66] This would seem to suggest, at least formally, that New Zealand and Australia are both voluntarily agreeing, step by step, about whatever initiative under TTMRA or whatever regulatory or other problem which might emerge. It would also suggest that the 'arrangement' is not binding, hence, would be incomparable with, say, the EU internally. Although in a legalistic sense, these conclusions would be correct, they completely miss out how the TTMRA works in actual practice. The TTMRA rests on a comprehensive set of formal and informal agreements, institutions and relationships which are a function of proximity, history etc. but go well beyond these. For example in the goods area it includes relevant provisions in the 1983 CER agreement, the 1988 MOU on TBTs, and Commonwealth, State, NZ ASAQ agreement (1990). In addition, New Zealand has been incorporated in the intra-Australian co-operative mechanisms, headed by COAG (Council of Australian Governments, chaired by the Australian Prime Minister). New Zealand's status in Australia and in the TTMRA's mechanisms is a result of the many favourable factors, mentioned before, but also reflects the long-standing trading relationship with Australia. Their first preferential trade agreement dates back to 1922, and has been deepening ever since, in a period when Australia, otherwise, was protectionist. In the early 1970s, an agreement on two-way labour mobility was even signed, a rare occurrence in today's world. This 'inside' position for New Zealand is unusual in economic co-operation, no matter how intense.[67]

65. Appendix A in Walsh (2012) shows 'referrals' (states refer a matter to the Commonwealth parliament), 'template' legislation (one jurisdiction adopts a law which is then adopted by other state parliaments), 'mirror' legislation (a model law is developed in co-operation and enacted everywhere but with variations to meet local circumstances) and a kind of framework laws.

66. The arrangement could not be signed as a treaty because the parties to it are the Australian states and the states are not able to enter into treaties under the Australian constitution.

67. One might compare it with the position of the three EFTA-EEA countries vis a vis the EU. They have no say whatsoever in EU decision-making, only in the early stages of 'decision-shaping' (a term from

One may conclude that the inside position for New Zealand as well as the depth and scope of mutual recognition of regulatory outcomes renders the TTMRA a unique 'arrangement'. It seems implausible to expect that such an arrangement would be literally imitated anywhere. However, other countries contemplating mutual recognition may nevertheless find the TTMRA interesting for other reasons such as the practical effects in markets, the attention given to preserving regulatory sovereignty, the need for safeguard clauses, possible ways of avoiding the heavier EU model, possible routes towards convergence in some areas, etc.

Trans-Tasman mutual recognition

The TTMRA is an arrangement between New Zealand, the Commonwealth of Australia, and each of the States and Territories. The TTMRA may be an 'arrangement', but both Australia (and all its states) and New Zealand have enacted general MRA laws for implementation.[68]

The core of mutual recognition of the TTMRA is based on the argument that "(…) a good that may be legally sold in the jurisdiction of any Australian party may be sold in New Zealand and a good that may be legally sold in New Zealand may be sold in the jurisdiction of any Australian party. Goods need only comply with the standards or regulations applying in the jurisdiction in which they are produced or through which they are imported" (Art. 4.1.1.). It is inspired by the Cassis-de-Dijon mutual recognition case law of the CJEU (as is acknowledged by the signatories). However, it is only one of the two constituting elements of mutual recognition applicable in the EU. The other one is about the 'equivalence' of regulatory objectives. The central difference between the EU and the TTMRA is that, in the latter, the equivalence of objectives is implicitly assumed to be valid, unless there is an explicit clause addressing such concerns. The notion of 'mutual recognition, unless' is basically a 'negative list approach' – as in trade policy. Assuming that the two countries have roughly equivalent safety, health, environment and consumer protection objectives, it follows that all goods fall under mutual recognition, unless explicitly excepted, exempted or excluded. Such an approach would be much harder to apply in a large group of countries and/or a group with a considerable degree of regulatory diversity or disparities in per capita incomes implying distinct risk profiles of citizens/voters. That is precisely why the favourable factors discussed before are critical to the confidence and trust of contracting parties to conclude such an 'arrangement'. Nonetheless, the radical nature of the origin principle contrasts sharply with the regulatory interventionism at various levels in Australia before (say) 1990 or so. It is the pressure to reform in a sustained, semi-automatic and credible way, given the exposure to world trade after unilateral tariff reductions and other openings, which helps to explain why the two countries resorted to such a daring principle.

With the principle being so radical, there are a number of goods or sectors on the negative list. Both the TTMRA and the implementing legislation provide that the mutual recognition principle does not affect the operation of any laws:

- That regulate the manner of sale of goods or the manner in which sellers conduct or are required to conduct their business, so long as those laws apply equally to domestic goods (registration of sellers or occupational licensing and franchise agreements are included under this head).

