Chapter 4

The need for stronger regulatory governance

Effective regulation to help meet the challenges facing governments will only be achieved through stronger regulatory governance, closing the loop between regulatory design and evaluation of outcomes. This draws attention to a range of issues, including institutional leadership and oversight; reviewing the role of regulatory agencies and the balance between private and public responsibilities for regulation with a view to securing accountability and avoiding capture; a renewed emphasis on consultation, communication, co-operation and co-ordination across all levels of government and beyond, including not least the international arena; and strengthening capacities for regulatory management within the public service.

The regulatory governance cycle

Regulatory governance gives practical effect to regulatory policy. Effective regulatory governance maximises the influence of regulatory policy to deliver regulations which will have a positive impact on the economy and society, and which meet underlying public policy objectives. It implies an integrated approach to the deployment of regulatory institutions, tools and processes (such as regulatory oversight bodies, administrative burden reduction programmes and Regulatory Impact Assessment). Regulatory governance is not a new idea. The OECD published a report in 2002 which advanced the idea of regulatory governance (see OECD, 2002). But the evidence of OECD country reviews since then shows that regulatory governance is at best poorly applied in most countries. The relative failure of regulatory policy to deliver consistently effective regulation so far can be linked to inadequate and undeveloped regulatory governance.

A core challenge for effective regulatory governance is the co-ordination of regulatory actions, from the design and development of regulations, to their implementation and enforcement, closing the loop with monitoring and evaluation which informs the development of new regulations and the adjustment of existing regulations.

Figure 4.1[1] below depicts an ideal state in which the different actions that make up effective regulatory governance are co-ordinated. It highlights a number of points:

- *Policy making is closely linked to rule making.* For much of the cycle the tracks converge, and when they separate (for example, when regulations are enforced and evaluated), they join up again later to inform the next phase of policy making. Policy making may give rise to the initiation of a law (or the amendment of an existing law), although this should not be automatic, as a core part of regulatory governance is to ensure that regulatory options are carefully evaluated before adoption.[2]
- *The application of regulatory policy is a dynamic and continuous process.* Like other aspects of public governance, it is, or should be, a permanent feature of the public governance landscape. Simple lists or principles of good regulatory management can fail to convey this point.
- *Different functions need to be met.* The image of the cycle is valuable for stimulating reflection on the functions which need to be met, and the actors who do (or should) take on these functions. Joining up is not just a matter of processes, but of institutions.

The concept and image of the cycle can serve as a starting point for reflection, both collectively and for each individual country, on what needs to be done to strengthen regulatory governance. Current regulatory institutions, processes and programmes have not necessarily failed as such. But how are they joined up? What are the gaps? What are their weaknesses? What existing regulatory governance models – or their particular characteristics – can be looked to for inspiration? How can the responsible institutions be imbued with a more holistic perspective of their contribution to the public interest?

How does the real world match up to the idealised picture? Three practical observations can be made on the actual state of regulatory governance across the OECD so far:

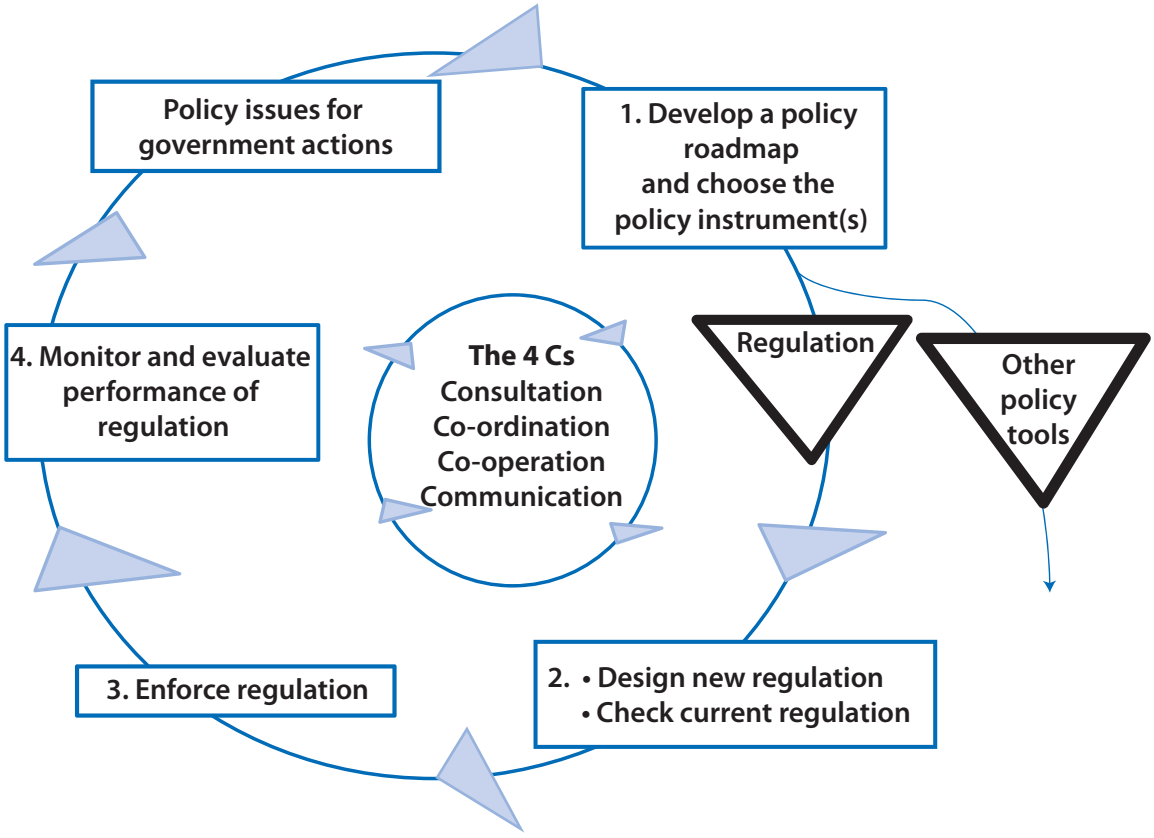
- Countries are, to a greater or lesser degree, failing to close the loop, in other words, failing to make strong connections between the design, implementation and evaluation phases of the regulatory cycle.
- Countries' regulatory policies tend to prioritise certain aspects of regulatory management. Very broadly, the Europeans have, until recently, put more emphasis on regulatory stock management, whilst others have put more effort into the design of new regulation. *Ex post* evaluation – whether of individual regulations, regulatory processes, or regulatory frameworks – is a near universal weakness. No country is strong in all aspects of regulatory management across the cycle.
- There is a widespread weakness in most countries as regards *ex ante* impact assessment of new proposals. Nearly all countries have principles, standards, procedures, criteria and mechanisms for the effective preparation of draft regulations both from the legal and policy perspectives. There is an important task of challenge, co-ordination and supervision to ensure that these principles and procedures are applied, before a final decision is reached on whether to go ahead with a draft proposal.

Ex post evaluation may be the weakest current link in the regulatory governance cycle. Yet evaluation of progress and outcomes is necessary in order to ensure that regulatory governance is delivering on its promises, and to inform the next stage in the policy-making cycle. Evaluation takes several forms:

- the evaluation of individual regulations;
- the evaluation of regulatory management programmes such as Regulatory Impact Assessment; and
- the evaluation of broader policy outcomes which have depended (at least in part) on the presence of an effective regulatory framework.

