TREASURY WORKING PAPER 01/01

Regulatory Harmonisation - Issues for New Zealand

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ABSTRACT

This paper discusses aspects of harmonisation of regulatory structures (occupational, product approval etc) between jurisdictions.

The primary focus is on trans-national arrangements, but many of the issues also apply to relations between central and regional/local government, and between regional/local governments.

The paper addresses a taxonomy of harmonisation approaches, who to harmonise with, how far and in what areas, and a range of implementation issues, before reviewing some relevant EU examples, outlining existing trans-Tasman regulatory relationships and current trans-Tasman harmonisation proposals, and noting some issues relevant to local government. It does not address wider economic integration issues or currency or political union.

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EXECUTIVE SUMMARY

This paper attempts to codify some of the issues involved in regulatory harmonisation. It is intended more as a common reference than as an attempt to "solve" the complex underlying issues.

Harmonisation tends to be driven by both ideological and economic arguments, and opposed on the same bases. Arguments of certainty, cost savings and critical mass are countered by national or regional identity, subsidiarity and reduced diversity, to name only a few of the grounds used.

One way of categorising the different approaches to harmonisation is by depth (internal, unilateral, mutual or joint decision making) and range (how harmonisation varies in depth over mechanisms from policy making through standard setting, enforcement and appeals). This approach highlights the varying difficulty of harmonising different mechanisms and the strains created by inconsistent depth of harmonisation in a particular sector.

Key issues in designing a sustainable regime include who to harmonise with, where to harmonise first and how far to go, requiring a framework for evaluation including a clear definition of goals and a firm target of an efficient and effective regulatory regime.

Those choices should be made before getting down to the detail of implementation, being informed by what is feasible in terms of implementation Key issues include the governance and legal form of any joint bodies, enforcement and appeals arrangements, the location, funding and staffing of joint bodies, and how to manage future rule-making processes.

The EU has a range of powers and decision-making procedures, and some common judicial arrangements, which have achieved a considerable degree of regulatory harmonisation. Which of these can be carried over to a less integrated group of countries or to a bilateral relationship is uncertain.

The 1983 Australia New Zealand Closer Economic Relations Trade Agreement (ANZCERTA or CER) is the most comprehensive trade agreement entered into by either country and among the most complete in the world. It is complemented by a range of existing and proposed joint regulatory arrangements.

The focus of this paper is on trans-national relations, but many of the issues also apply to relations between central and local government, and between local governments.

INTRODUCTION

This paper has been drafted as an initial step to codify some of the issues involved in regulatory harmonisation. It is intended more as a common reference than as a means of "solving" the complex underlying issues, and focuses on economic regulatory regimes (e.g. occupational or product approval rules).

The attached checklist and figure 1 illustrate how complex relationships can become in cross-jurisdictional regulation)[1].

The EU defines "regulatory co-operation" as:

(a) multilateral and plurilateral initiatives for the harmonisation or equivalence of standards, regulatory requirements and conformity procedures, or promoting best practices; and

(b) bilateral co-operation with trading partners in developing technical regulations, standards harmonisation, and regulatory reform.

Harmonisation is not specifically defined in this paper, but rather is used as a broad-brush concept to cover all means of combining or making compatible different jurisdictions' regulatory regimes, or determining where differences are preferable (harmony vs rhythm[2]).

WHY HARMONISE REGULATORY REGIMES?

Reasons For

There are differing motivations between harmonisation proposals, but they tend to reduce to a few common themes:

- Ideological:
    - "common "views" (culture, political systems etc). An example is the similarity of Australia and New Zealand in many ways and the "logic" of "doing things together";
    - the power of ideas (related to the above), e.g. a United States of Europe, the benefits of free trade;
- economic:
    - eliminating the barriers that exist between nations or regions may bring benefits by reducing both transaction costs for businesses and administration costs for government;

      costs of meeting multiple sets of regulatory requirements discourage cross-jurisdictional trading (also weakening competitive disciplines), while developing and administering separate systems is more costly for governments;

[1] These are from the report "Regulatory Co-Operation for an Interdependent World", OECD Public Management Studies, 1994, a comprehensive survey of issues related to this paper.

[2] Wolfe, R. (1999): Regulatory Diplomacy: Why rhythm beats harmony in the trade regime? In Courchene, Thomas J., ed. Room to Manoeuvre? Globalization and Policy Convergence (Montreal and Kingston: Published for School of Policy Studies by McGill-Queen's University Press), 191-238.
http://www1.worldbank.org/wbiep/trade/Std_papers.html

- greater effectiveness of regulation through extending its reach and reducing cross-jurisdictional "leakage": and

- achieving critical mass in R&D, market size etc.

In summary, harmonisation increases certainty of law, ensures similarity of regulatory outcomes, can reduce regulatory competition, reduces costs for transacting in other jurisdictions and increases access to markets.

Reasons Against

There are also of course countervailing arguments. These include:

- sovereignty (for trans-national harmonisation);

Sovereignty (supremacy, self-government) is often a relative rather than absolute concept. It can be seen as ultimate authority in a specified area, but must be compromised to achieve international co-operation. Sovereignty can be seen as overlapping and existing within international regimes – "implicit or explicit principles, norms, rules, and decision-making procedures around which expectations converge in a given area of international relations".[3]

Countries accept restraints on sovereignty when they make agreements, and in particular on accepting joint dispute resolution procedures. Explicit or implicit trade-offs of sovereignty for some form of gain are common. The EU represents a type of extreme in terms of accepting limits on sovereignty in return for a range of benefits

- the need to retain local decision-making, participation and accountability;

- national or regional identity;

National or regional identity is a more nebulous, but sometimes more potent, concept than sovereignty with little certainty about when or how strongly it will come into play.

- subsidiarity – making decisions at the most appropriate level;

- co-ordination costs;

- recognising differences between countries or regions (e.g. flora and fauna biosecurity and biodiversity); and

- harmonisation can ease movement of jobs and workers to other jurisdictions, reduce policy autonomy, create transition costs and tie a jurisdiction into a high cost regime. Also diversity in regulation can help develop better rules.