Jacques Delors). As Pelkmans and Boehler (2013) however point out, this term is mistaken. The three are only involved in 'proposal shaping' (by the Commission) as they have no formal right of access to, or of a hearing by, the legislator (EP and Council). This is a legal(istic) consequence of the EEA being a formal treaty, with two pillars. In contrast, New Zealand, having only an arrangement, can be accommodated in a more practically sensible way, doing justice to the ambition of mutual recognition between the two countries.

68. The New Zealand TTMR Act is available on www.legislation.govt.nz and that of Australia on www.comlaw.gov.au.

- Regarding the transportation, storage or handling of goods so long as they apply equally to domestic goods and are directed at public health, safety or environmental pollution.

- Regarding the inspection of goods so long as not a pre-requisite to their sale, the laws apply equally to domestic goods and are directed to protecting the health and safety of persons or environmental effects.

There are also exclusions about certain laws that cannot be undermined or by-passed: customs controls, tariffs, IPRs, taxation and specified international obligations. There are 11 permanent exemptions including agro & veterinary chemicals, risk-categorized foods, gaming machines.

Five special exemptions initially established for therapeutic goods; hazardous substances, industrial chemicals and dangerous goods including consumer goods; radio communication devices; road vehicles; and gas appliances were converted to permanent exemptions in 2010. There is scope for permanent exemptions to be narrowed or potentially removed over time. An example is the permanent exemption covering risk-foods. Changes in 2011 have resulted in several additional foods coming under the operation of the TTMRA.

There are temporary exemptions which can be invoked by individual jurisdictions but the (joint) Ministerial Council is then required to determine whether a standard should apply and, indeed, which one; with a two-third majority, a common standard must be accepted by all. Individual exemptions were often invoked for consumer products; in fact, curiously, such bans were frequent but the MRA temporary exemption process was not always set in motion, a lack of action which renders the ban unenforceable. The problem became so great that Australia has now moved to a national system of introducing bans for consumer safety reasons. This has also been welcomed by New Zealand, as it would reduce the fragmentation due to many local bans.

There are complaints about the actual functioning of mutual recognition. Co-operation schemes are regarded as heavy and involving administrative, study and reporting costs for many (of the small) states' governments. According to Australian Productivity Commission (2009), regulators do not always apply mutual recognition consistently or appropriately, in particular in the occupations area where they have a more active role. There also seem to be a number of ambiguities and omissions in the Acts of implementation. Finally, the oversight is not well organised and those involved have too few resources. Where enforcement powers do exist, especially with COAG Ministerial Councils, the process is reactive. The Australian Productivity Commission (2009) comprises many illustrations of the benefits, however, more often arising from the intra-Australian MRA than of the TTMRA.[69] When transcending all the micro-issues and regulatory detail, the Productivity Commission's overall judgment is rather positive: mutual recognition is a low-cost decentralised means of dealing with inter-jurisdictional differences in laws and regulations. Based on qualitative data and illustrations, the verdict is that the TTMRA has increased the movement of goods across the Tasman.

69. For instance, a long list in Table 3.1, p. 36.

Annex 3

Case-study: The US/EU MRAs in goods

Why this case?

The US/EU Mutual Recognition Agreement of 1998 was concluded after four years of negotiations, and various regulatory co-operation initiatives in the years before. It is of interest when trying to understand what MRAs are, what the potential benefits (both private and public) and the costs (mainly public) are, what the several challenges are before coming to an actual agreement (especially in the domestic regulatory domain) and how implementation can echo some of the problems of the negotiations. These aspects may well be encountered, although not necessarily in the same way, in a number of other MRAs which now exist. The US/EU case stands out for two reasons:

1. it was the first major MRA (with multiple sectors) and, moreover, between the two biggest economies of the world at that time, also frontrunners in the GATT, so it would be reasonable to expect the two to set a leading example;

2. the US/EU MRAs were quickly imitated in legal technique and style and, to some extent, in sectoral coverage in other continents, due to trade policy activism of both the US and the EU as well as several global business sectors. Indeed, the near-global 'domino' effect of the US/EU MRAs in the late 1990s is a manifestation of the early significance of the North Atlantic MRA.

Hence, it is plausible to expect that studying this case has a much wider relevance for governments and other interested stakeholders when trying to address TBTs in the modern world economy, without affecting domestic regulatory autonomy. The lessons drawn might be applicable for other countries, too.

Preparing MRA negotiations: drivers

The origins of the MRA go back to the second half of the 1980s when the EU began to deepen its internal market with new methods of removing regulatory barriers. The ambition and the speed of what was called "EC-1992" attracted the attention of the US business and policy communities, for fear of a 'Fortress Europe' but also expressing a keen interest to maintain or improve market access.[70] Such attention was anything but surprising because trade and FDI interconnectedness over the North Atlantic had already become profound. During the late 1980s, the US began informal talks about a much closer involvement of the US when preparing EU decision-making on technical regulation and directly in European standardisation. The Uruguay Round was not yet on steam but it was already clear that the shift from tariffs to TBTs and other regulatory barriers would become much more significant.

