MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
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Evaluation of conformity assessment mutual recognition agreements and arrangements

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New Zealand Government

1. Executive summary

The Ministry of Business, Innovation and Employment (MBIE) has evaluated New Zealand's conformity assessment mutual recognition agreements and arrangements (MRAs). These MRAs are designed to help exporters and importers by reducing the time and costs associated with obtaining approval for their products to be sold in a particular market. Traditional MRAs (including those considered in this report) involve the recognition of technical competence of conformity assessment bodies in the exporting party to perform conformity assessment to the rules and procedures of the importing party.

This evaluation reviewed the MRAs that New Zealand is signatory to, which cover electrical and electronic products with China, the European Union (EU), Singapore and Taiwan, and a range of manufactured products with the EU. MBIE has done this evaluation to find out how effective the MRAs are for businesses and how well they have achieved their aims. Other types of MRAs, such as those negotiated by the Ministry for Primary Industries and New Zealand Customs Service are not within scope of this evaluation.

The evaluation provided a snapshot and found that there is generally limited trade taking place under the reviewed MRAs, except for the MRA covering medicinal products with the EU. This particular arrangement works well and is delivering benefits to exporters and importers.

The evaluation also found that a lot of trade in products covered by the MRAs takes place with exporters self-declaring that their products conform to the importing jurisdiction's regulations, and third-party or official evidence is not needed to support that. Where supporting evidence is required, in most cases New Zealand and the other trade partner recognise conformity assessment bodies in the exporting jurisdiction that are accredited through 'private' (non-governmental) peer-to-peer networks of international standards and accreditation schemes, for example, International Laboratory Accreditation Cooperation (ILAC).

The emergence of multinational conformity assessment bodies also makes it easier for manufacturers to have conformity assessment procedures performed in the jurisdiction of export, rather than at import, which fulfils one of the aims of MRAs without requiring recourse to a government instrument such as an MRA.

An alternative to MRAs is regulators in the importing jurisdiction unilaterally recognising that the exporting jurisdiction's regulations ensure products are as safe and fit-for-purpose as anything conforming to the importing jurisdiction's regulations. There is potential for New Zealand regulators to adopt this approach more, which would reduce compliance costs for New Zealand businesses.

As a result of these findings, MBIE will:

- continue working with the Ministry of Foreign Affairs and Trade (MFAT) on MRAs and other forms of international regulatory cooperation
- continue working with regulators on how the MRAs fit with regulatory regimes in New Zealand
- consider options for making information about MRAs more readily available for businesses.

2. Introduction

What MBIE evaluated

Mutual recognition agreements and arrangements (MRAs) aim to facilitate trade by reducing the time and costs associated with obtaining approval for products to be sold in a particular market. 'Traditional' MRAs provide for mutual recognition of test results and mandatory certificates for covered products. They enable conformity assessment bodies nominated by one party to inspect, test and certify products to the standards of the other party.

These traditional conformity assessment MRAs do not include mutual recognition of the rules and/or standards underlying the conformity assessment, but rather the outcomes of processes to assess conformity with those rules and/or standards. New Zealand has also negotiated a number of other types of MRAs, for example MPI's Mutual Recognition Arrangement for Certified Organic Products with China, United States-New Zealand Food Safety MRA, and Customs' MRAs. These MRAs were not within scope of this study.

This study evaluated the following conformity assessment MRAs that New Zealand has in place:

China: electrical and electronic equipment and components

Singapore: electrical and electronic equipment

Taiwan (Chinese Taipei): electrical and electronic products

European Union:

- **electromagnetic compatibility**
- **low voltage (electrical) equipment**
- **machinery**
- **medical devices**
- **medicinal products**
- **pressure equipment**
- **telecommunications terminal equipment**

The evaluation aimed to assess the efficiency and effectiveness of these MRAs. It was intended to identify, as far as possible, factors that make it easier or more difficult for businesses to use an MRA, the extent to which MRAs have facilitated international trade and the features of different MRAs that contribute to their success.