While it is important to embed the principle of evaluation as an automatic reflex, the approach will need to take account of sensitivities, such as the potential political implications of critical feedback. For evaluation to be well grounded, performance measures will also be required. This is still at an early stage of development in the OECD community. The best placed institutions for evaluation will vary according to the country (and according to the nature of the evaluation). Most countries have not assigned this function to a particular body. It may be useful to build on existing institutions such as audit offices (which already review the efficiency and effectiveness of government spending).

Figure 4.1. The regulatory governance cycle



Source: OECD Secretariat.

Achieving effective regulatory governance

Beyond examination of the component parts of the regulatory governance cycle, there are a number of strategic considerations. These are:

- The issue of overall leadership and oversight;
- The role of regulatory agencies;
- Changing the culture of the administration;
- The need to engage all government players;
- Balancing public and private regulation;
- How to strengthen capacities for regulatory governance;
- The international dimension.

Leadership and oversight

Political commitment to regulatory reform has been unanimously highlighted by country reviews as one of the main factors supporting regulatory quality. Effective regulatory policy should be adopted at the highest political level, and its importance should be adequately communicated to lower levels of the administration. Political commitment can be demonstrated in different ways. As noted earlier, the adoption of a general policy framework for regulatory policy and the organisation of adequately financed training and capacity-building programmes highlight the government's determination to realise the regulatory policy agenda. However, the creation of a central oversight body in charge of promoting regulatory quality may be the most important element to show the political commitment of the central government and to spread awareness about the need for regulatory quality among the different actors involved in the regulatory process.

OECD reviews find a strong relationship between an effective, comprehensive regulatory policy and the existence of a central oversight body. Promoting regulatory reform often require the allocation of specific responsibilities and powers to monitor, oversee and promote progress across the whole of government and to maintain consistency between the approaches of the various actors involved in the regulatory process. In particular, if some countries rely on trust and informality for co-ordination, other countries, with more complex and sometimes fragmented institutional settings, have allocated this function to a structure created for this purpose.

More and more OECD countries have established central oversight bodies whose key roles include:

- oversight of the rule-making process;
- assisting policy makers in their evidence-based analysis;
- challenging the quality of regulatory proposals;
- advocating for quality regulation/ better regulation.

The existence of a specific body charged with regulatory oversight indicates per se a strong commitment to improving regulatory quality and is closely correlated with the development of an effective and comprehensive regulatory policy. The functions of central oversight bodies usually go beyond improved co-ordination between existing bodies involved in the rule-making process. In particular, they monitor the progress achieved by the different actors involved in the policy process and scrutinise new policy/regulatory proposals. They can also act as gatekeepers, with the power to veto a regulation which does not fulfil the necessary requirements.

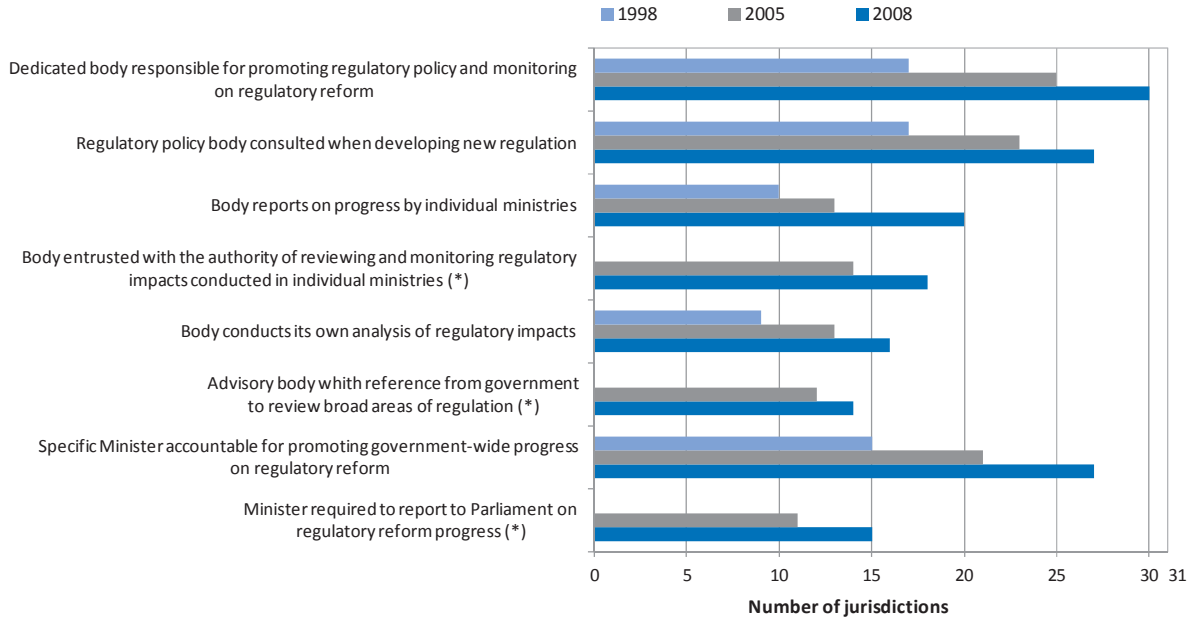
Beyond the need to oversee the rule making process (often referred as the "gate-keeper" role), there is a further need for independent, objective assessment of the quality of a proposal, which includes checking whether impact assessment, consultation and burden reducing processes have been properly carried out. The underlying issue is that regulators cannot self-assess their work. This challenge may be the most difficult function as it can be perceived as (and in some cases is formally set up to be[3]) a gate-keeping function, where the relevant body has the power to hold back a proposal until it is deemed fit to be considered and approved by the government. In some cases, the oversight body may publish its comments and assessments, thus providing a powerful "shaming" pressure for improved performance.

The advocacy function is important for ensuring that reform is understood and accepted, and it also provides a feedback loop for the views of business and citizens. Advocacy requires interaction with business and civil society, seeking support, but also seeking external assessment and perceptions, which will help to drive future regulatory improvements. Advocacy can be internally driven, and may be assigned as a ministerial responsibility, to give it more weight. A different approach is to put it with an external advisory body. This approach has the merit of ensuring that a truly external view of business and citizen needs is captured, countering the bureaucratic view and helping to broaden the "tunnel vision" which can prevail inside government.

Figure 4.2 illustrates the progress observed since 1998, when only 17 of the 27 OECD countries surveyed had a dedicated body responsible for promoting regulatory policy; in 2008 almost all did. The European Commission also reported having one (OECD, 2009a). In the majority of OECD countries, regulatory oversight bodies are placed at the centre of government – in a prime minister's office or a presidential office with some form of interdepartmental co-ordination. Ministries of finance and ministries of justice also play a significant role in hosting these functions (OECD, 2009a). The last decade has also witnessed significant reforms to empower regulatory oversight bodies. In 2008, it was reported that most bodies in charge of promoting regulatory reform were consulted when new regulations were developed. At the same time, the number of bodies that report on progress by individual ministries had almost doubled since 1998. However, the authority to conduct analysis of regulatory impacts remains limited to about half of the regulatory oversight bodies. In 1998, about half of OECD member countries had a specific minister accountable for promoting regulatory reform. By 2008, eight further countries had assigned this task to a specific minister (out of those countries for which data were available for both years). In about half of OECD member countries, this minister is required to report to parliament on the progress of the regulatory reform agenda.

Interesting examples of central oversight bodies include the Regulatory Reform Committee (RRC) in Korea, which has been set up by law with "a general mandate to develop and co-ordinate regulatory policy and to review and approve regulations." Its main functions are to give some strategic perspective to regulatory reforms, to undertake research, to monitor the improvement efforts of each agency and to make sure there is coherence between their actions. In the Netherlands, a regulatory committee co-ordinates fairly independent ministries, and extensive inter-ministerial co-ordination and supervision have been put in place. In the UK the Better Regulation Executive (BRE) is an example, perhaps counterintuitive, of an oversight body moving from the Cabinet Office to the Department for Business, Enterprise and Regulatory Reform (BERR). This transfer was motivated by the fact that the Cabinet Office had neither direct practical links with business and other stakeholders, nor direct responsibility for policy areas which need to be better regulated.