70. For greater understanding of what EC-1992 amounted to, how 'deep' it was, what type of proposals were enacted and how successful the seven-years internal market programme was, see: Pelkmans (2006), Pelkmans (1994), Sutherland & Pelkmans (1990) and Pelkmans (1991). For a well-informed political economy account, see: Egan (2001).

In Europe itself, EFTA-7 was also confronted with EC-1992. As the EU market was the lifeblood of their economies, not to speak of their multinationals, the dilemma for the EFTAns was: either far-reaching harmonisation and convergence, or, suffering a relative deterioration of market access compared with their competitors in the EU-12 (at the time). The choice was so stark that several multinationals announced that, if EFTA just remained a classical free trade area (FTA), they would engineer a significant shift of investments structurally to the EU. The upshot was that all EFTAns opted for the first choice, at first by negotiating the deepest and most ambitious FTA ever – the European Economic Area (EEA) - which came into force in 1994, and later – for three of them[71] - to become members of the EU.

The menu of options for the US was more limited. The US wanted to avoid a deterioration of relative market access, with the costs of TBTs dwindling inside the EU but not for US exporters. At the same time, harmonisation was not considered as an option. Indeed, for both the EU and the US it was basically a new kind of trade policy: regulatory trade policy. The crux was to come up with a new ambitious design for trade policy making between the two partners. This had to be accomplished amidst the ups-and-downs of bilateral trade policy, often bickering in Geneva and over the North Atlantic while collaborating in the Uruguay Round (Scherpenberg, 2006 and Pelkmans, 1986).

For years, informal talks and small accomplishments (for example, in 1990 a MoU was agreed between the Commission and the FDA on GMP in pharmaceuticals) yielded little.[72] The partners had their own regulatory systems and what was a TBT from the perspective of an exporter, was regarded, by the importing partner, as a natural corollary of the duty to protect SHEC objectives via their regulation and organisation of conformity assessment. In the early 1990s, the US and the EU began to publish annual surveys of market access barriers (to one another's markets) with an emphasis on TBTs and SPS. There was a declared willingness to open up their economies but without much of a link, let alone a structural involvement, of regulators or regulatory authorities.[73] It is against this background that the emergence of the MRA has to be understood.

The first drivers of the eventual MRA date back to the late 1980s and early 1990s, which were hey-days for trade diplomacy, whether in Geneva for the Uruguay Round,[74] or the emergence of APEC (on the initiative of Australia) and its intensification in 1993, the conclusion of NAFTA and the shaping of the EEA. The EU made it clear by the early 1990s that there was no such thing as Fortress Europe in the deeper internal market and that the Commission was mandated to negotiate MRAs.[75] Since market access

71. Sweden, Finland and Austria. Norway rejected EU membership in a referendum in 1994 and Switzerland rejected the EEA option in 1992 but subsequently worked closely with the EU to proxy the EEA for goods in a series of far-reaching bilateral sectoral agreements. Note that EFTA countries were long-standing members of the European standardisation bodies.

72. In 1990, US/EU talks of good intent led to the Transatlantic declaration, without firm proposals.

73. Interestingly, the US/Canada talks for a FTA in the late 1980s did turn out to have some consequences for enforcement at the provincial level inside Canada (e.g. the issue of intra-Canadian beer trade) but virtually no regulatory 'convergence' or harmonisation was opted for. Indeed, also NAFTA, a precursor of much of the Uruguay Round in non-tariff issues, services, etc., did not incorporate harmonisation or mutual recognition. Canada and the US had a tradition of joint private standardisation and the preponderance of the US market for Mexico made it attractive for Mexico to align with many US private standards.

74. The TBT Agreement of GATT was refined, among other things, with respect to MRAs.

75. By a Council of ministers decision of 21 September 1992.

to the post-1992 EU was also of concern to other OECD countries, the EU offered to negotiate with e.g. Australia and New Zealand, Japan and Canada as well.[76]

In 1995 the Madrid EU/US summit set up a New Transatlantic Marketplace. US business leaders initiated a transatlantic business summit to help drive the process of negotiating the MRAs with the EU. Several estimates of cost reduction of the intended MRAs were floated (up to beyond $1.5 billion) and time-to-market gains were emphasized by business as well. There is informal evidence (Devereaux et al., 2006 and Shaffer, 2002) that some business sectors considered the MRAs as an opportunity to also obtain domestic regulatory reform in the US in sectors where it was seen as unduly heavy, slow and costly. With the New Transatlantic Marketplace focusing, inter alia, on the MRAs under negotiation, and given the political attention at the highest political level, European business also became interested. The result was a unique initiative of a CEO-led Trans-Atlantic Business Dialogue (TABD) which often succeeded in formulating common views and positions on technical and sector-specific dossiers (the detailed history of the TABD is found in Green Cowles, 1996 and Stokes, 1996). The TABD exercised firm and consistent pressure to ensure that the motto ought to be 'one standard, one test, accepted everywhere', across the North Atlantic, and in fact worldwide. Business leaders began to lobby in a concerted fashion in Europe and the US. Some lobbying brought concrete results: in the US, for example, the business managed to get Congress to insert a new clause on MRAs and their facilitation in a revision of pharmaceutical legislation in 1997.