How MBIE approached this evaluation

This evaluation was a qualitative analysis, based primarily on interviews and a survey completed in 2015. Feedback was sought from users of MRAs, non-users (businesses trading in the product/market combinations covered by MRAs, but which have chosen not to use them) and potential users (businesses trading in the product/market combinations covered by MRAs, but which do not use them due to a lack of knowledge of the MRAs).

The methods of business engagement were:

- interviews with businesses known to have an interest in the MRAs
- interviews with business sector groups (some of which did their own polling of members)
- a survey of businesses identified as being relevant to the use of MRAs
- distribution of the survey to business and relevant sector groups to disseminate it to their members (such as through e-newsletters and websites). This was to reach other relevant businesses, including those that did not know about MRAs.
- follow-up interviews with some survey respondents.

This was supplemented by interviews with regulators, trade policy and business development agencies, and organisations that are part of the conformity assessment infrastructure (eg accreditation and testing bodies).

No quantitative assessment was done. Experience in New Zealand and internationally shows that it is very difficult, if not impossible, to quantitatively assess the impact of MRAs on trade flows.

3. How are MRAs being used?

3.1. Overview of survey results

Sixty-five responses to the survey were received. Of these, 65 per cent were importers only, 9 per cent were exporters only, and 26 per cent were both importers and exporters.

Overall, use of the assessed conformity assessment MRAs appears to be low. Few businesses indicated that they are using the MRAs and for most that did, it is unclear whether they are formally operating under an MRA. Instead, many businesses appear to be self-declaring that their goods comply with the appropriate regulations and using accredited testing facilities that operate outside the scope of an MRA. In some cases, New Zealand or overseas regulators opt to recognise these compliance measures, although this kind of unilateral recognition is not assured by the MRA and may not be reciprocal.

The exception to this general finding is the medicinal products annex to the EU MRA. This annex is highly valued by exporters, importers and regulators, and is significantly facilitating trade.

Survey respondents cited several benefits from 'using' MRAs, including lower certification or testing costs, time saving (eg faster time bringing products to market), other cost savings (eg lower indirect overheads), better knowledge of the importing economies' regulatory requirements, and a greater range of products available for consumers.

The survey also found that views on business awareness of MRAs varied, although most respondents thought their industry was aware of them. Few 'users' of MRAs said they found out about them from government. Respondents also said that they would like to find out more about MRAs (eg by putting information on all MRAs in one place). Other suggestions included running seminars on the MRAs, and having articles on MRAs in relevant industry journals or on websites.

3.2. Experience with specific MRAs

China: Electrical and Electronic Equipment and Components MRA (EEEMRA)

The EEEMRA was concluded in 2008 as part of New Zealand's Free Trade Agreement (FTA) with China, and the necessary steps for implementation were completed in March 2014. Although at the time of the evaluation it was early days for the operation of this MRA, its trade impacts had at that stage been minimal. Many of those spoken to in this evaluation did not expect that to change in the near future.

For exports to China, the Joint Accreditation System of Australia and New Zealand accredits certification bodies and the sole accredited certification body is Telarc SAI. The accrediting agency for testing facilities is International Accreditation New Zealand, and two such facilities have been accredited: EMC Technologies for electromagnetic compatibility, and Spectrum Laboratories for electrical safety.

There had been some business interest in using the EEEMRA to facilitate exports to China, but at the time of the evaluation, little or no trade had occurred under it. This is partly because the process for obtaining the Chinese Compulsory Certification (CCC) mark in New Zealand was not well established and therefore potentially too cumbersome and costly due to the initial setup costs.

In the early stages of its implementation, businesses and parts of the conformity assessment system considered that the EEEMRA was unlikely to have much effect on increasing choice and decreasing the cost of imports. This may have changed now that the EEEMRA has had time to embed.

EU MRA

The EU MRA was signed in 1998 and amended in 2012. It gives a legal underpinning to the procedures for designating and monitoring private, third-party conformity assessment bodies. The MRA includes sectoral annexes on:

- electromagnetic compatibility
- low-voltage electrical and electronic equipment
- machinery
- medical devices
- medicinal products good manufacturing practice inspection and batch certification
- pressure equipment, and
- telecommunications terminal equipment.

