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# **Comparing Regulatory Oversight Bodies in the US and EU:**

# The Office of Information and Regulatory Affairs in the US and the Regulatory Scrutiny Board in the EU

### Jonathan B. Wiener and Alberto Alemanno

Over the last four decades, governments have created a new set of institutional actors, the Regulatory Oversight Bodies (ROBs). These bodies tend to be located in the executive (or sometimes the legislative) branch of government. They review the flow of new regulations using prospective regulatory impact assessment (ex ante RIA), and they sometimes also review the stock of existing regulations using retrospective regulatory impact assessment (ex post RIA). ROBs have become an integral feature of administrative law and institutions in a large and growing number of countries (De Francesco 2013, OECD 2015, Parker and Alemanno 2015, Radaelli and De Francesco 2008, Renda and Castro 2016, Wiener 2013, Wiener and Ribeiro 2016). Virtually all of the 35 members of the OECD have now established ROBs, most located at the center of government, with the authority to oversee RIA (OECD 2015: ch. 1, 21-38, and ch. 4, 93-102).

In this chapter, we update our earlier comparison in Wiener and Alemanno (2010), focusing on the principal ROBs in two major jurisdictions: the United States and the European Union. We compare the origins, structures, powers, procedures and scope of the US Office of Information and Regulatory Affairs (OIRA) and the EU Impact Assessment Board (IAB), now renamed the Regulatory Scrutiny Board (RSB).

In important respects, the US and EU have now created quite similar mechanisms of regulatory oversight; each side now has an internal system for RIA and oversight, and an external counterpart to call across the Atlantic to foster regulatory cooperation (which may grow through the Transatlantic Trade and Investment Partnership (TTIP), see Wiener and Alemanno 2015). On the other hand, there are differences in the approaches taken to regulatory oversight on each side, which stem in part from the different governance structures in which these oversight bodies operate.

#### **1. Rationales for ROBs**

Regulation can be needed to protect the public from market failures such as externalities (e.g. health, safety and environmental risks), asymmetric information (e.g. in financial or labor markets), market power (e.g. monopoly, collusion or barriers to entry), and unfair discrimination (e.g. in education, employment, housing, credit, and other areas). Although well-designed regulation can remedy such problems, poorly-designed regulation can yield its own unintended consequences, including misplaced priorities, compliance costs, impediments to trade and innovation, ancillary impacts (side effects), unfair treatment, and interest group rent-seeking (Olson 1971; Ackerman and Hassler 1981; Breyer 1993; Wolf 1993; Graham and Wiener 1995; Wiener and Richman 2010; Adler 2012). As a result, where states deploy regulation, demand arises for oversight of the regulatory system in order to reduce the costs and ancillary risks, increase the benefits, promote cost-effective instrument choice, encourage consistency and transparency, ensure accountability, and improve the overall social outcomes of regulation. Regulatory oversight, particularly oversight by a centralised governmental body -- 'hierarchical supervision of regulatory action by executive and legislative actors' (Lindseth, Aman and Raul 2008: 3) -- has increasingly been adopted as a way to improve regulatory outcomes.

The aim of regulatory oversight is both democratic and technocratic: to enhance the accountability of regulatory agencies to democratically elected officials and the public, and to use analytic methods to improve the overall social outcomes of regulation by reducing the costs and side effects and increasing the benefits. Regulatory oversight, as it is typically carried out, uses several analytical tools which are heavily informed by economic analysis. The analytic tools that are generally employed have been discussed at length in the academic literature (Revesz and Livermore 2008, Graham 2008, Adler and Posner 2001, Adler and Posner 2006, Adler 2012), and also in several OECD reports (Deighton-Smith 2006, 2007, OECD 2009, OECD 2015). These tools include regulatory impact assessment (RIA),<sup>1</sup> often employing benefit-cost analysis, cost-effectiveness analysis (Graham 2008, Revesz and Livermore 2008, Wiener 2006),<sup>2</sup> risk-risk tradeoff analysis (Graham and Wiener 1995, Revesz and Livermore 2008),<sup>3</sup> and scientific analyses such as risk assessment (Bagley and Revesz 2006). Related tasks of an ROB (see OECD 2015: 36-37) may involve assisting agencies in improving the quality of their analyses, ensuring reducing administrative burdens (European Commission 2007), simplification of existing legislation and regulation (through codification, recasting and repeal) (Beslier and Lavaggi 2006), stakeholder consultation procedures at various stages of the policy cycle (OECD 2015: ch. 3; Alemanno, 2015b), and retrospective review (ex post RIA) (OECD 2015: ch. 5, 119-140).