The fact that Trans-Atlantic relations were deepening in the run-up to the 1998 US/EU summit in London, creating the Trans-Atlantic Economic Partnership (Pelkmans, 1998), and that EU MRA negotiations with other OECD partners went smoothly, eventually led to the signalling of the MRAs in 1997 and the formal conclusion in 1998 during the summit.

MRA treaty and implementation

Treaty structure and scope

Table 7 gives a summary of the MRA. The 'Framework' (umbrella) specifies the 'conditions by which each party will accept or recognise results of CAPs, produced by the other party's CABs or authorities, in assessing conformity to the importing party's requirements' (Art. 2). This is the purpose of the MRA. Art. 2 clarifies that the objective of such mutual recognition is to provide 'effective market access'. Apart from the pre-amble, 11 main provisions are listed in the top panel of Table 7. Much of it is procedural, e.g. about what designation precisely is, designation procedures, recognition conditions, transition periods for 'confidence building', rules for suspension and withdrawals (of CABs), some administrative provisions and a general one on the preservation of US and EU regulatory authority.

This is followed by six sectoral annexes covering 1) Telecoms equipment; 2) Electro-Magnetic Compatibility (EMC); 3) Electrical safety for appliances (and indeed also for telecoms equipment); 4) medical devices; 5) Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP) for pharmaceutical products; and 6) recreational craft (basically, boats for leisure).

76. As noted, strictly spoken, also with Switzerland. But the Swiss – EU relations with respect to goods are not comparable with the other OECD countries as CEN/CENELEC/ETSI standards are shared anyway and the approximation of laws between the EU and Switzerland (for goods) goes very far.

Table 7. Structure of the EU/US MRA

Framework	
• Pre-amble, emphasising market access, encouraging harmonisation and equivalent assurance • Specifying definitions (e.g. 'designations') • Specifies conditions by which each party will accept or recognize results of CAPs • Transition periods (confidence building) • Designation and listing procedures • Suspension rules of CABs • Idem for withdrawals • Monitoring of CABs • Exchange of information and contact points • Joint committee (plus sectoral ones) • Preservation of regulatory authority • Suspension of recognition obligations	
Sectoral annexes	
Telecoms Equipment	Specification of laws and requirements; CAPs; listing of authorities; designation; subcontracting; transitional arrangement: 24 months.
Electro-Magnetic Compatibility (EMC)	Similar setup as for telecoms equipment.
Electrical Safety	Similar setup as for telecoms equipment; cross-linkages to telecom and EMC. In EU, complete lab assessments under US OSHA procedures (but EU can do on-site visits).
Recreational Crafts	Specification of laws and requirements; scope and coverage; designating authorities; CAPs; transition of 18 months; link with EMC and electrical safety.
Good Manufacturing Practices (GMP) for pharmaceutical products	Pre and post approval inspections; 3 year transition period; equivalence determination at end of 3 years; nature of recognition of inspection reports; transmission of reports; suspension; joint sectoral committee; safeguard clause; appendix with applicable laws; criteria for equivalence in appendix.
Medical devices	Scope (different in EU and US); product coverage (quality evaluation systems; product evaluation; post-market vigilance reports); transition period: 3 years; other aspects similar to pharma GMP; alert systems.

Obligations, general and structural

Art. 3 of the treaty says that the US (EU) 'shall accept or recognise results of specified procedures used in assessing conformity to […] provisions of the US (EU), produced by the other party's CABs and/or authorities'. Once the transition periods have been successfully completed, such CAPs for this purpose assure conformity 'equivalent to the assurance offered by the receiving party's own procedures'. Art. 4 lists all the detailed provisions which follow and adds that the MRA shall not be construed to entail mutual recognition of standards or technical regulations. There is also – besides transition periods, suspension of listed CABs, withdrawal of listed CABs, monitoring of CABs, suspension of recognition obligations – a termination clause.

The sectoral obligations are far more detailed, with specifications of laws and requirements, the enumeration of CAPs and authorities and transition periods. Clauses may sometimes have a meaning that is not easily understood from legal texts. Thus, the subcontracting provision in telecoms in fact reflected a long-standing tradition of US producers to let US CABs subcontract certification to Notified Bodies in the EU. In this way they built up durable trusted relationships. The same is true for leisure boats. Whereas EMC, electrical safety and recreational craft have no appendices and telecoms equipment a minor one, the pharma GMP one has 5 appendices (with the many criteria for equivalence in Appendix 4) and the one on medical devices 2 appendices, but in addition a 21 pages table specifying hundreds of medical devices types under US legislation. The likely reason for this is that, in the EU, medical devices of lower risks classes are under the New Approach with SDoC, whereas in the US the FDA certifies them all; also, the risk classification of such devices differed somewhat between the US and the EU.