There are also limits on harmonisation through fundamental constitutional and legal features of each state. and distinct social or political objectives.

It should be noted that the above arguments can overlap; e.g. while retaining local decision-making capacity is an argument **against** harmonisation, the inability to do so can be a strong argument **for** harmonisation.

[3]Wolfe, R. 1999 "Rendering unto Caesar: How legal pluralism and regime theory help in understanding "multiple centres of power", Project on Trends Workshop on Multiple Centres of Power, University of Victoria 13 May 1999 http://www1.worldbank.org/wbiep/trade/Std_papers.html

Also in some cases harmonisation can be forced by external pressures. In these cases, the **how** becomes more important than the **why**.

Globalisation

Another relevant set of concepts revolves around "globalisation" to the extent that it refers to participation in international fora or adoption of international agreements in order to resolve issues of international commons or where cross-jurisdiction enforcement is required.[4]

This can involve groupings of countries on regional or common interests bases to achieve particular goals.

Dealing effectively with globalisation requires:

- internal prioritisation and co-ordination;
- weighing international goals against national goals and legal frameworks; and
- confronting consistency between international credibility and domestic democratic accountability; i.e. giving firm commitments to partners while maintaining the right of domestic stakeholders to have input on decisions.[5]

HOW DO JURISDICTIONS HARMONISE?

Practically, jurisdictions can harmonise:

- *to varying depth:*

  internal= autonomous;
  unilateral = recognition of another jurisdiction's rules without reciprocity;
  mutual = two or more jurisdictions recognising each other's rules;[6] or
  joint = combined institutions.

- *over a spectrum of mechanisms affecting a particular policy area (the set of mechanisms listed below is indicative only and not complete):*

  policy making;
  standard setting;
  enforcement; and
  appeals and dispute settlement);

The ***depth*** of harmonisation (unilateral etc) can vary across the ***spectrum*** of regulatory mechanisms.

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[4] Washington, S. "Globalisation", OECD Observer No.199 April/May 1996, p24-27.
[5] "Globalisation: What Challenges and Opportunities for Governments?", OECD 1996, OCDE/GD(96)64.
[6] Mutual recognition can itself operate at several levels:
- recognition that compliance with one set of rules satisfies all sets;
- agreement that rules must include certain minimum standards;
- limiting freedom to regulate – non-discrimination, least restrictive means etc; or
- agreement on outcome targets for regulation.

"Regulatory Competition or Regulatory Harmonization? A Silly Question?", A, Sykes in Journal of International Economic Law (2000) 257-264.

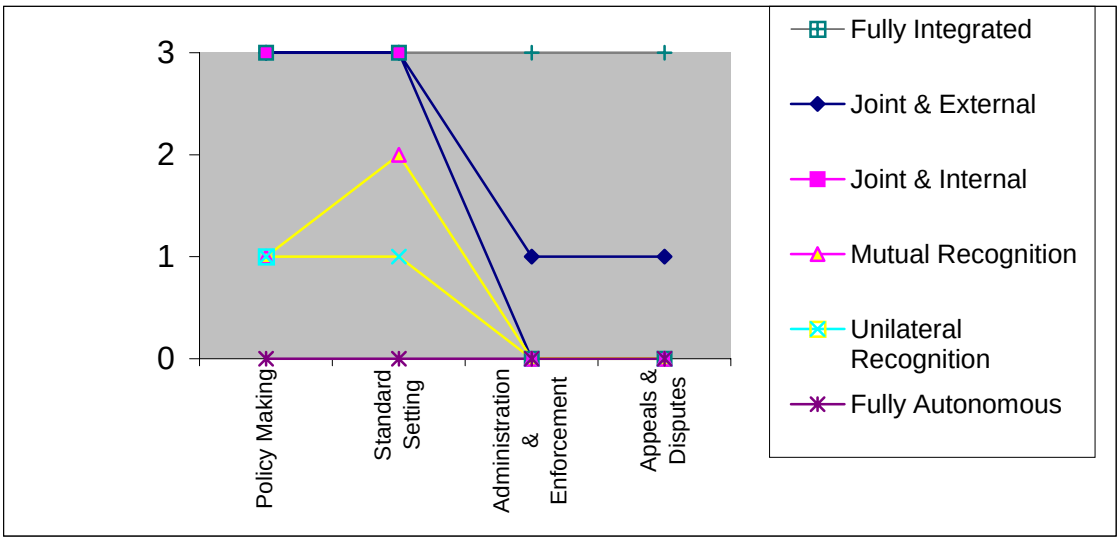
The table below summarises some common structures (using standards as an example) – there is no truly precise nomenclature and names aren't that significant. The margin between structures depends on individual circumstances. Many other structures are possible, combining differing degrees of harmonisation for different mechanisms.

		Spectrum of Regulatory Mechanisms			
Structures for Harmonisation	**Depth of Harmonisation**	*Policy making*	*Standard setting*	*Administration & enforcement*	*Appeals & Disputes*
Fully autonomous standards		Internal	Internal	Internal	Internal
Unilateral recognition of standards		Unilateral	Unilateral	Internal	Internal
Mutual recognition of standards		Internal	Mutual	Internal	Internal
Joint standards – internal enforcement		Joint	Joint	Internal	Internal
Joint standards – external enforcement		Joint	Joint	Unilateral	Unilateral
Integrated standards & enforcement		Joint	Joint	Joint	Joint

The key point is that when looking at what depth of integration to operate a particular mechanism, e.g. standard setting, it is important to consider how deeply integrated are the other mechanisms in the same policy area, and whether those differences matter.

If two jurisdictions set policy internally, mutually recognise standards, and retain internal enforcement and adjudication, what will happen long-term?