Figure 4.2. Institutional arrangements to promote regulatory policy



Notes: Data for 1998 are not available for the European Union, Luxembourg, Poland and the Slovak Republic. This implies that this figure is based on data for 27 countries in 1998 and for 30 countries and the EU in 2005/2008.

*: No data are available prior to 2005.

Source: Indicators of Regulatory Management Systems, 2009 Report, OECD, Paris, available at *www.oecd.org/regreform/indicators.*

It should be recognised that some countries find the concept of new central bodies for regulatory quality promotion hard to accept on the grounds that the guiding function is already embedded in existing policies and structures. In particular, such units may be perceived in large countries as undermining or competing with other more established centres, as well as raising a possible threat to ministerial discretion. By contrast, in small countries, with small government administrations characterised by close and informal networks and consensus-based governance, central bodies are sometimes seen as unnecessary (OECD, 2008). The lack of a central regulatory oversight body, however, need not imply the absence of co-ordination of regulatory policy. Instead, it can be the result of a relatively decentralised model of government administration. Denmark is a striking example where the development of a generally favourable regulatory environment has not been promoted by a central oversight body as traditionally understood.

Box 4.1. The Co-ordination Committee in Denmark

The Co-ordination Committee (Koordinationsudvalget) is a ministerial committee which vets and approves major new policy initiatives and changes. It is also the focal point for the government's Better Regulation policy. It reviews the final version of the annual law programme before approval by the cabinet, and approves individual draft laws before they are sent to the parliament. It endorses ministries' action plans to reduce administrative burdens on business and reviews progress reports from ministries on the De-bureaucratisation Programme. The Co-ordination Committee is headed by the prime minister and includes the most important ministries. Participation can extend to other ministries on occasion. Its Regulation Committee prepares the Co-ordination Committee work on Better Regulation policy. This officials' committee, established in 1998, is formed from the Group of Permanent Secretaries that prepares meetings for the Co-ordination Committee and is the highest level for co-ordination between civil servants. It includes the permanent secretaries of the Prime Minister's Office (chair), the Ministry of Finance, the Ministry of Economic and Business Affairs and the Ministry of Justice. The group vets ministers' proposals for inclusion in the annual law programme, including the impact assessments that must be carried out before a proposal can be tabled, and develops policy on regulatory quality.

Source: OECD (2010g), *Better Regulation in Europe: Denmark*, OECD Publishing, Paris, available at *www.oecd.org/gov/regref/eu15*.

Cordova-Novion and Jacobzone (2011) analyse the key factors contributing to success of regulatory oversight, including the mandate, powers, structure, location, resources and co-ordination mechanisms. The findings are as follows:

- Oversight bodies are generally *located close to core executive functions*: either at the centre of government itself, or as part of central ministries. Despite significant institutional heterogeneity, *a key issue for success is the existence of a structured unit or dedicated secretariat.* It can be set up within the executive, or as a Council/Committee as part of an arms' length arrangement.
- The credibility of the core unit builds on technical expertise and political support, and is important to ensure coherence, leadership and efficiency. In some countries, the core functions of oversight remain divided among different institutions, with implications for co-ordination.
- *The system of regulatory oversight involves checks and balances*, and often includes opt-out exemptions and time limits. A constant concern is to minimise infringements to ministerial responsibilities, while ensuring commitment at the political level. A balanced approach is necessary, so that no significant loopholes can undermine regulatory quality oversight, such as omitting tax issues, or checking only part of the new regulations. Transparency and accountability mechanisms are required.
- *Countries increasingly tend to adopt networked approaches for regulatory oversight*. A core body, enjoying direct explicit or indirect implicit powers, co-ordinates a network of units in the various ministries. This contributes to policy coherence, while ensuring the interface with policy making in sectoral areas. The units collaborate and complement each other in a dynamic way when fulfilling the core functions. While decentralising the substantive work helps to foster change in the sectoral areas, this also entails issues in terms of balancing powers and priorities.

Box 4.2. The Australian Productivity Commission

The Productivity Commission (PC) is an independent research and advisory body that advises the Australian Government on a range of economic, social and environmental issues that affect the welfare of Australians. Its charter is to improve the productivity and economic performance of the economy, taking into account the interests of the community as a whole, considering environmental regional and social dimensions; not just the interests of particular industries or groups. An important function of the PC is modeling the economic costs and benefits of alternative policy options. It may make recommendations on any matter that it considers relevant, and it is up to the government to determine how to use the advice provided.

The PC plays an important role in advising the government on the impacts of existing regulations by providing *ex post* analysis of the effectiveness of regulatory policies and programs. The PC has an established institutional function that has been effective at separating the policy evaluation process from the political process. A number of factors contribute to this. It has statutory independence and a standing function that is accepted by all major political parties. The PC ensures that it gives clear consideration to the stated objectives of government policy objectives; it does not substitute its own policy objectives. The conduct of reviews is undertaken transparently using broad welfare analysis that takes into account a diversity of policy considerations and the impacts on the overall economy. The review processes of the PC ensure that it receives input from multiple actors, but it provides only one voice in policy debate without crowding out others. All reviews by the PC take a national focus, thereby overcoming the policy fragmentation associated with multiple layers of regulatory authority. The formal processes for consideration of the reports of the PC include a response by government and the tabling of reports in Parliament. Accordingly, although the recommendations of the PC are not always agreed to immediately, the analysis remains in the public domain as a reference to assist policy debate and often proves to be influential in guiding future policy development.

The Government directs the PC on what areas to study through the issuance of formal terms of reference, but the PC is independent in its analysis and findings. The processes of inquiry are public, allowing the opportunity for the participation of interested individuals and groups, and the inquiry reports must be tabled in Parliament within 25 sitting days of the Government receiving the report. The PC cannot launch its own inquiries, although it can initiate supporting research and publish the results via Commission or staff research papers.

The PC is unique among OECD members for its standing inquiry and policy advising work across a range of economic, social and environmental issues.

Source: Productivity Commission (2003), *From industry assistance to productivity, 30 Years of 'the Commission'*; Productivity Commission (2005), "Regulation and its Review 2004-05", *Annual Report Series*; Productivity Commission (2008a), "Annual Report 2007-08", *Annual Report Series*; Productivity Commission (2008c), *A Quick Guide to the Productivity Commission*, Productivity Commission, Canberra.