The analytical tools and methodologies that are typically employed in regulatory oversight could, in principle, be employed by a variety of actors, including legislatures and their accountability arms, courts, auditors, executive officials, advisory bodies, review commissions, and non-governmental organizations. The distinctive institutional development of the past four decades in the US and during the past two decades in Europe has been the emergence of regulatory oversight bodies (ROBs) in the executive branch, located at the center of government (attached to the presidency or prime minister's office), charged with supervising regulation government-wide. Three-quarters of the 35 members of the OECD have now established such center-of-government ROBs (OECD 2015: 35, Fig. 1.8), although most of these OECD members have also established multiple ROBs in multiple institutional locations (OECD 2015: 34, Fig. 1.7).

One key attribute of an executive ROB is expertise, in the form of a trained professional staff capable of undertaking technical evaluation of regulatory impacts and options. These staff may be economists, but also may include experts in other fields of social

<sup>&</sup>lt;sup>1</sup> IA can be defined as the process of systematic analysis of the likely impacts of a policy or intervention by public authorities. It may employ each of the analytic tools noted here. An IA also refers to the report or document containing such an analysis.

<sup>&</sup>lt;sup>2</sup> While BCA compares benefits and costs, seeking to maximize net benefits, cost-effectiveness seeks to minimize cost for a given objective or maximize benefits for a given cost.

<sup>&</sup>lt;sup>3</sup> Including both ancillary harms (countervailing risks) and ancillary benefits (co-benefits).

science, law and policy, life science and physical science. Expertise enhances the ability of the ROB to oversee regulatory analyses, improve regulatory quality, and help regulators choose and evaluate policies to promote overall social well-being.

A second key attribute of any ROB is political accountability, such as through the center of government (e.g., the president or prime minister) to the electorate (Ackerman 1993, 1998, Lindseth, Aman and Raul 2008, Tushnet 1995, Mendelson and Wiener 2014: 469-471). Political accountability enhances the ability of ROBs to influence regulators who also have their own political constituencies, while also recognizing that, just as regulators need oversight, so too ROBs warrant oversight, by the President or Prime Minister, as well as (perhaps) by the legislature or parliament, courts, and the public.

An ROB faces possible tensions between these two key attributes. Technocratic expertise, if well implemented, can foster political accountability, by ensuring transparent analysis of the pros and cons and tradeoffs of policy alternatives, by overcoming interest group distortions, and by ensuring that regulation broadly improves social well-being (Stiglitz 1997). As Adam Smith (1776) observed, expert analysis can be an antidote to hasty enthusiasms and politicised distortions of public policy. But expert technocratic criteria for regulation may or may not coincide with political democratic criteria. That is, the president's or prime minister's policy program (or statutes enacted by the legislature) may differ from and conflict with the experts' advice regarding the socially optimal policy (Shapiro 2006, Graham 2007b). In such cases, the ROB may need to explain its expert technical analysis to a political leader with a different priority and try to convince the leader to change course, or the ROB may help make the impacts and tradeoffs transparent while recognizing that the political leader's authority will override the ROB's expert technical analysis. The ROB may have both a need for independence from political micro-management, to assure its analytic objectivity, and simultaneously a need to be close to power in order to have influence over other ministries and to carry forward the president's or prime minister's regulatory policy program (E. Kagan 2001). How these tensions are handled can depend in part on who appoints the head of the ROB and its members and to whom the ROB reports.<sup>4</sup>