International Accreditation New Zealand is New Zealand's designating authority under the MRA. There are currently no conformity assessment bodies in New Zealand designated under the MRA, but there are 57 designated conformity assessment bodies in the EU:[1]

Number of conformity assessment bodies within the EU designated under the MRA, by sector

Country	Total	EMC	Low-voltage	Machinery	Medical devices	Pressure equipment	Telecoms equipment
Czech Rep.	**3**	1	1		1		
Finland	**2**	1	1				
France	**11**	3	3	1	1	2	1
Germany	**10**	1	4	4		1	
Italy	**1**				1		
Netherlands	**2**	1					1
Spain	**9**	3	2	1		2	1
UK	**19**	7	5	4		2	1
Total	**57**	17	16	10	3	7	4

It seems there is little or no trade taking place under the sectoral annexes on electromagnetic compatibility, low-voltage electrical equipment, machinery, medical devices, pressure equipment and telecommunications terminal equipment. In some cases, there are no exports of these products from New Zealand. In others, the use of suppliers' declarations of conformity and reports from conformity assessment bodies accredited by International Accreditation New Zealand (which is recognised internationally through its participation in ILAC) is sufficient for market access in the EU, making it unnecessary to use the MRA.

[1] http://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=mra.list&cou_id=554

An exception to this is the medicinal products annex which is being used for both exports and imports for human and veterinary medicines. This annex relies on official inspection services, rather than notified conformity assessment bodies.

For imports of goods other than medicinal products, New Zealand regulators often take a broader approach that achieves the aim of the MRA. This includes the use of suppliers' declarations of conformity for low-risk items, and acceptance of conformity assessment results provided by ILAC-accredited testing facilities (and not only those designated by the EU under the MRA).

New Zealand regulators generally have a high degree of confidence in EU regulators and the EU standards and conformance regime. This confidence helps support New Zealand unilaterally recognising (at least in part) that EU regulations deliver a level of safety at least equivalent to that provided by New Zealand's regime.

Electromagnetic compatibility and low-voltage sectoral annexes

The evaluation found that these annexes are not being used for exports, and there appears to be little business demand in New Zealand for them. This is generally because under the relevant EU directives, exporters can easily trade using suppliers' declarations of conformity.

Most imported products into New Zealand need to be accompanied only by a supplier's declaration of conformity, and any supporting test results do not need to be provided by an accredited laboratory. Higher-risk products must be accompanied by documentation issued by an ILAC-accredited laboratory. Test results from ILAC-accredited laboratories in New Zealand are also widely recognised in the EU however, so it is not necessary to use laboratories that are designated under the MRA. Any requirements for a particular type of testing in the destination country appear to be infrequent and easy for businesses to manage.

In relation to electrical safety, the International Electrotechnical Commission System of Conformity Assessment for Electrotechnical Equipment and Components Certification Body Scheme (International Electrotechnical System) is designed to facilitate trade in electrical equipment. In general, New Zealand regulators check only whether test results are from an ILAC-accredited laboratory or International Electrotechnical System certification body, and not whether they are from one of the small number of conformity assessment bodies in the EU designated under these annexes.

Another issue is that the scope of the MRA may now not be wide enough due to the increase in sophistication of certain goods since the MRA was negotiated. In some areas for example, such as radio communications, a wide range of conformity testing is now required, for example in relation to fire safety, radio frequency performance, human exposure to radiation and even explosive atmosphere safety. This may mean that even if a company worked with conformity assessment bodies designated under the MRA for electromagnetic compatibility and electrical safety, it might still need to make other arrangements for the remaining conformity testing.

Machinery sectoral annex

This sectoral annex does not seem to be applied to trade. However, there may be potential for lowering business compliance costs by reviewing regulatory requirements in this area, particularly around the importation of cranes. Greater awareness of the advantages of the MRA may also lead to different results.

Mutual recognition of conformity assessment procedures for cranes has been replaced by unilateral recognition of EU regulations in New Zealand, but only in a partial way. Design verification of imports must be carried out in New Zealand by a design verifier approved by WorkSafe NZ. This adds costs and delays to the importation of cranes. There may be an

opportunity to consider options to reduce the duplication of regulatory requirements in the future (eg full recognition of the equivalence of EU regulations).