Cordova-Novion and Jacobzone (2011) also look at the performance of regulatory oversight from a political economy of reform perspective and offer the following observations:

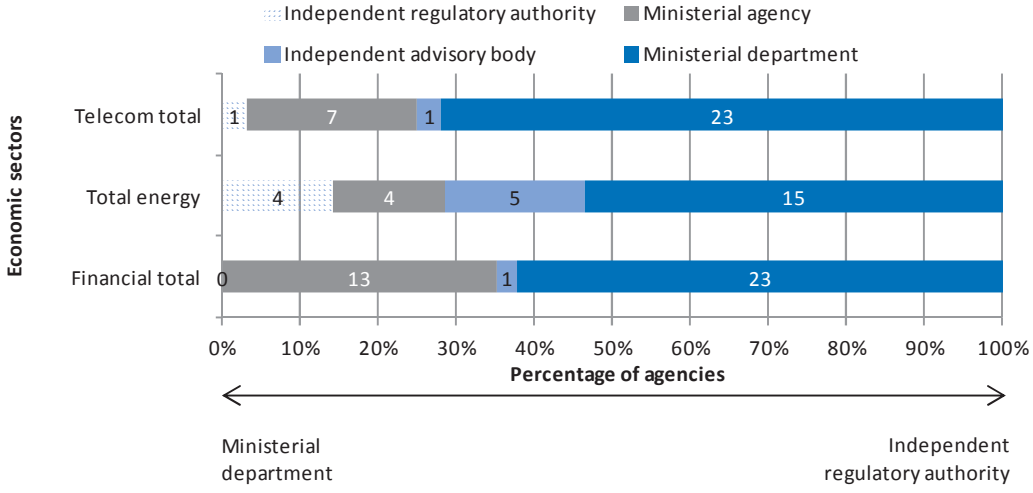
- *Regulatory quality oversight is a key tool for policy coherence*, and benefits in turn from internal coherence in the reform agenda.

- Regulatory oversight needs to be articulated with other core policies, such as microeconomic and competition-oriented reforms, as well as overall reforms of the public administration. This may help to overcome bureaucratic resistance and scepticism.
- Oversight bodies require *institutional stability over time* to sustain the changes that transform "quick wins" into real outcomes. This needs to be reflected through recruitment and resource endowment across economic and political cycles. Countries face different options for reform, *between gradual approaches, or more "big bang" strategies.* Gradualism helps to adapt the rulemaking environment progressively, starting off simple and raising standards through innovation over time. Big bang approaches have often been chosen during crises, with significant opportunities for reform.
- *Forging of a political constituency* requires active communications, political buy in and support from a champion, and an external constituency of interested parties to support advocacy.

The role of regulatory agencies

Independent regulators are another key institution, frequently used by OECD countries, which establish separate "agencies" at arms' length from the political system, with delegated powers to implement specific policies in a number of sectors. The term covers regulators found in utility sectors, such as energy and telecoms, but also in other sectors where sector-specific oversight is needed, such as financial services. Their main functions vary significantly across countries and sectors.

Figure 4.3. Institutional status of regulators (by sector)



Source: OECD (2005b), "Designing Independent and Accountable Regulatory Authorities for High-Quality Regulation", Proceedings of an Expert Meeting in London, United Kingdom, 10-11 January.

In all OECD countries, a regulator's primary role is concerned with rule enforcement and the application of sanctions for non-compliance with rules relating to their areas of competence and authorisations for the issue of licences and permits (OECD, 2008). OECD experience shows that independent regulators have been most effective and credible where their independence and roles are based on a distinct statute with well-defined functions and objectives. Their independence requires an adequate resource base and staffing policy and should be carefully counter-balanced by the introduction of accountability mechanisms.

The reasons for setting up an independent regulator are well known.[4] The key benefit sought from an institutional framework based around these agencies is to shield market interventions from interference from political and private interests. They therefore have the authority to deal with complex issues, assuring market participants that their decisions are not vulnerable to uncertain, politically driven government action. In particular, independent regulators are often important for providing non-discriminatory access to essential facilities and guaranteeing "fair" regulations. Independent regulators are also a necessary institutional development for marking out the separation of the State's roles as policy maker and owner of productive assets. This is a role which is especially important in countries which have chosen to maintain a significant ownership interest in network industries. The move to establish independent regulators also offers great potential in improving regulatory efficiency.

Box 4.3. The structure of regulatory bodies

Regulatory bodies responsible for the design and enforcement of regulations encompass a wide range of institutional settings. They can be classified in four distinct groups.

First, ***ministerial departments*** are agencies that are part of the central government and do not have the status of a separate corporate body. They are part of the civil service and headed by or report directly to a minister. They are typically and largely funded from tax revenue. They can have statutory independence in carrying out some regulatory functions and can have considerable administrative autonomy from other ministries.

Second, ***ministerial agencies*** are executive agencies, set at arm's length from central government, which may or may not have a separate budget and autonomous management. They may be subject to different legal frameworks (where administrative procedures laws or civil service regulations may not apply). They may have a range of powers, but are ultimately subordinate to a ministry and subject to ministerial intervention.

Third, ***independent advisory bodies*** are agencies with the power to provide official and expert advice to government, lawmakers, and firms on specific regulations and aspects of the industry. They may also have the power to publish its recommendations. The scope for public decisions to depart from the advice or recommendations may vary.

Finally, ***independent regulatory authorities*** are agencies charged with regulating specific aspects of an industry. They are typically under autonomous management, and their budget may be under a Ministry. However, there is no scope for political or ministerial intervention with the body's activities, or intervention is limited to providing advice on general policy matters rather than specific cases. These bodies have a varying range of powers. As indicated in Charts 2 and 3, independent regulatory authorities account for approximately two thirds of regulatory agencies operating at arms' length from the government.

Source: OECD (2005b), "Designing Independent and Accountable Regulatory Authorities for High Quality Regulation", Proceedings of an Expert Meeting in London, United Kingdom, 10-11 January.

At the same time, independent regulators represent a significant challenge to the executive and parliamentary powers of government. They represent a special form of institution in most OECD countries, which is neither directly elected by citizens nor managed by elected officials. It is an institution that governments have established to delegate authority at arms' length from elected public authorities. Independent regulators exist at the border between policy formulation, which remains the remit of the elected public authorities under a rule of law, and enforcement of the regulation which is delegated to them.

Defining the respective roles of the regulators and the executive raises a number of political and institutional considerations, in particular how the exercise of regulatory power is to be controlled. The increasing role of independent regulators has raised concerns in certain countries; that they could result in "governments in miniature," blurring the traditional separation of powers (see OECD, 2002a). At the same time, independent regulators can never be fully independent from the political process. They will always operate under the authority of laws and governance structures that can be altered directly by the legislature and courts as well as indirectly by the executive. Thus, effective regulators have to be able to respond to the long-term political direction which will ultimately justify their continuing existence.

The framework based around an independent regulator is also subject to a number of shortcomings. Perhaps the most cited is regulatory capture. Posner (1982) perhaps stated the problem of regulatory capture most directly, "Regulation is not about the public interest at all, but is a process, by which interest groups seek to promote their private interest ... Over time, regulatory agencies come to be dominated by the industries regulated." Robust transparency and accountability procedures are needed to limit the risk that regulators are captured by the regulated firms. Even if OECD reviews of regulatory reform have not found this problem to be extreme there is a considerable body of literature on the problems of regulatory capture.

The design of regulatory agencies

Independent regulatory agencies – at arm's length from executive agencies, should be considered in situations where:

- There is a need for the regulatory agency to be seen as independent in order to maintain public confidence.
- Both the government and private entities are regulated under the same framework and questions of competitive neutrality need to be addressed.
- The decisions of regulatory agencies can have significant economic impacts on regulated parties.
- Significant enforcement activities are performed.
- There is a need to protect the agency's impartiality.

Creating independence between the regulator and the government also raises a number of practical design issues:

- Governance structured independent regulatory agencies are an important consideration to ensure accountability. In theory, a board should offer more opportunities for collegial decision making, thus ensuring a greater level of independence and integrity in decision making.

- Even when independent regulators have been granted some powers and some autonomy, their independence can often be subordinated by administrative regulations. This can be reflected in the provision of instructions to these agencies, or in the possibility of lodging ministerial appeals after decisions have been made.
- The terms of appointment can have considerable influence on the level of independence of regulatory agencies. In general, longer appointments that span political cycles ensure the greatest degree of independence.
- Finally, an important practical issue is also to ensure that independent regulators receive sufficient financial resources to carry out their mandate and that the funding mechanisms will not impact their independence. Several arrangements have been used in OECD countries, including directly levying fees from the regulated entities to central funding from the state budget. Funding is often constrained by the nature of the agency and the possibility of levying sufficient fees from the sector being regulated. It may also be influenced by the need to reduce the risk of capture.