### 2. Origins of ROBs

A brief historical perspective can help to illustrate the origins and objectives of these bodies in OECD countries. In the past, countries with a Roman law tradition set up forms of ROBs, as part of Councils of State, as in France (Robineau and Truchet 2002) and Italy (Caretti and De Siervo 1996). These bodies served as advisors to the government on the legality of regulatory decisions. They were also the superior level of the administrative courts, so they also exercised an adjudicative role meant to protect governments and avoid litigation in the civil courts regarding specific regulations. For example, in France after the Revolution, the *Conseil d'Etat* and the system of administrative courts were designed to shield the administrative state from being unduly constrained by the separate system of civil courts; the civil court judges were viewed as more sympathetic to the legislature and to its efforts to redistribute power and wealth in France after the Revolution. Today, the *Conseil d'Etat*, acting as both a court of appeals for the administrative courts and a supervisory body for the administrative state, brings significant expertise to bear on the legality of regulatory decisions (Breyer 1993: Part III).

<sup>&</sup>lt;sup>4</sup> By contrast, judicial regulatory oversight typically involves generalist professionals who are neither experts in one regulatory topic (though they are experts in administrative law) nor politically accountable – rather, they are often intended to be independent, at least partly shielded from political influence via secure job tenure. See Jordao and Rose-Ackerman 2014.

Since 2009, the *Conseil d'Etat* also reviews impact assessments before proposed new regulatory legislation is sent to the National Assembly.<sup>5</sup>

Modern ROBs, established since the 1970s, have a different origin. They were mainly created in response to concern over the economic impact and social performance of the growing array of regulations, the need for expert analysis, the need for public accountability and transparency, and the desire by executive branch leaders (presidents or prime ministers) to manage the regulatory state.

**2.1 The origin of the US Office of Information and Regulatory Affairs** In the late 18<sup>th</sup> century, the US Constitution's system of checks and balances among branches of government was designed to avoid the concentration of power that existed in monarchic regimes. By the 20<sup>th</sup> century, that foundational strategy continued to animate the evolution of regulatory oversight. The US Administrative Procedure Act (APA) enacted in 1946 was in part a response to the 'New Deal' expansion of federal regulation in the 1930s and 1940s. In turn, the US Executive Orders on regulatory impact assessment issued by several Presidents, beginning in the 1970s, were in part a response to the 'Great Society' expansion of health and environmental legislation in the 1960s and 1970s, as well as the slowing economy, accumulated economic regulation, and academic analysis. (On this history, see Mendelson and Wiener 2014: 454-463.)

In 1978, President Jimmy Carter (a Democrat) issued Executive Order (EO) 12044, requiring economic analysis of new regulations, and he created the Regulatory Analysis Review Group, an interagency working group that gathered when needed to review these economic analyses. Then in 1980, President Carter signed the Paperwork Reduction Act, which created the US Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB). OIRA was thus located in the Executive Office of the President. The Administrator of OIRA is appointed by the President and, since the 1986 amendments to the Paperwork Reduction Act (Pub. L. 99-591), is subject to confirmation by the Senate. OIRA had approximately 80 expert non-political staff in the 1980s; that number has declined to about 40 today. Whereas the RARG had been an interagency group that met on occasion, OIRA is a standing centralized expert oversight body.

Just after Ronald Reagan (a Republican) became President in 1981, he issued Executive Order (EO) 12291, formally giving OIRA the role and authority of a ROB. The Reagan EO required agencies to conduct regulatory impact assessments using benefit-cost analysis, to ensure that regulations' benefits 'outweigh' their costs, and to submit those RIAs to OIRA for review, while giving OIRA the power to 'return' an unsatisfactory regulation or RIA to the agency. Some viewed the EO as an intrusion on the agencies' duties to carry out statutory instructions from the Congress; but others replied that the EO expressly provided that it did not override statutes, and that the President still has the authority to manage the executive branch. The Reagan EO also received criticism from those who saw it as antiregulatory. President George H.W. Bush continued OIRA's role under EO 12291.