The graph below illustrates how the degree of integration varies across the structures in the table above, from "0" for internal autonomy to "3" for joint institutions. The depth of harmonisation tends to decline systematically.



This *variation in the degree of harmonisation across the spectrum of regulatory mechanisms* is likely to arise from differences in the nature of the mechanisms and the incentives of the parties; e.g. it appears that joint standard setting is more acceptable than joint enforcement authorities or courts.

That same variation, however, creates an *inherent tension*. Differences in the degree of harmonisation between regulatory mechanisms dealing with the same subject matter cause inconsistencies in development and application of policies and offer scope for a type of regulatory competition.

This tension then drives jurisdictions towards *greater (or lesser) integration over time* as there are few stable equilibria. To put it another way, once you start moving inertia drives you towards an equilibrium.

One example is a common stock exchange bringing pressure for common listing requirements, securities law etc.

The extreme version of this is the idea that once you take the first step towards harmonisation, full integration is inevitable. Whether this is true (can particular areas be ring-fenced?), and at what speed depends, however, on circumstances.

One example is a joint therapeutics agency between two countries to approve new pharmaceuticals, but national discretion on licensing for sale - pressures would include companies wanting to sell in both countries and easy access to direct importing by tourists.

From a different angle, mutual recognition (an intermediate degree of harmonisation) creates tensions through potential regulatory competition.

HARMONISATION CHOICES

Who to harmonise with?

Criteria might include, but not be limited to:

- similarity and stability of regulatory regimes, and degree of confidence in the other jurisdiction's regulatory capabilities;

  As similarity increases, gains from harmonisation reduce but transition costs reduce as well and economies of scale may be easier to achieve.

- degree of market integration;

  More integrated economies are likely to face fewer shocks from increased harmonisation.

- relative size of partner economy;

  A significant disparity in size will affect the incentives of either jurisdiction – the larger partner has little to gain – and the magnitude of transition shocks.

- similarity of legal system and precedents; and

  Given the greater apparent sensitivity of harmonisation at the enforcement and judicial end of the regulatory spectrum, the less adjustment is required to achieve harmonisation, the more likely it will be to occur.

- cultural issues

  This is the most complicated area to evaluate, and overlaps with issues of national identity. EU experience indicates that it is not necessarily insurmountable.

Naturally existing arrangements also affect the choice of harmonisation partners, with CER being a prime example.

Overall, the more similar the two jurisdictions, the lower the transitional cost will be. At the same time, however, any gains from harmonisation, other than economies of scale, are may well diminish.[7]

Where to harmonise first and how far to go?

This issue will be heavily shaped by particular circumstances. A few useful principles, however, might include:

- a focus on scope for dynamic gains – the potential benefit from dynamic efficiency improvements will often exceed static changes; and

- look at market failures that require cross-jurisdiction co-ordination to effectively address.

Usually the easiest area to begin harmonisation is around the setting of standards and assessment of conformity with standards.

Product standards *outline the features and characteristics of processes, products, services, and materials.*
Process standards *specify systems to ensure product quality is maintained. Standards can be voluntary or mandated. There are numerous national standards-developing bodies and some international organizations. The most established international standards-developing bodies are the International Standards Organization (ISO) and the International Electrotechnical Commission (IEC). The ISO and IEC develop voluntary consensus standards, such as the ISO 9000 series on quality, or the ISO 14000 series on the environment.*
Conformity Assessment *involves product testing, plant inspections, and other procedures to determine if a product conforms to the specifications set forth in a standard and is usually conducted by an authorized third party.*
Product certification *involves written documentation that a product meets detailed technical specifications* [8]

Regulatory heterogeneity can be "good" (arising from honest differences in tastes and incomes and other related factors) or "bad" (arising from chance, indifference, inadequate information or regulatory capture).[9]

Does an ideal world mean complete uniformity or retention of bona fide differences? What are bona fide differences?

Complete homogeneity is not therefore necessarily a desirable outcome, but at the same time not all differences are worth protecting. At a minimum, national treatment might be appropriate; i.e. regulators must impose the same burdens on all firms regardless of where they are based or owned.

Other useful concepts in considering regulatory heterogeneity include:

- policed decentralisation – regulatory independence subject to some constraints; e.g. EU states within Treaty of Rome;

- non-discrimination requirements – national treatment, i.e. businesses must face the same rules regardless of where they are based or owned;

[7] One possible exception is intra-industry trade, e.g. the Canadian-US auto industry.
[8] http://www1.worldbank.org/wbiep/trade/Standards.html#Introlecture
[9] OECD: TD/TC(96)8 Strategies for Increasing Market Access Under Regulatory Heterogeneity.

- the "sham principle" (where the real motive for regulation is protectionist) and the obligation to give reasons for regulatory decisions;

- transparency requirements;

- generality requirements (drafting regulations at the highest level of generality that achieves regulatory goals) and requiring regulators to use the least restrictive means; and

- the role of international standards and standard-setting institutions.

Specific identified differences between the situations of Australia and New Zealand include:

- Commonwealth/State Relations;

- culture;

- differing biosecurity and biodiversity risks – flora/fauna; and

Will foreign standards and testing processes detect that a new substance, plant or species is dangerous to kiwis? Is Britain a useful example of retaining some independent quarantine and other controls within a wider union?

- immigration policy.

EVALUATION OF A HARMONISATION PROPOSAL

While not specifically dealt with in this paper, full cost-benefit analysis of any harmonisation proposal is an implicit assumption.

It is desirable to have a framework that is broad enough to assess any proposal for regulatory integration, while retaining the ability to assess detailed features of a specific proposal.

MED's draft framework for responding to integration opportunities groups New Zealand's goals under: [10]

- CER goals; (broader relationship, mutually beneficial trade expansion, gradual and progressive elimination of trade barriers);

- standards and conformance goals; (WTO TBT & SPS obligations, COAG Principles for Standards and Conformance, APEC Framework for Standards Setting and Regulatory Action, TTMRA)[11];

[10] Possible Framework for Constructing a New Zealand Response to the Opportunity for Trans-Tasman Regulatory Integration – Ministry of Economic Development.