Creating a culture for regulatory quality

OECD countries are increasingly interested in utilising whole-of-government approaches to policy development and implementation. Whole-of-government approaches are associated with a desire to ensure the horizontal and vertical co-ordination of government activity in order to improve policy coherence, better use of resources, and to promote and capitalise on synergies and innovation that arise from a multi-stakeholder perspective. The promotion of regulatory quality culture can and should benefit from such an approach. Yet in many countries, administrations have not yet fully integrated the need for regulatory quality into their policy processes. Much deeper reforms are needed to embed an awareness of regulatory quality and its importance across public administration.

The ways to implement and practice a whole-of-government approach in regulatory policy vary based on country experiences and contexts. Thus, there is no single approach – but rather a spectrum of practices with countries each developing and adapting its use as appropriate to their circumstances. The backbone of a whole-of-government approach is the establishment of co-operative structures in order to more effectively meet government objectives. These structures can be created by hierarchical pressure or can be driven by informal networks and values. Achieving government objectives utilising hierarchical structures implies gaining agreement among the political and administrative spheres on organisational design or intentional re-organisation. Utilising a networked approach implies negotiation as a driver to accommodate differing views that political and administrative actors will have *vis-à-vis* regulatory policy. It is important to keep in mind that working as a single government does not necessarily mean becoming a single institution. Rather, working in a whole-of-government manner means balancing increasing centralisation with decentralisation to achieve a more joined-up public administration.

In order to strengthen their capacity to operate in a single government fashion, public administrations need to utilise a combination of formal cross-cutting structures and mechanisms and informal norms. Among those countries that are explicitly moving towards the use of whole-of-government approaches in regulatory policy (e.g., Australia, Canada, the Netherlands, the United Kingdom and the United States) there is a growing focus on the importance of formal elements such as standardised procedures on evidenced-based analysis and compliance codes for regulators. In addition, performance measurement systems are being developed (where Canada is taking a lead), that provide a common language across organisations on performance expectations and results.

Box 4.4. Whole-of-government approaches in Canada and the United Kingdom

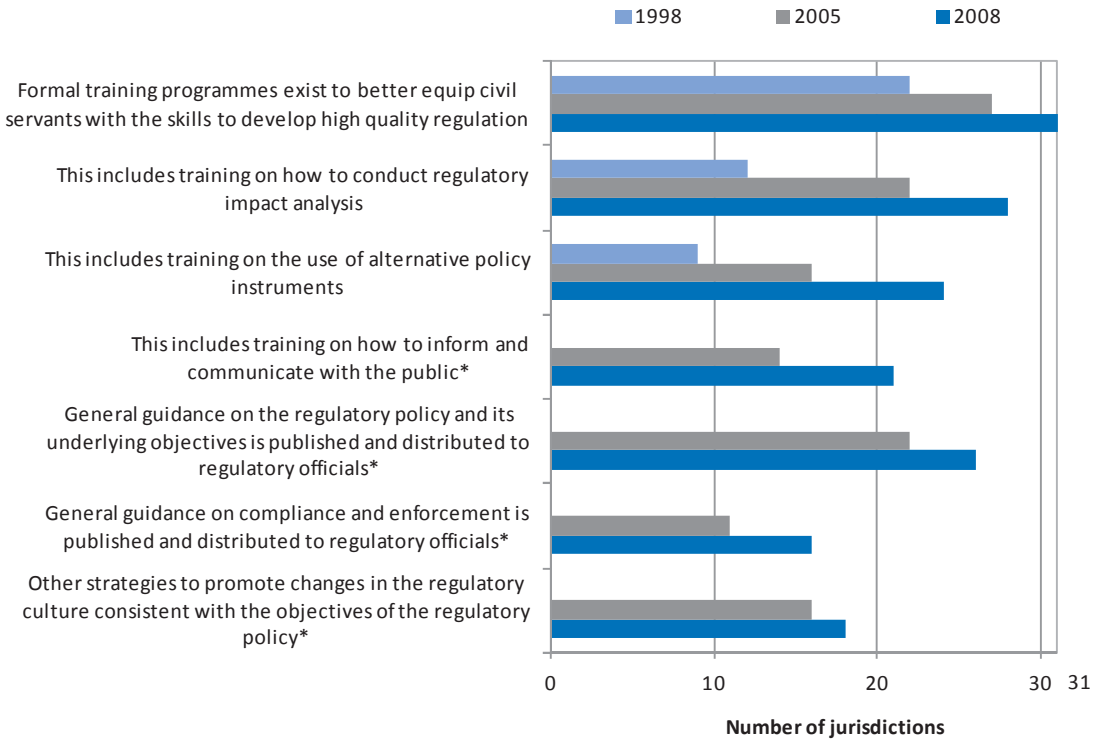
The *Cabinet Directive on Streamlining Regulation (CDSR) of the Government of Canada* requires results-based management and performance information for high-impact regulations. It requires policy analysis and impact assessment that embeds a process of monitoring, evaluation and review. This includes a requirement "measuring and reporting on performance; evaluating regulatory programs; and reviewing regulatory frameworks." High-impact regulations require a Performance Measurement and Evaluation Plan (PMEP) which applies to regulatory activities as well as to related programme activities. They are intended to provide an accurate account of progress and results and demonstrate if the regulatory activities are not achieving the intended outcomes. Since 2007, over 20 PMEPs have been developed for high-impact regulations. The process of developing the plans is time consuming, but it engages departmental senior management with the effects of regulation and promotes cultural change, engaging several units in enforcement and compliance, corporate planning and performance evaluation and by breaking down silos within an organisation. Canada's longer term aspirations are to develop meaningful indicators that assess the impact of Canada's regulatory system on innovation, the economy, the environment, health and the safety and security of Canadians.

The *national audit office* in the United Kingdom scrutinises public spending on behalf of parliament and has produced a number of reports since 2001 on aspects of regulatory reform, in particular the impact assessment process, the administrative burdens reduction programme, and business perceptions of regulation. One important finding is that despite considerable efforts to improve the business experience of regulation, there has been little discernable progress in improving business perceptions of regulation.

In February 2011 it produced a report entitled *Delivering Regulatory Reform*. The report examines the overall management of regulation across central government, focusing on the impact of regulation on business, how departments choose to regulate, and the implementation of regulation. In concludes that as with government spending, achieving sustainable reductions in regulatory costs whilst maintaining public value requires a structured and planned approach sustained over a period of years. While departments and the better regulation executive have developed important elements of such an approach and have delivered significant benefits since 2005, they are not yet in a position to achieve value for money in their management of regulation. This is because gaps remain in two important areas: understanding the impact on businesses and developing a coherent framework to manage regulatory reform (available at *www.nao.org.uk/publications/1011/delivering_regulatory_reform.aspx*).