The sectoral obligations and the details seem relatively 'light' in the cases of telecoms, EMC and recreational craft, heavier for electrical safety (with OSHA lab assessment procedures) and heaviest for pharma GMP and medical devices. The latter even has a post-vigilance process with reporting, presumably a kind of market surveillance.

Transition periods

The transition periods differ between the sectors due to complexity, the staff and resources needed and the differences in requirements between the US and the EU. There are indications from the literature that these differences also had to do with concessions to regulators which were not so willing. The shortest period foreseen is in recreational craft: 18 months. For telecoms, EMC and electrical safety the period is 24 months, but it ought to be noted that, in electrical safety, this also included lab assessment under OSHA specifications (in the EU, done by EU authorities). Electrical safety (for lower voltages) in the EU is under SDoC, and regulated by the Low Voltage directive and, eventually, market surveillance. Therefore, such lab assessments – and under specifications presumably different from world lab certification standards – do not exist. For pharma GMP and medical devices, the transition period was three years. The success of the tests and experience during that period are a prerequisite for the MRA in these sectors to work.

From treaty to implementation

Implementation issues

Dependent on the sector, implementation of the sectoral MRAs has been relatively smooth, difficult or a stumbling block. Three sectors proved to be relatively easy - telecoms equipment, EMC and recreational craft – although only two Annexes (Telecoms and EMC) are in operation now. The first two had always been central aspects of the MRA from the beginning, and especially telecoms was rapidly turning into a truly global equipment market, based more and more on international standards. In telecoms by June 2001, the US had designated 23 CABs, and 43 for EMC (Shaffer, 2002). The EU had designated a

similar number of CABs for EMC. In 1998 the EU relaxed its rather strict 1992 telecoms equipment directive towards one where SDoCs would be allowed. This meant that the designation of CABs for telecoms equipment had become much less important.

Recreational craft has a simple annex on safety aspects and a short transition period. The need for a MRA in this sector arose from the EU's requirement of certification by a Notified Body; the US Coast Guard, the relevant US authority, already permitted to self-certify recreational craft. However, US exporters did not exercise much demand for US CABs able to obtain certification (on EU requirements); they preferred to continue using pre-existing subcontracting arrangements with EU CABs (probably, Notified Bodies) as they had built up long-run relations.[77] The recreational craft annex has not been in operation since 2006 – after a revision of the EU directive in this area, adding emissions and noise requirements, and thereby moving beyond 'safety' issues, the focus in the annex, in US legislation and conformity assessment.

Matters turned out to be more difficult in electrical safety. The EU saw the electrical safety annex as an imbalanced set-up because US exporters had relatively easy access – in terms of compliance costs and time-to-market – to the EU market given the Low Voltage directive (with SDoCs), whereas EU exporters faced regulatory reviews and approvals by OSHA. But OSHA was unsatisfied by the way the EU filled in the designation procedure: it accepted, without significant review, applications from no less than 15 EU Member States, largely in languages other than English.[78] Once the MRA had been agreed, OSHA insisted to conduct on-site reviews - which for the EU went against the spirit of the MRA - and began asking a fee in October 2000, given the cost burden of the process. In fact, there are signs that there was little actual co-operation in the joint sectorial committee. Perhaps, with a greater degree of willingness and co-operative spirit, the EU CABs could have been capable without any effort to submit applications in English. On the other hand, section VI of the electrical safety annex says clearly that "… CABs from the EC shall be designated by the EC authorities …" and "OSHA shall rely on the EC designating authorities… for conducting on-site reviews at the respective Member States' CABs". OSHA rejected a number of applications on the basis of languages and incompleteness, typically issues that could have been addressed in a properly functioning sectorial committee. This refusal was threatening not only this specific sectorial MRA, and indirectly that of telecoms equipment (as electrical safety plays a role), but the entire MRA for reasons of 'imbalance' and a lack of trust.

On medical devices, the story is little different, only more complicated. Regulatory culture, views on risks and sensitivities about the balance of costs and benefits of (how far) bringing risks down for patients all differed between the EU and the US. In pharmaceuticals the problems were probably even greater. Although the agreement is on GMP, the definitions of the US and the EU are not harmonised in the annex: in Art. 1.3 both definitions have been included, with a clause stating that the parties have agreed to 'revisit' these concepts. The core of the annex is the recognition of the 'equivalence of the regulatory systems of the parties' (Art, 2, called – in the wording of this article itself – the 'cornerstone of this annex'). The three years transition 'aimed' to arrive at this recognition which is closer to an 'endeavour' than to a fully-fledged MRA. The FDA felt that not only did it have to review multiple EU directives and related EU documents but also each Member State's implementing legislation, regulatory structures and practices. Before recognising an EU country's 'equivalence', the FDA required EU countries to engage their officials

77. Shaffer (2002) notes, only UL applied to be a US CAB under this annex but must have lost interest since the Commission Newsletter on MRAs of April 2012 states that no US CABs are designated. See trade.ec.europa.eu/doclib/docs/2012/may/tradoc_149385.pdf

78. Shaffer (2002). There were 11 EU official languages in the late 1990s.

in joint training and joint inspections.[79] All this suggests that the underlying idea of mutual recognition of assuming that other countries also care about the health and safety of their citizens and patients, as a starting point to set up a MRA, was firmly lacking. In addition, in both the cases of medical devices and pharmaceuticals, the agreed confidence building activities were not completed – and were not able to resolve key technical challenges to implementation of the annexes.