[11] WTO World Trade Organisation
COAG Council of Australian Governments
APEC Asia Pacific Economic Co-operation
TTMRA Trans Tasman Mutual Recognition Agreement

The SPS (Sanitary and Phyto-Sanitary Agreement), in force on 1 January 1995, aims to allow governments to provide an appropriate level of health protection, while ensuring these rights are not misused for protectionism. Measures to ensure food safety and protect the health of animals and plants should be based as far as possible on objective and accurate scientific data. Countries must notify new or changed requirements affecting trade and make known factors considered, assessment procedures and the level of risk determined to be acceptable.

The WTO TBT (Technical Barriers to Trade) Agreement of 1994 covers all technical regulations, voluntary standards and related procedures, except for sanitary or phyto-sanitary measures. Governments may decide international standards are not appropriate for reasons (including include fundamental technological problems or geographical factors(other than scientific assessments of health risks, and may introduce TBT regulations when necessary to meet a number of objectives, such as national security or the prevention of deceptive practices. The agreement includes the principle of national treatment and non-discrimination and exhorts harmonization of conformity assessment through mutual recognition. [12]

- *economic goals*;

  (better living standards for New Zealanders?); and

- *sector-specific goals*

  (these of course vary by sector and would need to be specified in each case).

*For **therapeutics**, sector-specific goals include:*
- *enhancement of public health and safety;*
- *development of therapeutics goods sector;*
- *maintenance of competence and expertise in therapeutics regulation; and*
- *maintenance of public and professional confidence in medicines regulation.*

A number of models may exist for regulatory integration to achieve the above goals, but the one chosen needs to be both the most efficient and effective.

IMPLEMENTATION ISSUES

Once the decision is made to proceed with a particular harmonisation approach, there arise immediately a number of implementation issues. While these may be largely matters of detail, they can have a crucial influence on how the approach functions in practice and set precedents for future harmonisation.

These issues include:

- location, funding and staffing;
- appeal and jurisdiction issues;
- governance, legal form and structure of any joint body; and
- rule-making processes.

Location, Staffing and Funding

For specific examples, it may well make sense to base agencies in the larger jurisdiction or jurisdictions, or in the busiest transport hubs.

[12] http://www1.worldbank.org/wbiep/trade/Standards.html#Introlecture

If joint agencies become common, however, the issue of location becomes a more serious issue in terms of economic impact and employment opportunities. Should this issue be confronted early on?

The employment status of staff is another issue that will grow in importance. There are implications for parity of salary and conditions within an agency, between joint agencies, and between joint agencies and other government entities.

What about continuity of service and pension arrangements? For trans-national harmonisation, while staff will presumably pay tax in their country of residence, should they be employed by one civil service, by either or by both?

***ANZFA** is based in Canberra and staff are Australian civil servants?*

Funding of joint agencies is a critical issue which will be impacted by differences in appropriations procedures and accounting standards, even before considering how funding should be allocated or procurement procedures (presumably non-discriminatory but in practice affected by the location of the agency). This is not insuperable but requires detailed attention in each case.

User funding in some ways offers a "solution" to the funding issue, but requires a common approach to what should be paid by users and strong governance arrangements to deal with the lack of direct public accountability of a joint agency to users in each jurisdiction.

Appeal and Jurisdiction Issues

All the structural options raise enforcement issues, which rapidly become major constitutional concerns for trans-national harmonisation arrangements. In particular the handling of appeals from regulatory bodies carries major uncertainties:

- courts in different countries have varying powers and apply varying interpretations; and

New Zealand has a largely unwritten constitution and uses the Privy Council as its ultimate appeals jurisdiction. Australia has a written constitution which defines the role of courts and no longer uses the Privy Council.

ANZFA appeals are through the Administrative Appeals Tribunal in Australia. An alternative for future regulatory harmonisation would be a joint appeals structure.

- a joint Court approach could have major constitutional problems (e.g. clashes between written or written and unwritten constitutions and access or not to the Judicial Committee of the Privy Council) and potential jurisdictional clashes with national Courts. It is also unlikely to be viable, if at all, until harmonisation was very widespread.

Governance and legal form of a joint body

The legal form of a joint body is an esoteric issue but a vital one for how the body operates. Whether a body is a department, a government entity, a company, a trust or something else has a variety of effects on how it operates and to whom it is accountable.

With joint bodies, particular issues will include:

- allocation of responsibility for regulation-making and for administration/enforcement (i.e. to the same or different bodies;

- who exercises authority over the operations of the body;

- who the body reports to on regulation-making matters and how the regulation-making process operates (including influence over how the regime evolves over time);

- who is accountable to which national parliament or local council for performance and funding; and

- which government's balance sheet must reflect its assets and liabilities.

Structural options for a trans-national joint body include:

- a joint regulatory body with a foreign government, having an identity in both countries - whether established by parallel legislation (which would have to be identical) or by treaty with subsequent enabling legislation;

***ANZFA** is a Commonwealth entity with staff employed as Australian civil servants. The two national governments and eight state and territory governments have equal status in the responsible Australia New Zealand Food Standards Council (ANZFSC)*

- New Zealand participation in an entity created within another country's legal framework.

In the trans-Tasman relationship, is a 2-government model (Australia and New Zealand) preferable to a 10-government model (national and state governments), given relative voting power and extent of possible involvement in domestic Australian debates? If the former, when and where is it achievable?

For trans-Tasman arrangements, treaties may be relevant to the issue of Australian Commonwealth/State competence.

Should a new trans-national joint body be created by treaty with implementing legislation, or by parallel legislation? It is difficult to identify practical differences between these proposals.

In theory, however a treaty is less flexible but at the same time more likely to ensure consistency – passing and maintaining identical statutes in different national parliaments without a binding treaty framework is likely to be difficult.