Equally important to institute a whole-of-government approach is the use of cultural change within the public administration and as applied to processes and behaviour. This includes the use of a strong and unified set of values, values-based management, trust, collaboration, team building, involvement of outside stakeholders, and improved capability (e.g., training and self development) of public servants. A climate of trust and co-operation and the promotion of a regular exchange of information continue to be critical for the development of effective regulatory management. The enhancement of a programme of continuous training and capacity building within the government provides an important contribution to the improvement of regulatory culture (see Figure 4.4 for recent progress across the OECD). This kind of initiative not only improves the technical skills needed in certain processes, such as RIA or plain language drafting, it also communicates the importance attached to the regulatory quality agenda by the administrative and political hierarchy. Training and capacity-building programmes create opportunities to meet and to discuss the need for high-quality regulation, thus fostering a sense of ownership of reform initiatives and facilitating communication within and beyond individual institutional settings. Moreover, the use of adequate financial resources to support the organisation of these initiatives is an important sign of political commitment, drawing further attention to the regulatory policy agenda.

Figure 4.4. Training in regulatory quality skills in OECD countries



Note: The sample includes 31 jurisdictions for 2008 and 2005. For 1998, 27 jurisdictions are included as no data were available for the European Union, Luxembourg, Poland and the Slovak Republic.

Source: Questions 13a), a(i), a(ii), a(iii), b(i), b(ii), c), 2008 OECD Indicators Questionnaire, *Indicators of Regulatory Management Systems*, *2009 Report*, OECD, Paris, available at *www.oecd.org/regreform/indicators*.

Engaging government actors across levels of government

Effective regulatory governance needs a firm anchor across all the relevant parts of a country's institutional architecture and the support of all the relevant institutions and actors. Governments need to acquire a complete picture of the players in order to improve their regulatory governance. Who is engaged in the regulatory process? Who decides whether regulations should be developed? Who produces regulations? Who implements and enforces regulations? Regulation includes a wide range of activities, including, for example, the individual decisions that are taken by regulatory agencies and local governments to give effect to regulations in matters of planning and licensing. It may also cover the activities of the judiciary, insofar as some judicial systems involve active review and reshaping of regulations.

The overall institutional setting and the institutional sources of regulatory activity have grown in complexity. The range of actors is more than was previously understood. This has emerged as one of the key findings of the EU 15 reviews. Strengthening regulatory governance to support an integrated regulatory policy starts with the question of who exercises regulatory power, a comprehensive understanding of "who does what" in terms of regulation, and how the different actors interact (including, and not least, private sector actors). A core challenge for governments is to build up a more comprehensive picture of the regulatory landscape. This complete overview tends to elude countries (and the international community).

Again, there is scope for both collective reflection, as well as reflection by individual countries. If, for example, a country's regulatory policy aims to capture primary laws, then the role of parliament becomes important. If the legal system is based on common law rather than civil law, then there may be interest in engaging the judiciary or reviewing what emerges from their decisions that is relevant to future regulation.

Subnational levels

Application of regulatory quality to the local level needs further attention. In most OECD countries the local level of government has important responsibilities which may include the delivery of public services, enforcement of higher-level regulations, and the delivery of licences and permits. Efforts to integrate subnational levels of government into regulatory governance are considerably more in evidence than they were a few years ago. In particular, efforts are being made to secure better co-ordination between national and local levels, so that the latter have an opportunity to help shape the regulations which they will need subsequently to enforce. Co-ordination across local levels is also beginning to take off. Although federal jurisdictions raise some different issues, the evidence of the OECD reviews suggests that whatever the nature of the jurisdiction, there are delicate issues of autonomy that need to be respected across the different levels of government. The impact on regulatory policy of fiscal arrangements for the different levels of government is an important issue that has so far not received enough attention. For example, some of the EU 15 reviews hinted at perverse incentives to take regulatory actions, such as setting higher licence fees, linked to a shortage of local revenues.

Box 4.5. Multi-level regulatory governance

In Australia, it is acknowledged that initiatives to improve regulation are required at all levels of government. Regulatory reform has been an important undertaking for state and territory governments, with most implementing or continuing regulatory reform. In March 2008, the Council of Australian Governments (COAG) agreed to a regulatory reform agenda covering 27 specific areas of business regulation where significant gains could be made through applying a nationally consistent approach, as well as broader work on regulatory reform processes and an invigorated programme to progress a series of national competition reforms. On 29 November 2008 COAG agreed on a new National Partnership that provides funding of USD 550 million over five years to the states and territories to facilitate and reward the delivery of these reforms. The COAG has also published "Best Practice Regulation: A guide for Ministerial Councils and National Standards Bodies". This document provides guidance on regulation making and review as a way "to maintain effective arrangements to maximise the efficiency of new and amended regulation and avoid unnecessary compliance costs and restrictions on competition."

In Belgium, the regulatory policy is framed by the progressive federalisation started in 1970, which aims at the distribution of competences between national and regional governments (the government of the 3 regions and the 3 communities are federated authorities whose competences remain at the same level as those of the national government). Each federated entity houses its own legislative, executive and administrative powers. Law is issued by federal parliament, royal and ministerial orders by the federal executive power, and the federated entities rule through decrees and ordinances. Local governments, provinces and communes have a residuary power derived from either decentralisation or deconcentration. Co-operation mechanisms among federal entities have been established in parallel to guarantee the harmonisation of rules and equal treatment.

In Canada, a Federal, Provincial and Territorial Working Group on Regulatory Reform has been created as a forum to help build a shared approach to regulatory reform. Its work includes developing common regulatory principles, developing a consistent approach to regulatory impact analysis and sharing best practices. The aim of the group is to develop government's capacity to produce quality regulation and encourage regulatory co-operation across jurisdictions. Over the last 10 years, municipalities have been the object of provincial regulatory reform – moving from a traditionally rule based system to today's flexible framework. This new legislative framework allows municipal councils greater discretion in making decisions on behalf of their electorate in an open and accountable manner.

In Mexico, subnational governments have extensive regulatory powers, and there is considerable scope to improve the regulatory quality of its subnational units if it is to create a friendly business environment and improve competitiveness. There has been progress by state governments: 18 out of 32 states have issued regulatory reform laws, 12 have decentralised commissions working on regulatory improvement, and 20 have a unit within a state ministry (usually, the Ministry for Economic Development) addressing the issue. Despite these achievements, the progress and sophistication varies from state to state and even the most outstanding ones have wide scope for learning from best international practices.

In Sweden, there is no explicit regulatory policy framework for multi-level governance. The democratic basis of local government is set out in the Constitution, as the basic notion is that local governments are mainly the implementers of national policies and regulations, while retaining limited areas where they may regulate as well. General principles on regulatory quality are stated in a number of binding ordinances and guiding documents to ensure uniformity and high quality in the legislation.

Source: Charbit and Michalun (2009), "Mind the Gaps: Managing Mutual Dependence in Relations among Levels of Government", *OECD Working Papers on Public Governance*, No. 14, OECD Publishing, Paris, *http:// doi:10.1787/221253707200*.

The OECD's 2005 Guiding Principles for Regulatory Quality and Performance refer in general terms to the need for better regulation at all levels of government. The EU 15 reviews and other recent OECD reviews highlight the need to go further in defining how this is to be done. Effective regulatory management across levels of governments matters because poor multilevel regulatory management affects competitiveness, in particular by raising barriers to the seamless operation of internal markets (an issue which has received considerable attention at the level of the EU but less so within countries). The economic objective, however, may generate tensions with political sensitivities over the autonomy of local governments. A degree of creative competition in approaches is also desirable. Processes and tools to help define the right balance are needed to determine in what cases it makes sense to harmonise approaches and when an issue deserves a jurisdiction specific response.[5] Performance measures need to be developed to assess the effectiveness of processes and achievements.

The regulatory governance cycle may be a useful way of identifying where actions need to be engaged or existing initiatives strengthened. Central and subnational levels of government may read the chart in order to identify the areas where they have autonomy of action and those where they depend on, or are closely associated with, the actions of other levels.