The sectorial MRAs after five years

By 2003, three sectorial annexes were operational: telecoms equipment, operational since 14 December 2000; EMC, operational since 14 December 2000; and recreational craft, operational from 1 June 2000 to 2006. Since EMC is of importance for both electrical goods and telecoms equipment, this helped the telecoms sector to some extent, but it meant little for electrical goods.

Electrical safety had not gone into operation due to the tension between the Commission and OSHA. After OSHA's rejection of CABs designated by EU countries, the Commission felt that letter and spirit of the MRA were violated. In May 2002, assertions circulated in the press that the EU was likely to suspend the electrical annex or withdraw from it (Shaffer, 2002). In June 2002 discussions were held on the pharma annex as well. The press suggested that US experts felt the Commission was ambiguous about the annex because it feared that GMPs of individual EU countries would appear to be inconsistent (Shaffer, 2002). The two sides 'agreed to disagree'. Hence, the electrical annex was never made operational (but neither suspended nor terminated) and the pharma one has never come into operation, but regulatory co-operation and information exchange exists (also here, the annex has neither been suspended nor terminated).

Medical devices had seen an extra transition period of 2 years, but in 2003 the entire annex became defunct. Formally it is not in operation and no CABs are designated. The Commission's 2012 MRA newsletter states that regulatory co-operation between the two sides exists and the annex is 'regarded as superseded' by this co-operation. The benefits of a MRA in medical devices are foregone but perhaps this regulatory co-operation (the FDA can and does designate/recognise foreign labs and GMP but on its own, not in a 'mutual' context) might nevertheless reduce the actual costs of accessing the US market for EU exporters.

Two inferences are immediate. First, the MRA of 1998 had failed for one half and was (is) successful for the other half; however, in trade flow terms, the MRA coverage was around 20% of the 1995 total for five sectors (without the recreational craft one), with the EU experiencing a negative trade balance.[80] Second, the EU's attempt to 'balance' the MRA package in the negotiations – so typical for trade negotiators - did not work out: precisely in the sectors brought in by the EU in 1995, and problems eventually led to a failure due to regulatory diversity.

Adding marine equipment

In April 2004 the MRA on marine equipment was formally agreed, as a separate agreement. It is an "enhanced" MRA that involves far-reaching underlying harmonisation. This harmonisation has not been negotiated between the US and EU but within the International Maritime Organisation (IMO). Therefore,

79. Shaffer (2002) quotes a FDA official that the FDA has 'refused to compromise its mission of protecting health for balance of trade purposes' whilst, at the same time, claiming that the FDA received insufficient resources for the additional and costly burden of implementing the MRA.

80. In Devereaux et. Al (2006), 1995 trade flows are provided. On the EU side telecoms equipment exports to the US amounted to around 12% of the total flows for the 5 sectors; on the US side, its telecoms exports amount to 23% of total flows.

the MRA was relatively easy to conclude. Given alignment of both sides with IMO rules, designated products which comply with EU requirements (with certification by Notified Bodies) under the marine equipment directive will be accepted for sale in the US without any additional testing or certification, and vice versa for products conforming with US requirements (certified by the US Coast Guard). The US Coast Guard is in charge on the US side and the autonomous European Maritime Safety Agency (EMSA) is in charge in the EU. Some 49 types of marine equipment are covered.

Regulatory dynamics emanating from the MRA

The new EU MRA policy

The mismatch between many years of efforts and the actual outcome in 2003 led the EU to revise its MRA stance in 2004. This was not only due to the EU/US case. There were other disappointments with MRAs with other countries. For example, with Canada, medical devices turned out to be problematic due to a desire of Canada to have control over CABs in the EU; with Japan the pharma GMP annex is only partially operational since 2004, and the electrical one is formally operational but no CABs seem to have been designated. On the other hand, the five sectorial MRAs with Australia and New Zealand work well, although the amount of trade under them appears to be rather modest.

In a somewhat low-key document[81] the European Commission reviewed its MRA drive since the early 1990s and changed its priorities. The document first reviews the experience with MRAs. The Commission notes that "[c]onfidence building becomes even more difficult where the technical requirements and overall regulatory approach of the two parties differ substantially". "Our experience with the US and Canada MRAs has shown that, despite considerable investment on our side, good will is difficult to obtain in cases where there are substantial differences in the regulatory requirements /approach." Where MRAs have been delayed or implementation was difficult, "… the market has found other ways of achieving the same result in a more efficient way". The last point is of great importance: apparently, subcontracting (under retained responsibility of the CAB of the other party) is more efficient and quicker, not least because in this way well-established exporters can maintain a relationship with CABs on both sides, familiar with their products.