A treaty approach is the slowest to implement, but carries the highest potential leverage through national government level discussions.

Rule-making processes

Maintaining joint institutions requires some integration of procedures for making and modifying the rules by which those institutions operate.

In the CER context, an example is the COAG and Ministerial Council arrangements in Australia.

Rule-making between jurisdictions raises particularly difficult co-ordination issues, and even more so for trans-national arrangements. The establishment and maintenance of trust and confidence within regulatory networks is likely to be both crucial and difficult.

Ultimately, success will require a degree of joint policy development and decision making (as well as consistent judicial treatment as noted in the section on implementation) which could lead to far-reaching changes in Government procedures.

The implications for organisational structures and networks can be illustrated through the following "Policy Co-ordination Scale" developed in the EU: [13]

9. Overall Strategy
8. Establishing Priorities
7. Setting Parameters for Action
6. Arbitration of Policy Differences
5. Search for Agreement on Policies
4. Avoiding Divergences among Organisations
3. Consultation with Other Organisations (Feedback)
2. Communication to other Organisations (Information Exchange)
1. Independent Organisational Decision-Making

The scale is uni-directional, qualitative and cumulative. It does not relate to an organisational hierarchy, but rather to measuring co-ordination between organisations.

Cross-jurisdiction rule-making also poses particular problems as to how to ensure that non-governmental parties are able to participate in regulatory development as they would in a purely internal process.

SUSTAINABILITY ISSUES

When considering alternative means of harmonisation, a crucial aspect is whether a particular approach is sustainable in the medium to long term, and how it constrains subsequent options. Also, is going it alone sustainable?

The other options available will generally fall into the following categories:

- unilateral recognition of an alternative jurisdiction;
- unilateral recognition of multiple jurisdictions (which may require retention of an internal capability for resolving differences between them);
- participation in a multilateral harmonisation programme; or
- going it alone (this will normally be the status quo).

Which options exist in a particular case will vary depending on technical factors and the existence or not of multilateral fora. Issues that will be crucial to evaluation of their viability include:

- ability to maintain an adequate internal capability given cost and availability of expertise;

[13] "Regulatory Co-Operation for an Interdependent World", OECD Public Management Studies, 1994, p60.

- whether the option requires retention of an internal capability anyway, for its operation or as a backup;

- the viability of providers limited to a narrow market due to differing regulatory regimes; and

- availability of any other potential harmonisation partners.

Once we have relinquished an internal capability, e.g. stock exchange regulation or pharmaceuticals approval, can it practically be rebuilt? If we sign up to a joint arrangement with one jurisdiction, how does this limit our other bilateral or multilateral options?

Is there any long-term difference between the various harmonisation options, e.g.:

- what is the likelihood that mutual recognition would evolve into adoption under pressure of regulatory competition (as noted above);

- sustainability of differing regulatory regimes or philosophies within a common institutional structure – can a single institution consistently develop and operationalise conflicting regulatory approaches?

In considering any particular trans-Tasman integration proposal there would, of course, be a need to determine how it fitted in with the wider direction of CER, and the dynamics of the Australia-New Zealand governmental relationship.

Is it feasible to entrench provisions up front in a trans-national regime that would protect a jurisdiction's interests? Issues include whether another jurisdiction would accept such provisions, and if so insist on comparable neutralising provisions, and whether it is possible to adequately foresee what provisions would be required.

Alternatively, could up-front benefits offset possible later costs? This would depend on negotiating leverage and anyway would only be viable if the provisions could be protected over time. Ultimately, the only real influence over the evolution of a harmonised regime would be through governance arrangements.

In a one-to-one relationship with this could have problems. Leverage might exist where an international treaty relationship offered particular advantages to the other country's government in terms of domestic political or constitutional considerations.

In the end it must be recognised that a joint regime results in a reduced ability to influence outcomes. Whether this is good or bad depends on evaluation of the viable alternatives.

INTEGRATION EXAMPLES

This section covers:

- EU - regulatory strategy and technical harmonisation;

- past and projected Trans-Tasman experience; and

- relations between central and local government.

EU - regulatory strategy and technical harmonisation

EU activities are based on three pillars:

- One: a wide range of policies (agriculture, transport, environment, energy etc) where Commission proposals go to the Council;

  A co-decision procedure between the Council and the European Parliament applies to some legislation (internal market, consumer affairs, education and health etc).

  In most cases the Council decides by a qualified majority vote, but unanimity still applies in some cases (taxation, industry, culture etc).

- Two: Common Foreign and Security Policy; and

- Three: Justice and Home Affairs.

  On Pillars Two and Three the Council promotes initiatives and takes decisions, always by unanimity except when implementing joint actions.

Major EU harmonisation decisions are therefore taken by the appropriate Council of Ministers, mostly by qualified majority voting but in some areas by unanimity.

Primary sources of law are treaties which require national parliamentary ratification. Secondary sources are:

- **regulations** which apply directly;

- **directives** which bind on outcomes but states determine form and means;

The deadline for implementing the Commission's single market proposals was 31 December 1992. In May 1998 almost 20 percent of Single Market legislation (i.e. directives) had still not been transposed into national law in all member states.

- **decisions** which are binding on specific parties; and

- **recommendations** and opinions which are not binding.

Legal cases and appeals are usually handled at the national level as most law is embodied in national legislation, but the Commission can investigate and take action to the European Court, and both the Commission and Member States can take any Member State to the European Court.

European Court rulings are binding and for national issues only one court in one country has jurisdiction unless the national law breaches EU law.