Balancing public and private regulation

Governments may be responsible for regulatory policy, but they cannot do their job alone. Regulatory governance involves addressing public-private co-operation more effectively, and taking a closer look at the place of self regulation in the mix. Governments need to assign (and review) responsibilities which they have, or intend to delegate to the private sector, international organisations (such as private standard setting bodies), the charitable (or voluntary) sector, and even citizens.[6] The regulatory structures of the twentieth century, however efficient in themselves, tended to be silo-based, creating barriers (sometimes embedded in law) to co-operation across the public-private sector divide, frustrating good governance (and in the case of the financial sector, generating a crisis). There is debate about the right balance, especially in the wake of the financial crisis, which shook assumptions about the merits of self regulation. The debate raises important issues of accountability, regulatory capture and the need to avoid regulatory gaps as well as overlaps.

The debate needs to be set in a broader context, and take account of important differences between OECD countries. These offer a complex and very variable picture of state and private interactions, with differences in the definition of the public sector, linked to deeply embedded views about the role and responsibilities of the state in the economy and society. This means that the role of the private sector is not the same everywhere. In some parts of Europe, for example, state ownership has traditionally been seen as the best way to manage a wide range of activities, some of which may be deemed commercial activities that could be carried out in a competitive environment under private ownership. As well as health and education, activities have also included industrial sectors such as the car industry. Although the extent of state ownership has declined significantly across Europe over the last decade or so, it remains extensive in some European countries, including at local level. A specific effect of these differences is in the relative role of ministries (as owners of enterprises) and regulatory agencies in shaping the regulatory environment.

Many countries have traditionally assigned an important role to the social partners (the unions and employers' representatives) in regulatory management.

Box 4.6. Public consultation in Austria

Austria's public consultation approach is structured around formal and informal institutional relationships (including not least with the social partner) and the individual practices of ministries. The approach is robust in many respects, as the institutionalised relationships cover a wide range of relevant interests, and there is evidence of specific good practices. Some ministries, for example, put consultation results on their websites. The consultation process has a pre-consultation phase, and an official consultation phase. There is no administration wide forward legislative plan to use as a practical starting point for citizen engagement. In the first phase the competent federal ministries are responsible for commencing the development of regulations, including initiating contact with colleagues in other ministries as well as with relevant stakeholders including the Social Partners, the *Länder* and the Court of Audit. This part of the consultation exercise is not public, but depending on the political salience of the issue, Ministries may use the internet or mass media to inform the public.

The approach is largely dependent on formal and informal relationships with the Social Partners, which can raise issues of exclusion. Of itself, the emphasis on consultation with the Social Partners is not necessarily detrimental to the development of good policy. The Social Partners can together claim membership representative of the majority of Austrian citizenry. The role of Social Partners at the pre-consultation stage is important for ensuring that representative views are taken into account in the development of regulations. But care is needed not to block out other interests. There is a risk that consultation processes do not provide opportunities to account for the views of all citizens, and may not pick up innovative perspectives. An effective system of public consultation must be able to assure the public that there is an opportunity for their views to be heard and considered outside the institutional relationships. The main challenge here appears to be to develop a systemic approach to facilitate early and open participation of citizens and other groups in policy development.

Improving the governance of risk regulation

The issue of how OECD governments prepare for the assessment and management of risk through regulation to avoid the phenomena of reactive regulation and to promote better regulatory practices is of considerable importance to regulatory policy. The gap between the level of risk that is targeted by policy makers and the level that is achievable through regulation is inevitable and has to be explicitly recognised and managed. This will require increased guidance on general principles on risk assessment and management and international co-operation. The lessons from recent crises is that in the future regulators will have to pay more attention to background risks and systemic risk, as well as build in mechanisms for learning from past failures and near misses.

The OECD report on *Tools for Regulatory Quality for Financial Sector Regulation* (Black, J. *et al.*, 2009) states that among the acknowledged main regulatory shortcomings that contributed to the global financial crisis, was a lack of co-ordinated integration of relevant information by supervisors nationally and internationally, and ultimately fatal weaknesses in risk assessment and risk management by all those involved, including but not limited to regulators. It concludes that there are a number of areas relating to regulatory practice where the OECD principles could be further developed, with wider application than just the financial sector. These are notably with respect to risk

management and the need for regulators to have a detailed understanding of the dynamics of the organisations and systems that they regulate. Revisions to the principles should reflect these lessons.

The global nature of risks creates the need for increased convergence between risk management procedures internationally. Collaboration and convergence on risk issues have been advanced through the work of the Transatlantic Risk Assessment Dialogue. This joint work by the EU, the USA and Canada was launched in July 2008 and aims to promote a better understanding of the systems of the respective jurisdictions, and to establish a framework for convergence on methodological aspects and some substantive risk issues, such as emerging risks. It aims to move towards more consistent approaches through the exchange of information and the launching of common projects regarding particular risks or methodological issues. It provides a mode of working that could potentially be extended to other countries.

The failure in financial regulation was an example of deficiencies in regulatory frameworks for the governance of risk. Well designed risk governance frameworks have the potential to improve social welfare by ensuring that regulatory approaches are efficient, effective and account for risk/risk tradeoffs across policy objectives. They include the development of guidelines to ensure that risk assessors do not deal with risk issues in variable and inconsistent ways. Arbitrary variation in analytical practices undermines the credibility of agencies and can spur political backlash from stakeholders. Despite this few governments in the OECD have attempted to develop a coherent policy on the management of risks through regulation (OECD, 2009e).

There is considerable potential for further work by the OECD on the development of risk governance practices, including research on country practices that are transferable between regulatory agencies that can lead to guidance for regulatory bodies and central agencies. It could focus on the important organisational features for ensuring effective risk management by regulators. This would, for example, refer to how regulatory agencies use stakeholder participation and public deliberation in the development of risk responses and the use of scientific and economic assessment in these processes. This work is necessary to help to diffuse good practices among the regulators of different countries in spite of cultural and institutional differences.

The international challenge

Increasingly, regulatory impacts need to be achieved across and beyond national boundaries. This has been brought into sharp focus by the financial crisis. Countries need to work together, not separately, to build a resilient and effective regulatory environment. How to achieve closer collaboration requires further discussion. Issues include the identification of important areas for cross-border regulatory co-operation, and standards for openness, consultation and communication across jurisdictions. Problems with a strong regulatory dimension that do not respect national boundaries have become widespread, a side effect of globalisation and greater mobility.

A relatively recent phenomenon is the emergence of bilateral regulatory co-operation initiatives. This process has been fostered by discussions on good regulatory practice in the WTO TBT (Technical Barriers to Trade) Committee with the emphasis on eliminating or reducing regulatory barriers to trade. Such efforts are seen as an element of good regulatory practice. Activities to date have been largely embryonic in nature but they represent a new element in the regulatory reform and market openness agenda. Regulatory co-operation initiatives are largely voluntary and informal in nature where regulators from different countries exchange information on their regulatory systems and different national approaches to regulation and conformity assessment. However, these efforts offer longer term promise for improved international harmonisation leading to the reduction in regulatory barriers to trade.

Box 4.7. The regulatory framework for EU countries

Perhaps half or more EU member country rules now come from Brussels. The EU is also shaping whole regulatory regimes. The single EU market agenda involves a mix of deregulation and market opening alongside rule harmonisation, so that goods and services can move freely within the EU/EFTA region. The coverage is wide. It includes product markets (such as cars), professional and other services, and horizontal policies such as state aids, public procurement, and competition policy, as well as social and environmental issues.