The Commission explicitly considers two alternatives of MRAs: one is direct recognition of foreign CABs [but without, as in MRAs, conceding the *right* of such recognition to authorities of the other party], based on accreditation, in turn supported by network like ILAC and IAF; another is about 'voluntary schemes' such as energy labels promoting energy efficiency[82]. The overall conclusion of the Commission paper is that (i) 'traditional' MRAs without underlying 'alignment' are difficult to both negotiate and implement and that it is "not worth pursuing new negotiations on this type of MRA"; (ii) 'enhanced" MRAs, with such alignment or even harmonisation, offer the best prospects of implementation and trade facilitation. On bilateral MRAs, the Commission holds that "no more 'traditional' MRAs should be concluded with the US" and "no more sectors should be added" but efforts should concentrate on the three MRAs from 1998 which are operational.[83] For Australia and New Zealand MRAs, it is noted that they

81. A Commission Staff Working Paper, not a Commission 'communication'; see SEC(2004) 1072 of 25 August 2004, Priorities for bilateral/ regional trade related activities in the field of MRAs for industrial products and related technical dialogue

82. The Commission notes it had concluded a MRA with the EPA in the US on 'Energy Star' labelling.

83. "Other 'enhanced' type MRAs should be pursued only where… Agencies responsible for implementation are interested (our experience … has been that political agreements cannot guarantee their implementation… when implementation is an independent agency's responsibility").

work well but trade impact is small and the expectation of some degree of regulatory convergence has not been borne out.

Do MRAs and regulatory reform interact?

In international regulatory co-operation, often the hope or expectation is expressed that, once authorities/regulators are confronted with regulatory solutions or systems employed in other countries, there will be, sooner or later, a 'learning effect'. This learning could simply consist of 'familiarisation', hence, lead to a more relaxed attitude when recognizing practices or institutions in other countries (like CABs) or, in a stronger form, to adopt similar approaches via domestic regulatory reform. MRAs are based on the legal and political premise that domestic regulation, its objectives and institutions remain unaffected. But such a starting point need not imply that nothing will actually change.

One can discern two types of regulatory reform linked to MRAs, and derived from the US/EU case: one caused by the MRAs and one affecting the working of MRAs or even rendering them superfluous as alternatives take over. As to the first category, Shaffer (2002) holds that the US/EU MRAs prompted some regulatory reform but that it was primarily the US which felt compelled to do so. The principal reason would be that inside the EU there was much experience of such processes of comparing national regulatory regimes whereas the US was unaccustomed to exposure, let alone to requests to adapt its practices. Three such changes are mentioned in Shaffer (2002): (a) the US has adopted some international standards that mirror EU ones, (b) on two occasions US Agencies have begun to allow private CABs to test and certify inspired by the EU approach and insisted on by US business (in 1998, the FCC began to allow this for telecoms equipment and the FDA began a programme for private testing and certification for most medical devices); (c) coordination and oversight of private laboratories under a new NIST programme, hoping for greater confidence with regulatory officials. One may also argue that the spread of MRAs to other OECD countries at the time would help the EU New Approach flexibilities to become more acceptable elsewhere, which, in turn, would increase the (business and public) pressure on the US to accept further regulatory reform (Nicolaidis, 2000). This seems to be a little too easy because, as noted, Canada and Japan were most prudent on e.g. medical devices and electrical safety, and only Australia and New Zealand (already used to mutual recognition under the TTMRA) embraced the EU model in five sectoral MRAs, without however going for regulatory convergence.

The second type of regulatory reform consists of more or less autonomous domestic reforms which subsequently turn out to affect the MRAs. During the last two decades the issue of regulatory burdens and red tape has been prominent in all OECD countries, if not worldwide. In some cases, reforms reducing red tape or other 'unnecessary' burdens were directly relevant for the operation of an MRA. Linked to the MRAs are EU reforms such as the revision of the telecoms equipment directive in 1998, allowing SDoCs, as well as the EU reform for EMC in 2004 (amending the 1989 directive) no longer requiring third party certification and hence relying on SDoCs. With SDoCs, one way of the two-way MRA is no longer needed. However, this also happened the other way around: in recreational craft, it is the EU which requires third party certification and the US accepts SDoCs. In Canada, for example, third party certification for EMC was abolished in 2003 and because that was already the case in the EU, the MRA in EMC has become pointless. What has not happened is deeper or wider regulatory reform on the basis of imitation.[84]

84. See Quick (2008) for a broader discussion of IRC between the US and the EU and its inability of generating regulatory reform until 2008.