EU regulatory strategy

There are three core questions for EU regulation of the internal market:[14]

- *what to regulate* – EU member states are subject to:
    - a Maastricht Treaty requirement to uphold the market economy with free competition;
    - a monitoring system run by the Commission;
    - a committee that can check and stop any proposed national economic regulation; and
    - judicial review within a context of judicial mutual recognition; and
    - a prohibition on regulating products or services already regulated at EU level;

Competition Policy

*- **Mergers** above a certain EU-wide or worldwide turnover must be notified. The Commission has a month to approve, not it is outside the regime or move to detailed examination. Within 4 months it must then approve, conditionally approve or prohibit with appeal to the European Court of Justice (ECJ)within 2 months.*

*- For **State Aid**, notification is mandatory, the first stage is 2 months, approval or refusal is 6 months, with appeal to the ECJ.*

*- For **Anti-Trust** the firm, the Commission or a third party can initiate action. The Commission can then in four stages (1) drop the case or continue, (2) hold hearings, (3) consult with states and (4) either approve, exempt or fine, with appeal to the ECJ.*

- *at what level to regulate* – two key rules are:
    - whether there is direct assignment to the EU or exclusive powers at EU level in the relevant area; or
    - the subsidiarity test.

***Subsidiarity** - is EU-level regulation indispensable or will judicial mutual recognition and a proportionality constraint at national level be adequate? Subsidiarity does not appear to be strictly enforceable, but is more of a political choice.*

- *how to regulate at the EU level* – proportionality is the key here with implementation and enforcement usually done at national level.

EU technical harmonisation[15]

The Treaty of Rome required approximation of national regulations for the "proper functioning of the common market. From 1969 a detailed timetable was adopted for directives on technical standards and conformance assessments for such standards could be performed by designated bodies in any EU nation.

[14] OECD: TD/TC(96)9 Removing Regulatory Access Barriers – The Case of Deep Integration.
[15] "Regulation of the Single Market", Simon Hix, 1999 in "The Political System of the European Union".

Following limited progress the New Approach to technical harmonisation and standardisation was adopted from 1985 as part of the single market programme on physical (border inspections and customs formalities), technical and fiscal barriers. The Global Approach then sub-divided conformity assessment into a number of operations (modules) with general guidelines and detailed procedures. [16]

On technical barriers the New Approach involved a presumption that differing national standards were different means of achieving the same goals. Differing standards could only be allowed to function as barriers to trade if the least trade restrictive means to a legitimate purpose.

Standards *are developed by organisations such as CEN (European Standardisation Committee) and CENELEC (European Electrotechnical Standardisation Committee). The "CE mark" was introduced for products that met essential European standards.*

Technical harmonisation was to be achieved by EU directives, with detailed specifications and compliance standards left to private standards bodies. The standards were voluntary in that a firm could deviate if a designated body certified compliance with essential requirements.

The New Approach does not apply where Community legislation already existed or where provisions for finished products and related hazards cannot be laid down; e.g. foodstuffs, chemical products, pharmaceutical products or motor vehicles.

EU relevance

The relevance of EU experience to the trans-Tasman situation is not necessarily all that clear. While the types of harmonisation considered are similar, the dynamics of a two-country model may, or may not, be quite different. In particular, with two countries of markedly different size, the largest of which is a federal state with a written constitution, the balance of power may be quite different than with the EU.

Trans-Tasman arrangements – past and future

The 1983 Australia New Zealand Closer Economic Relations Trade Agreement (ANZCERTA or CER) is the most comprehensive trade agreement entered into by either country and among the most complete in the world. There are also a number of more specific trans-Tasman agreements.

Existing trans-Tasman arrangements

Existing trans-Tasman regulatory harmonisation arrangements include TTMRA, ANZFA and JAS-ANZ.

The *Trans-Tasman Mutual Recognition Act 1997* (TTMRA) provides that:

- goods that may be lawfully sold in one jurisdiction may be sold in the other jurisdiction without complying with requirements for composition, performance, quality, labelling, packaging, inspection etc; and

[16] Detailed information is at http://europa.eu.int/comm/enterprise/newapproach/legislation.htm. and http://www.newapproach.org/Home.asp Other relevant sites include:
http://www.eotc.be/ EOTC - European Organisation for Conformity Assessment; and
http://www.european-accreditation.org/ EA, The European Co-operation for Accreditation

- anyone who is registered in one jurisdiction in respect of an occupation may be registered in the other jurisdiction and carry on the equivalent occupation.

A new joint authority, the *Australia New Zealand Food Authority*[17] (ANZFA) was established by the "Agreement between the Government of New Zealand and the Government of the Commonwealth of Australia Establishing a System for the Development of Joint Food Standards":

- to develop an Australia New Zealand Food Standards Code;
- with funding to be provided by Australia and New Zealand on a pro rata to population share of the total agreed cost; and
- appeals to the Administrative Appeals Tribunal and Australian courts.

ANZFA is a statutory authority under the Australia New Zealand Food Authority Act 1991, with a Council of 10 (National and State) Health Ministers: the Australia New Zealand Food Standards Council (ANZFSC), to develop and maintain laws and systems to regulate food in Australia and New Zealand. The Parliamentary Secretary to the Australian Commonwealth Minister for Health and Family Services has executive responsibility for ANZFA, which has a part-time Chairman, a Managing Director and seven other members, two nominated by New Zealand. The head office is in Canberra with another office in Wellington.

In Australia, ANZFA also:

- coordinates surveillance of food available in Australia;
- coordinates food product recalls in cooperation with the States and Territories;
- conducts research on matters that may be included in a food standard;
- undertakes food safety education initiatives in cooperation with the States and Territories;
- develops Codes of Practice for industry on any matter that may be included a food standard; and
- develops risk assessment policies for foods imported into Australia.

The *Joint Accreditation System – Australia and New Zealand* (JAS-ANZ)[18] was established in 1991 to accredit conformity assessment bodies in order to:

- remove the need for multiple audits of certification bodies in the Australian/New Zealand market; and
- assist exports of goods and services to third countries by gaining international recognition of our certificates of conformity.

[17] http://www.anzfa.gov.au/
[18] http://www.jas-anz.com.au/

JAS-ANZ is a not for profit international organisation established under a Treaty. It has no geographic limitations. Accreditation programmes are open to all Certification Bodies whose operations include activities for which accreditation programmes are available. Six members of the Governing Board are appointed by the Australian Government, and three by New Zealand. The Executive Director of JAS-ANZ is the tenth member. The Secretariat is in Canberra.