Medical devices sectoral annex

It seems there is no trade under the provisions of this annex.

Class I (low-risk) medical devices can be exported to the EU with a supplier's declaration of conformity based on a quality management system being in place. For higher-risk devices, New Zealand manufacturers exporting medical devices to the EU have their production facilities audited regularly by conformity assessment bodies notified under the EU medical devices directive. The frequency and cost of these audits depend on the class (risk level) of product being produced. Manufacturers know this system and are accustomed to it, and the cost is factored into the cost of the product.

Medical device manufacturers sometimes become audited to European standards by an EU conformity assessment body, even though they do not export to the EU because these standards are high, and are accepted in most markets.

For imports, there is currently no requirement for pre-market approval for medical devices in New Zealand. Medical devices manufactured or imported into New Zealand must be notified on MedSafe's Web Assisted Notification of Devices database to assist with post-market surveillance. Entries on the database are classified according to European risk-based classification guidelines.

European standards are *de facto* adopted in New Zealand. District health boards and most private hospitals require medical device suppliers to provide evidence (through Product Evaluation Health New Zealand, a coordinating body for clinical product procurement) that products have the European CE mark, US Food and Drug Administration approval, and/or are included in the Australian Register of Therapeutic Goods.

Medicinal products Good Manufacturing Practice inspection and batch certification sectoral annex

This sectoral annex is being applied to trade in both human and veterinary medicines. The New Zealand medicinal products sector sees this annex as being very important.

The annex provides for mutual recognition of the results of inspections of manufacturers carried out by the official inspection services of the other party. In New Zealand, these are Medsafe for human medicines and the Ministry for Primary Industries for veterinary medicines. In the EU, they are the Medsafe and MPI equivalent body or bodies in each member state. There is no use of non-governmental conformity assessment bodies.

Human medicines

Pharmaceutical manufacturers are able to export to the EU on the basis of Good Manufacturing Practice (GMP) certification issued by Medsafe. Medsafe GMP certification is accepted in all EU member states, and New Zealand manufacturers can export to any state provided the product is registered there.

The outcomes of this annex are highly valued by the industry and provide significant benefits. For example, all the quality control and conformity assessment procedures done for finished products in New Zealand do not have to be repeated for the country of destination. The manufacturer also does not need to be audited in New Zealand by authorities of destination countries, which saves both money and time. Compliance costs are much higher for non-EU markets.

In terms of imports, the MRA facilitates and speeds up the process of registering medicines in New Zealand. Many pharmaceutical importers in New Zealand are branches of EU-headquartered companies that have manufacturing hubs there, so favour the EU as a source of products.

The New Zealand regulator, Medsafe, maintains a list of authorities in 28 countries whose GMP certifications it will accept.[2] This comprises authorities in most (though not all) EU member states, and some other countries where regulators are members of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Convention Scheme. It may also recognise manufacturers' GMP credentials on the basis of its own audit, and in recent years it has audited production facilities in several other countries.

Veterinary medicines

The MRA allows veterinary medicines to be exported to the EU without further testing or approvals. The EU MRA also facilitates access for New Zealand exporters to some other countries, which recognise approval for export to the EU as sufficient to meet their own regulatory requirements.

Businesses highly value the way the MRA facilitates exports to the EU for these products. There is never any re-inspection of testing in the destination country and, in recent times at least, EU authorities do not appear to have ever carried out (joint) inspections in New Zealand, despite being entitled to.

In terms of imports, the MRA provides a solid, legal basis for facilitating veterinary medicine imports from the EU. The Ministry for Primary Industries recognises EU GMP certificates, which it requires as part of product registration. The vast majority of veterinary medicines used in New Zealand are imported. Importers of veterinary medicines highly value the ability to import products on the basis of EU GMP certificates. One importer surveyed commented that it is "vital to the trade."

Pressure equipment sectoral annex

This annex is not being used for exports but it seems there is no export interest in this sector in New Zealand.