Lessons

MRAs reflect a conscious choice of governments not to engage in regulatory change, and solely focus on reducing transaction costs of market access in case of relatively more regulated products. Both (or more) countries do this not unilaterally but jointly. Lowering transaction costs usually consists of reducing or eliminating duplicative controls/certification and tests, and this, in turn, can be achieved when both governments accept (subject to a safeguard clause only) that the other government has a system which is competent in assuring conformity with the other country's requirements. If this acceptance is lacking and country A in product x insists on direct control, the MRA risks degenerating into a heavy structure for processes that can also be executed *without* a MRA, namely unilaterally. In the case of the US and the EU, the difference in a few sectors can be traced to the combination of a number of factors, including the difficulty in implementing the MRA across jurisdictions and agencies whose independence may not act in the spirit of the MRA.

MRAs are feasible in markets which are less heavily regulated, but ironically, in these cases they are also less needed because alternatives to MRAs (in particular, SDoCs) might serve as a low cost and swift solution. When SDoCs are not permitted, alternatives may nevertheless be used by market players. Thus, in particular large US (EU) exporters with a steady customer base (or as part of a value chain) in the EU (US) have a great interest in durable relationships with CABs. The costs of getting to know their products and the associated risks are lower and communication faster and easier when CABs regularly test their product range or new variants. It might also facilitate the planning of testing which may help time-to-market. In other words, for large and regular exporters there are costs of switching CABs and therefore they will favour subcontracting via 'their' CAB. The practical working of the MRA will then be significant only for new entrants or occasional exporters or in cases of overload. New entrants may well be SMEs, so for them and possibly the emergence of 'new' competitive rivalry, the MRA would still fulfil a useful function.

MRAs in heavily regulated markets are only possible once a considerable degree of alignment has taken place. Medicines and high-risk medical devices are heavily regulated and that may well be justified. Between the US and the EU, however, high-risk medical devices were excluded whereas for low-risk medical devices the FDA was simply unwilling to alter its approach (and control) and for pharmaceutical products 'only' GMP was at issue, be it both with pre- and post-approvals, but even that was an 'acceptance' bridge too far.[85] At the same time, at world level cautious attempts were initiated to come to greater harmonisation for pharma and medical devices[86], such as (similar) data and shorter time-to-market, in which the EU and the US played a leading role. These world fora move extremely slowly and may be read as a sign on the wall that underlying regulatory convergence facilitating a MRA is highly ambitious. The experience suggests not so much that it is impossible (e.g. pharma works with Canada since a few years, and for EU/Israel MRA since 2013) but that MRAs in such sectors are not suitable unless all stakeholders (including regulators) agree beforehand what it will take and that sufficient time is foreseen to evaluate and build trust.

MRAs in other heavily regulated sectors such as cars and trucks, chemicals (including pesticides), metrology and tractors would require far-reaching alignment and presumably common alert systems. However, the transaction costs of market access are high. No cases are known except the partial one on automotive components between the EU and Australia. Also here some international initiatives can be

85. Shaffer reports that Canada was capable of evaluating the 15 regulatory systems of EU countries within the transition period, and this period was shorter than in the US case. Note 221, p. 40.

86. The Global Harmonisation Task Force for medical devices, active since the mid-1990s, and the International Conference on Harmonisation of Technical Requirements of Pharmaceuticals for Human use (ICH), founded in 1989.

noted (e.g. in chemicals [OECD] and cars [UNECE]) but, again, they move cautiously and slow and are still far away from serving as a basis for possible MRAs.

The merits of the US/EU MRAs are partly found in what they accomplished and partly in what they engendered. For the latter there are signs and indications but no hard proof. In an era where the costs of regulation are at issue everywhere and the costs of market access are largely attributable to regulation as well, the US/EU MRA negotiations inevitably led to discussions about the costs and (marginal) benefits of heavier regulation, and about possible alternatives, and not only between regulators. The latter were challenged by trade policy makers, eager to bring results of trade facilitation, and by international business having to deal with duplicative tests and red tape. This may spill-over to political decision-makers and lead to greater legal accommodation, but that is far from certain. In the US/EU case the TABD was a unique move. Its strength consisted not only in the fact that CEOs were running these meetings but that they succeeded, time and again, to assume common positions, also on the MRAs. The TABD also managed to involve top political decision makers in an issue as technical as MRAs. As one can observe in US/EU relations broadly, MRAs have had a kind of crowbar function, as transatlantic co-operation has routinely incorporated many regulatory issues ever since.

The MRAs between the US and the EU have also shown the limitations of this instrument. Despite the unique and powerful TABD, the significant shortcomings in the areas of medical devices, electrical safety and pharma could not be prevented. The US business' hope that the procedures of the OSHA and the FDA could be simplified as a corollary of the MRAs was not fulfilled. There was also a perceived degree of mistrust, which the agreed confidence building activities through the transition period did not manage to overcome. A sectorial committee established under an MRA can only work when the spirit is one of co-operation and the willingness to solve problems as they arise.

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