In 1997 a new Treaty gave effect to a new governance structure, new accountability arrangements and a new liability regime for JAS-ANZ. JAS-ANZ is funded entirely from third parties

Other trans-Tasman agreements include:

- the **Trans-Tasman Travel Arrangement** (TTTA) which allows for free access by New Zealand citizens to travel to and to work and reside in Australia, and for reciprocal access by Australian residents to New Zealand.

- a reciprocal **Social Security Agreement** signed in July 1994, New Zealand and Australia signed.

- the Australia/New Zealand reciprocal **Health Agreement**, signed in 1986, allows Australians and New Zealanders visiting each other's country on a temporary basis to receive "immediately necessary" medical care on the same terms as residents of that country.

Projected trans-Tasman arrangements

Specific areas where trans-Tasman harmonisation is currently under discussion include therapeutics, health and safety, business law harmonisation, triangular taxation and social security. There is also a wider CER review underway.

Therapeutic Goods – a proposal for a joint trans-Tasman regulatory body (established by parallel legislation or treaty) to approve therapeutic goods.

Therapeutic goods include medicines, medical devices and complementary medicines/healthcare products. The joint agency would replace Australia's Therapeutic Goods Administration[19] (TGA) in Australia and New Zealand's Medsafe[20] (in the Ministry of Health).

Public Health & Safety – a major Australian review considering:

- better coordination of regulatory policy, more effective administrative arrangements and greater regulatory coherence;

- from the perspective of both consumers and industry;

- within and between Commonwealth and Australia-New Zealand agencies involved in the public health and safety regulation of therapeutic goods, food, chemicals and gene technology.

Business Law – aligning business law in Australia and New Zealand in parallel with the stock exchange merger.

[19] http://www.health.gov.au/tga/
[20] http://www.medsafe.govt.nz/indexie4.htm

Taxation – proposals to deal with the triangular tax issue.

The triangular tax problem is when a New Zealand shareholder receives dividends from an Australian company that derived income in New Zealand. The shareholder will not receive imputation credits arising from New Zealand tax paid. The same applies to Australians who invest in New Zealand companies with Australian operations This can apply across any border.

Child Support – A reciprocal agreement currently under negotiation, which would enable each country to recognise and enforce the child support assessments of the other.

Relations between central and local government and between local governments

As noted earlier, many of the issues discussed in this paper also apply to regulatory arrangements within countries e.g. in New Zealand to arrangements between regional and territorial authorities and within groups of territorial authorities.

In theory at least, however, central government retains a clearly legitimate over-riding authority which does not normally exist for trans-national arrangements.

Specific issues that relate to local government situations include:

– identifying the appropriate level of government at which regulation should take place;

– jointly making laws or plans, or adopting those made by another jurisdiction;

– establishing joint agencies;

– transferring responsibilities for interpretation or enforcement of legal requirements to another jurisdiction;

– funding of joint bodies or of transferred responsibilities; and

– the merits of regulatory homogeneity vs heterogeneity (e.g, national consistency vs reflecting local circumstances).

PRIORITIES FOR FURTHER INVESTIGATION

Given the status of the discussion in this paper, likely future research priorities include:

- how issues of sovereignty and national or regional identity are managed;
- governance, enforcement and appeal arrangements for joint regulatory bodies; and
- parallels and interactions between trans-national vs national government, central vs local government, and local vs local government relationships.

Annex - Checklist for Regulatory Co-operation[21]

1. *What fundamental communal values or preferences must be reflected in whatever agreement (formal or informal) emerges?*

2. *Are there alternative non-regulatory approaches that, in conjunction with regulatory co-operation could be used effectively to protect these non-negotiable values?*

3. *Have the important costs and benefits, with regard to affected national values, been clearly identified? Are the benefit-cost trade-offs from regulatory co-operation acceptable to the public?*

4. *Would regulatory co-operation contribute wider or longer-term social benefits, beyond the immediate policy objective, such as greater openness or better communication with other governments?*

5. *What are the likely "dynamic effects" on the economy of reduced trade barriers due to regulatory co-operation?*

6. *Is there evidence that the regulatory co-operation will increase the benefits or reduce the costs associated with the specific regulatory programme under consideration?*

7. *Will there be important redistributive effects from co-operation? If so, should disadvantaged parties be compensated to preserve the benefits of co-operation?*

8. *What arrangements will be needed to support the co-operative agreement so as to save money?*

9. *What new negotiating fora and what new institutional objectives, roles, duties and mechanisms will be required to put effective regulatory co-operative arrangements in place and maintain them? Will these be cost-effective?*

10. *Will regulatory co-operation improve organisational learning within the bureaucracy? Has a strategy been developed to ensure that officials both understand the rationale for co-operation and are supportive about making it work?*

11. *What new communications links and participation strategies will be required to ensure meaningful participation by affected and interested parties? In particular, have the potential costs and benefits of regulatory co-operation been adequately communicated to the public?*

12. *Have procedures been developed to ensure an open and transparent decision-making process – a process characterised by "quality" information for citizens?*

13. *Can citizens be guaranteed that if regulatory co-operation does not work in practice, it will be possible to disengage?*

14. *Do potential network partners have in place procedures to ensure that their citizens accept regulatory co-operation?*

15. *In identifying opportunities for co-operation, where are the gains for all sides highest? Where are there few if any interest groups, entrenched bureaucracies or firms which have something to lose? To demonstrate the utility of co-operating with other governments in the development and management of regulatory programmes, early successes are needed. A demonstration of mutual benefit should increase the attractiveness of harmonisation efforts in the eyes of interested and sometimes sceptical observers.*

16. *Are there areas of immediate interest where other governments have significant experience and expertise? Governments should normally look first to international standards and regulatory approaches to see whether they can adopt what is already current practice elsewhere.*

17. *Have rules of behaviour been clearly identified and agreed to by all parties?*

18. *What procedures are available to verify compliance with the requirements of the co-operative arrangement?*

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[21] "Regulatory Co-Operation for an Interdependent World", OECD Public Management Studies, 1994, p110-111.