For imports, New Zealand unilaterally recognises EU conformity assessment procedures for some products but this is not being done under the MRA. Any EU conformity assessment body recognised by WorkSafe NZ can sign pressure equipment declarations and affix its notified-body number for CE-marked vessels imported into New Zealand, not only those designated under this annex.

Separate design verification for seismic resilience is still required to be done in New Zealand for vessels over one tonne or one metre off the ground.

Telecommunications terminal equipment sectoral annex

There is no trade taking place under this annex. Some of its references are also out of date, so it is no longer current.

Products intended to be connected to the public telephone network in New Zealand must be approved by Spark (referred to in the annex by its former trading name Telecom), which acts as a regulator for the annex. Approval is given through a 'permit to connect' which allows the Telepermit mark to be applied to the equipment. The first stage in certifying a product as fit for

[2] Medsafe (2018) *Guidelines on the regulation of therapeutic products in New Zealand. Part 4: Manufacture of medicines* (draft) http://www.medsafe.govt.nz/regulatory/current-guidelines.asp

being connected to the network is to have it tested by a recognised testing authority against the appropriate 'permit to connect' specification and other relevant standards (eg for electrical safety, electromagnetic compatibility and radio transmissions).

In principle, Spark relies heavily on international or European telecommunications standards to avoid the need to develop New Zealand-specific standards. These international standards are developed by the International Telecommunication Union Telecommunication Standardization Sector and the European Telecommunications Standards Institute. Where there are significant differences between the New Zealand and European networks, Spark does develop some unique specifications. Spark also recognises conformity assessment procedures carried out by a testing facility that is not designated under this annex.

Singapore MRA: Electrical and Electronic Equipment

The Singapore MRA is seldom, if ever, used. For exports, businesses have reported few market access issues with Singapore. In this type of market (and other Southeast Asian markets – Taiwan and Thailand were cited as similar examples) regulation is light, and access is easy by demonstrating conformance with New Zealand regulatory requirements or the standards of other countries. Singapore does accredit laboratories in Singapore for exports to New Zealand, but we are not aware of any products having been imported into New Zealand relying on the MRA.

One of the regulators surveyed cited an example of when the Singapore MRA added value. There was an informal agreement between Singapore and New Zealand (both before and after the MRA was signed) that Singapore would use New Zealand certificates as a basis for issuing the Singapore electrical mark. When Singapore was negotiating an MRA with Japan, Japan requested that Singapore shut down its informal arrangements. Singapore agreed to this, and a New Zealand exporter found its trade to Singapore stopped for several months. New Zealand officials were able to rely on the MRA to get a test laboratory accredited and trade eventually resumed.

Taiwan MRA: Electrical and Electronic Products

There was little awareness of the Taiwan MRA among policy and business development agencies, conformity assessment organisations or businesses. No bodies have been accredited under it, and no business is known to have used it. Businesses have reported no market access problems with Taiwan. There seem to be no imports from Taiwan that require certification as provided for under this annex.

4. Analysis, discussion and conclusions

4.1. Benefits of MRAs

The limited use to date of the MRAs evaluated in this report suggests that they are providing only a small direct benefit to New Zealand business and consumers, except for the medicinal products annex to the EU MRA. In general, any trade effects of MRAs reported by businesses were minimal, and attribution was weak or non-existent. Furthermore, some benefits attributed to MRAs actually arise from unilateral recognition by New Zealand regulators of conformity assessment procedures in other countries, or of other countries' regulations as providing equivalent safety to New Zealand regulations.

While limited trade is taking place under the EU MRA, there is some value in this MRA because it:

- avoids the cost of overseas authorities auditing New Zealand manufacturing plants
- avoids the cost and delays incurred by inspection and re-testing in the export market
- avoids duplicative animal testing, which could create ethical concerns and affect consumer perceptions of the products involved, and
- provides an assurance, with the status of international law, that the results of 'private' conformity assessment procedures (and official assurances) will be accepted by both parties' regulators.