The EU plays a prominent role in the reform of network industries (telecoms, energy, rail, posts, etc.), where it usually sets *de minimis* regulatory requirements, such as the nomination of an independent regulatory authority, and the separation of competitive from non-competitive activities. The EU's common external trade policy is another large area of relevant work. The single market programme has been a major driver of deregulation and regulatory harmonisation. It has helped to open up economies and promote trade and investment flows. EU rules have often helped to enhance social, environmental, health and safety, and consumer interests.

At a broader level the EU has helped in the development of the concepts of proportionality and subsidiarity in the application of rules.

The EU also generates an increasing number of rules, which confronts it with the same rule inflation problem as its member states. Reflecting the EU policy-making process itself is an issue that needs to be tackled from both ends: efforts from Brussels (not just the European Commission, but all the EU institutions), combined with efforts from member states too. Influencing the EU decision-making process, consulting with and informing the business community and other interested parties, effective implementation and transposition of EU rules, avoiding confusion between national and EU laws, and co-ordination with national sector regulators are issues requiring ongoing attention. The EU interface was a strong theme of the EU 15 reviews. There is a particular desire to improve the articulation of EU impact assessment with national impact assessments.

The EU is perhaps the most obvious current example of an international dimension to policy and rule making within which national authorities need to work, see Box 4.7. Important work in this regard also has been the adoption of the Regulatory Co-operation Framework by Canada, the US and Mexico in 2005. The Framework outlines policies and approaches for regulatory co-operation through multilateral engagement. International co-operation is seen as an important mechanism to improve competitiveness and promote innovation and investment by reducing duplicative regulatory requirements. Among the Framework's proposals are:

- to strengthen regulatory co-operation, including at the outset of the regulatory process;
- to streamline regulations and regulatory processes;
- to encourage compatibility of regulations, promote the use or adoption of relevant international standards, as well as domestic voluntary consensus standards, in regulations;
- and to eliminate redundant testing and certification requirements, consistent with our WTO obligations.

The adoption of international standards will likely be a key tool for regulatory harmonisation (and an important mechanism for facilitating trade.) However, outside the WTO SPS Agreement,[7] there are no mechanisms to monitor the domestic adoption of international standards, guides and recommendations. The lack of comparative data on national adoptions of international standards makes it difficult to assess the relevance and impact of international standardisation on domestic regulatory policy. This requires greater co-operation between governments, national standards bodies and international standards bodies in order to develop the appropriate tools. National data bases of both standards and standards referenced in regulation are also important factors in the adoption of standards by facilitating regular revision and updates and increasing knowledge of foreign market requirements.

Scope for different approaches

There are important differences among OECD countries as regards underlying public governance and institutional frameworks, and not least legal traditions (Box 4.8). Institutional arrangements for effective regulatory governance need to take account of these. One of the major lessons of recent OECD country reviews, especially under the EU 15 project, is that "one size does not fit all" and that effective governance may even be held back by efforts to introduce institutional arrangements and processes that do not take account of existing structures. A single central oversight body, for example, has been consistently recommended by the OECD for a number of years, yet many countries have found it difficult to establish. There is a need to look behind these difficulties to understand why this approach does not always work, and whether there are viable alternatives.

It is not an issue if differences emerge as each country constructs its institutional framework for regulatory governance, so long as there is clarity about leadership, and who is accountable and responsible for what. Different bodies may in fact be necessary for different functions to preserve objectivity, reduce the risk of capture and corruption, and ensure freedom from short term political influence. For example, *ex post* evaluation of regulatory outcomes is probably best carried out by an institution other than the one that develops the regulation or regulatory framework in the first place.

Box 4.8. Civil law and Common law: Implications for regulatory governance

Broadly speaking the legal systems of OECD countries are based on two approaches: common law and civil law. Common law originated in England in the Middle Ages. Civil law systems originated in Continental Europe, based on Roman law and the French Napoleonic Code of the early 19th century. Neither is wholly distinct from the other, both have points in common, and modern legal systems have evolved to integrate elements of each. However, their roots are very different, and this has implications for the institutional framework, which need to be taken into account in the development of stronger regulatory governance.

Systems based on common law

Common law, also known as case law, is developed by judges through decisions of courts, rather than through legislation enacted by parliament or actions by the executive branch of government. The core principle of common law is that it is based on precedent. If a similar issue has been resolved by a court in the past, the court is bound to follow the reasoning used in the prior decision (a principle known as *stare decisis*). However, if the court finds that the current issue is fundamentally distinct from all previous cases, judges have the authority and duty to make law by creating precedent.

Legal systems in modern societies based on common law are more complex. Common law usually interacts with other forms of legal authority which may include:

- *Constitutional law* (the highest level of legal authority which cannot generally be contradicted by lower level legislation or decisions with legal force).
- *Statutory law* (law which is enacted or approved by parliament).
- *Regulatory law,* which is promulgated by agencies attached to the executive branch of government.

In common law jurisdictions, legislatures operate under the assumption that statutes will be interpreted against the backdrop of pre existing common law.

The increasing interaction with other forms of law, notably constitutional and statute law, means that the distinction between common law based systems and civil law based systems is becoming less sharp.

Systems based on civil law

Jurisdictions based on civil law (which is also known as code law because it is traditionally structured around codes – groups of related laws) give less weight to precedent, which means less freedom of interpretation for the courts. Interpretation of the legal text is paramount in civil law systems. Academic legal experts can play a significant role in the interpretation of legal texts. Civil law statutes tend to be more detailed than statutes under common law systems.

As with systems based on common law, civil law based systems are more complex and the boundaries of each system are becoming increasingly blurred. Thus the growing importance of jurisprudence (case law in all but name) is bringing civil law systems closer to common law systems.

Implications for regulatory policy

Countries with a civil law tradition tend to place emphasis on the clarity of legal texts, and the need to ensure that the structure of the law overall remains coherent (through codification and related measures).

Box 4.8. Civil law and Common Law: Implications for regulatory governance (*cont.*)

There are also important institutional implications. Countries with a civil law tradition are more likely to have institutions such as constitutional courts and councils of state (although constitutional courts may also be a feature of common law jurisdictions such as the United States). These institutions may play an important *ex ante* or *ex post* role in review of regulations from the perspective of their legal basis, or the "opportunity" of a regulatory proposal. In some cases, councils of state may be powerful advocates of regulatory improvement. The overall role of the judiciary (courts) in countries with common law traditions is likely to be stronger than in civil law countries, because of the importance of precedent.

Judicial review of administrative decisions may also reflect the underlying legal system. Courts in common law-based systems are likely to have more power in this regard.

Notes

1. Different jurisdictions may use different vocabulary to express the functions depicted in the figure, which are not always easily translatable. They are so closely associated with the country context that some terms take on a country specific meaning. For example, in Europe, enforcement may also be referred to as supervision, inspection or execution.
2. In some, especially European countries, it nearly always does give rise to a law or regulation.
3. In the United States, for example, the Office of Information and Regulatory Affairs (OIRA) has the authority to return draft regulations to agencies for consideration. In other countries, such as Japan, the role is more limited, checking compliance with basic requirements.
4. There is a rich body of theoretical and empirical research covering independent regulators in network industries. For seminal reviews see Laffont and Tirole (1993, 2000); Levy and Spiller (1994) and Newbery (1999).
5. In Australia, The Council of Australian Governments (COAG) agreed to a new model of co-operation underpinned by more effective working arrangements. Area by area, jurisdictions are to consider the merits of a uniform, harmonised or jurisdiction specific model.
6. For example, the United Kingdom government has proposed the "big society" theme under which citizens, communities and independent providers have greater delegated responsibilities for managing issues.
7. The WTO Agreement on the Application of Sanitary and Phytosanitary Measures.