19. *Have the pressures that have led or might lead to non-compliance of network partners been identified? Can anything be done to relieve or offset them?*

20. *Should sanctions be applied to non-compliance? If not, how will non-compliance with norm be addressed?*

21. *What contingency plans are needed to cope with a breakdown in co-operation?*

22. *Will the approach chosen to ensure compliance appear credible to the public?*

23. *Is the regulatory program flexible enough to permit harmonisation or other forms of co-operation with other governments?*

24. *Are there particular administrative practices (or administrators) in the way?*

25. *Are there specific laws or delegated regulations that should be altered to facilitate co-operation where it makes good sense?*

26. *Can more responsive solutions to regulatory problems be usefully incorporated into the co-operative arrangement?*

27. *What aspects of current regulatory programs duplicate efforts elsewhere? Where can more be accomplished by combining forces with other jurisdictions?*

28. *Where is it difficult to promote the public interest because of the behaviour of individuals, firms or governments in other jurisdictions? Where are such problems likely to be reciprocal, that is, affecting all jurisdictions in the same way?*

29. *Where does it make sense to have regulatory programs managed in whole or in part by other jurisdictions?*

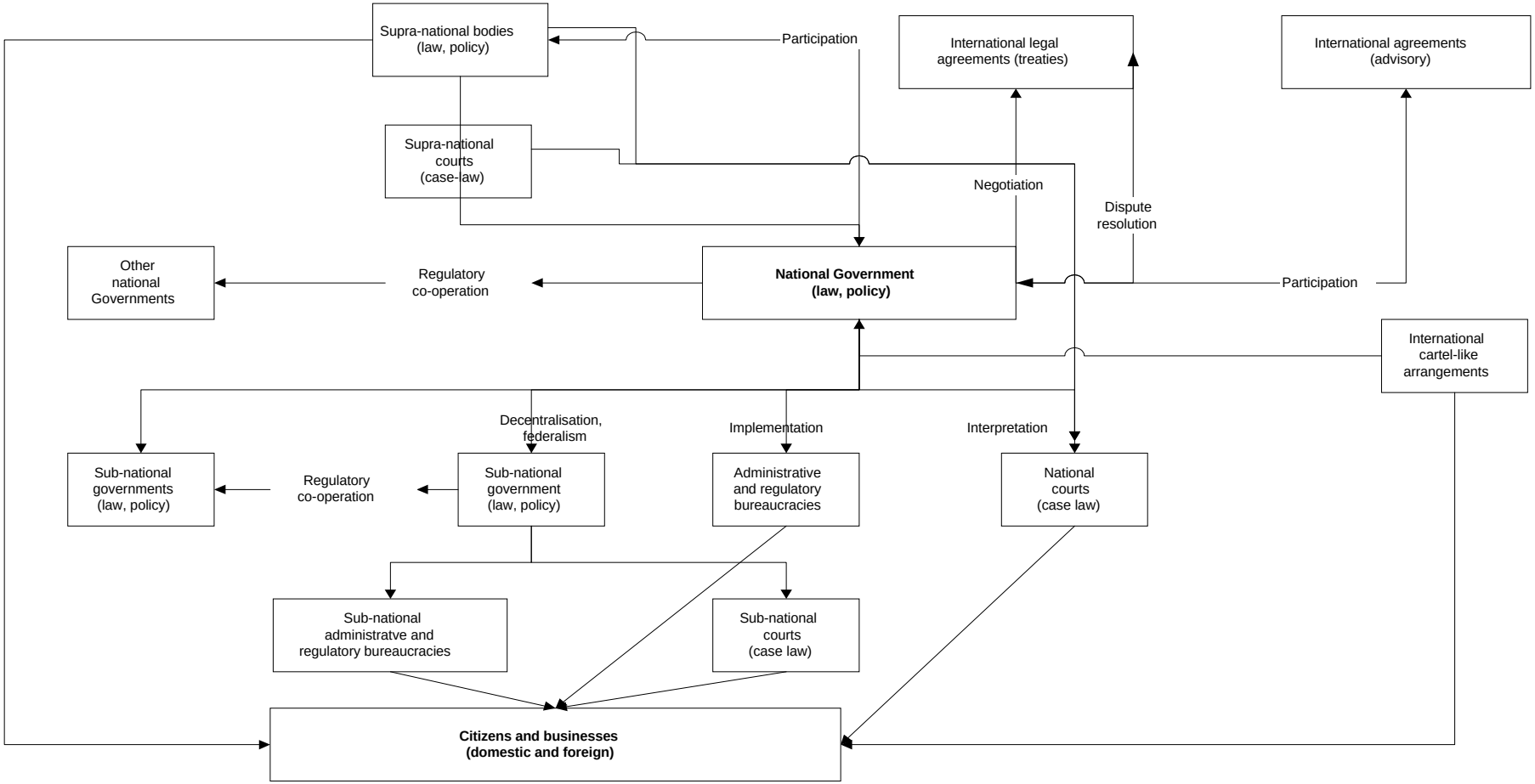
30. *What quid pro quo arrangements, if any, are needed to enter into administrative or formal legal arrangements to delegate authority?*

31. *Do adequate international consensus standards already exist in the area of interest? if no, are trading partners willing to work together to develop them?*

32. *How can one achieve the needed balance between stability and responsiveness to change in arrangements for regulatory co-operation? Has a review and updating mechanism been built into the agreement?*

33. *What conditions are needed to take into account changes in the future (e.g. from new technology)?*

Figure 1 - A Multi-Layered Regulatory System



"Regulatory Co-operation for an Interdependent World", OECD Public Management Studies, 1994, p18