It could be argued that by establishing and building confidence between regulators, MRAs can support unilateral recognition of the parties' regulations, reducing costs for importers. While this is the case under some of the sectoral annexes to the EU MRA, New Zealand regulators also have enough confidence in some overseas regulators to allow unilateral recognition even in the absence of MRAs. This occurs particularly for countries with regulatory systems that are sufficiently similar to New Zealand's (eg Canada and the US), and where recognition is supported by peer-to-peer networks such as the Pharmaceutical Inspection Convention Scheme. However, while this benefits importers and consumers, it does not benefit exporters as this is not reciprocated in the same way as occurs under an MRA.

MRAs can also provide an easier means of resolving trade impediments than are available through the World Trade Organisation (WTO). A good example of this was under the Singapore MRA, which was used as an alternative means of providing conformity assessment when informal arrangements between New Zealand and Singapore regarding the use of New Zealand electrical safety certificates were shut down during Singapore's MRA negotiations with Japan.

MRAs also provide for consultations within a joint committee about the application of the arrangement or agreement, including the designation or suspension of conformity assessment bodies. Where an MRA is associated with a free trade agreement, the more formal consultation and dispute resolution provisions of that agreement can also be applied. Both approaches can be much more straightforward than raising issues in the Technical Barriers to Trade committee of the WTO, or seeking recourse to the WTO dispute settlement procedures.

Indirect benefits of MRAs

Lowering costs for businesses has not been the only objective for negotiating MRAs. Other reasons have included building a stepping stone to closer bilateral regulatory cooperation, supporting regulatory cooperation work in plurilateral and multilateral bodies, adding value to an FTA, and acting as a practical expression of the parties' WTO obligations. For example:

- New Zealand's MRA with the EU helped demonstrate the credibility of New Zealand's conformance infrastructure. It also helped establish accreditation-based schemes as the prevailing international approach to demonstrating the competence of conformity assessment bodies.
- The Singapore MRA was a sectoral annex to the New Zealand–Singapore Closer Economic Partnership. It provided an additional outcome to an FTA with a partner that already had zero tariffs.
- Negotiating the Taiwan MRA complemented cooperation on standards and conformance between the two economies in APEC. As part of its accession to the World Trade Organisation, the MRA was also useful for Taiwan to show that it could implement WTO provisions on technical barriers to trade beyond the TBT Agreement.
- While the EEEMRA with China followed a pattern of negotiating electrical and electronic MRAs, the form and operation of this one was very different. It reflected New Zealand's desire to try and implement as comprehensive an FTA as possible. The MRA was also seen as a prototype for further MRAs with China and was a catalyst for extensive engagement and regulatory cooperation between MBIE and the relevant Chinese counterpart organisation, AQSIQ.

Assessing how well some of these indirect benefits have been achieved is difficult. There is evidence that MRAs have built mutual confidence in regulators and regulatory systems. However, the MRAs have not yet been replicated in additional sectors. Furthermore, their demonstration effect in plurilateral forums like APEC and ASEAN does not appear to have been strong.

4.2. Costs of MRAs

There are a number of costs associated with the negotiation, implementation and maintenance of MRAs, particularly for government. For example, negotiating an MRA requires considerable policy, technical and diplomatic resource. Once the MRA has been concluded, further policy and technical work may also be needed to bring the MRA into effect.

Ongoing maintenance of an MRA is needed for it to remain effective and relevant to business. Periodic meetings or consultations between the parties are needed to ensure MRAs stay relevant and technically current. If this does not happen, MRAs can become outdated and the actions of the regulators out of step with an MRA's provisions. An MRA may also lose its profile and becomes less well-known among businesses.

There are also costs to firms before they can take advantage of an MRA. This is mostly associated with accreditation and certification, particularly where an MRA has unique procedures such as under the China EEEMRA.

4.3. Features of more (and less) successful MRAs

An aim of this evaluation was to identify what factors make it easy (or difficult) for businesses to use MRAs, and the features of different MRAs that contribute to their success. The low awareness and limited use of MRAs means there is insufficient data to address in detail the question of what makes a successful MRA. However, some observations can be made about features that may encourage use and non-use of MRAs, and features that may make use difficult.

Features of MRAs that influence usage

Based on the MRAs reviewed, the following factors may influence the extent to which MRAs are used, and their effectiveness:

- Whether the MRA provides tangible reductions in costs or processing times (such as avoiding the need for re-inspection or retesting in the destination, or audits of manufacturers by regulators in the importing jurisdiction)
- The number of accredited conformity assessment bodies or approved factory inspectors that can support the operation of the MRA
- The level of awareness by regulators and/or businesses of the MRA
- The extent to which the MRA is based on international standards or (conversely) is subject to specific testing or accreditation requirements
- Whether New Zealand regulators regularly review the MRA to ensure it is technically current and relevant to businesses, and ensure that their own internal procedures reflect the current state of the MRA
- The level of ongoing engagement with business in support of these actions
- Whether New Zealand regulators have unilaterally recognised overseas conformity assessment bodies
- Whether the regulators from both jurisdictions have recognised the equivalence of regulations in the exporting jurisdiction.

Possible future MRAs

The general features noted above may influence whether any future MRAs are successful. The most appropriate features of an MRA however will depend on what the specific regulatory barriers or problems are in a particular market. Once these are identified an MRA can be developed to address specific needs.

Before deciding whether to negotiate an MRA incorporating any features however, the likely benefits and costs of the MRA need to be considered, and whether the trade-facilitation aims can better be achieved by other means should also be taken into account. The feedback gathered in this evaluation suggested that governmental arrangements such as MRAs are most helpful in highly-regulated or newer/developing markets.

4.4. Alternatives to MRAs

There are two main alternatives to MRAs: voluntary (non-governmental) conformity assessment arrangements or networks, and unilateral recognition of conformity assessment outcomes.

When New Zealand began to negotiate MRAs in the late 1990s, voluntary (non-governmental) conformity assessment arrangements were just starting to develop. For instance, the International Laboratory Accreditation Cooperation MRA was signed in 2000 – two years after the New Zealand-EU MRA was concluded, and the same year the Singapore MRA was signed. Organisations that are part of the conformity assessment infrastructure in many countries have since formed extensive, voluntary, quality networks that are based on International Standards Organization (ISO) or International Electro-technical Committee (IEC) standards for such bodies, and on peer review.

These networks both support MRAs and supersede them. Voluntary networks support MRAs by providing regulators with assurances about the reliability of their conformity assessment processes. However, voluntary networks are now so extensive and respected that a significant amount of trade takes place using conformity assessment bodies that are members of the

networks, outside of any governmental MRA. However that in a number of New Zealand's markets, these voluntary networks are not sufficient and governmental agreements are required.

The second main alternative to MRAs is the unilateral recognition of another jurisdiction's conformity assessment procedures or declarations of conformity. New Zealand is a small country remote from markets and, in some sectors, mainly dependent on imports. In many product areas covered by MRAs regulators have adopted a pragmatic approach: the use of supplier's declarations of conformity for low-risk items, and acceptance of evidence of conformity assessment provided by any ILAC-accredited laboratory. In other areas, there is (partial) recognition of EU regulations as delivering equivalent outcomes to New Zealand's. Unilateral recognition by New Zealand regulators (where there is confidence in the exporting jurisdiction's regulatory regime and accreditation of conformity assessment bodies) can provide a least-cost way to meet New Zealand's aims that products are safe and fit-for-purpose. However, this approach only benefits New Zealand importers and consumers, and not New Zealand exporters unless it is reciprocated.

4.5. The future

This evaluation provided a snapshot of how these MRAs are being used, and what benefit they bring to businesses. It is an initial step, and the information gathered will be used to help MBIE decide where to allocate resources in future — for instance in developing existing MRAs, negotiating new MRAs, developing other forms of regulatory cooperation as a way to facilitate market access and reduce business compliance costs.

In building on this evaluation, MBIE will discuss the findings of the evaluation and possible responses with relevant regulators (Medsafe, the Ministry for Primary Industries, Radio Spectrum Management unit of MBIE, and WorkSafe), relevant industry bodies, and MFAT and New Zealand Trade and Enterprise.

In the longer term, MBIE will:

- continue working with MFAT on MRAs and other forms of international regulatory cooperation
- continue working with regulators on how the MRAs fit with regulatory regimes in New Zealand
- consider options for making information about MRAs more readily available for businesses.