When Bill Clinton (a Democrat) became President in 1993, there was much speculation that he might issue a new EO diminishing or ending OIRA's role in regulatory oversight. Instead, Clinton's EO 12866 reaffirmed the role of OIRA in reviewing agencies' policy proposals and RIAs using benefit-cost analysis. It replaced the word 'outweigh' with the word 'justify,' thereby emphasizing the importance of qualitative as well as quantitative criteria, and orienting benefit-cost analysis to inform the considered judgments of publicly

4

<sup>&</sup>lt;sup>5</sup> Loi organique n° 2009-403 du 15 avril 2009 relative à l'application des articles 34-1, 39 et 44 de la Constitution [Law of 2009-403 of Apr. 15, 2009 for the Application of Articles 34-1, 39 to 44 of the Constitution], Journal Officiel de la République Française [J.O.] [Official Gazette of France], Apr. 16, 2009, p. 6528.

accountable officials, not dictating decisions arithmetically. Clinton's EO also broadened the scope of the impacts to be considered in RIAs to include distributional impacts and ancillary impacts, and it enhanced the transparency of OIRA review. The Clinton administration also issued best practice guidelines on preparing IAs.

George W. Bush (a Republican) was elected president in the contentious 2000 election, and soon speculation arose again that he might issue a new EO enhancing OIRA's oversight role. Instead, Bush retained Clinton's EO 12866 (with only minor modifications made in his second term, such as adding coverage of agency 'guidance documents'). During the Bush administration, OIRA also issued guidelines on the conduct of RIA, notably through Circular A-4 in September 2003.

Barack Obama (a Democrat) took office in 2009 and also maintained EO 12866 issued by President Clinton, and Circular A-4 issued by OIRA under President Bush. President Obama also adopted further EOs: to promote retrospective review (EO 13563), impact assessment by 'independent' agencies (EO 13579), and international regulatory cooperation (EO 13609) (see Mendelson and Wiener 2014: 454-463).

Thus, the creation and role of OIRA has now come to reflect a bipartisan consensus among all the US Presidents of the last four decades, of both political parties, that the executive branch needs tools to oversee the regulatory state and manage its choices, employing both expert analysis and political accountability, regardless of which political party is in power (E. Kagan 2001; Mendelson and Wiener 2014: 457-458).

**2.2 The origin of the EU Impact Assessment Board/Regulatory Scrutiny Board** In Europe, regulatory review was not formally established until after 2000. Nonetheless, this history reflects a similar pattern to that seen in the US.

The European Union (EU) launched its formal impact assessment (IA) procedure in 2002 as a regulatory review system within the European Commission. This process scrutinizes the quality of IAs conducted by the Commission services (directorates general, or DGs) on proposals for new or revised policies. From 2002 to 2006, these IAs were shared and discussed among the Commission services. Then in November 2006, a ROB was established to oversee the IA process: the EU Impact Assessment Board (IAB), located in the office of the Secretariat-General of the European Commission (Alemanno, 2008). The IA process and the creation of the IAB grew out of the EU 'Better Regulation' initiative (Wiener 2006), which was spurred by the Lisbon Agenda and the Mandelkern Report of 2001. The Commission issued Impact Assessment Guidelines in 2003, and revised them in 2005, 2009 and 2015.

In May 2015, the Commission under new President Juncker renamed the IAB the Regulatory Scrutiny Board (RSB). The primary role of the IAB/RSB has been to oversee the quality of the IAs produced by the DGs when the latter propose new policies, and to support DGs in their analytic efforts. The IAB was a five-member board (later expanded to nine), made up of high-level Commission officials from several DGs. The RSB consists of seven members, including three 'independent' members (e.g. from academia) (still yet to be named as of April 2016). Both the IAB and the RSB are chaired at the Director-General level, and, in particular, as in the past, the current Chair is one of the Deputy Secretaries-General. The structure of the IAB/RSB is thus more akin to the interagency RARG than to the standing body of OIRA with its single Administrator and permanent staff. It remains to be seen how well this new multi-member setup will function (Alemanno 2015a).

As in the US, albeit with a different institutional history and structure, the EU Better Regulation initiative and its Impact Assessment program, including the creation of the IAB/RSB, have been in part a response to the growth of EU-level regulation, notably following the 1987 Single European Act and the 1992 Maastricht Treaty (Alemanno 2008: 45-46). The EU's adoption of the IA review process was also a way to support the Lisbon strategy for economic advance. The setting up of the IAB drew lessons from the US (Wiener 2006), but also from the UK and other member state examples, where significant improvements in the regulatory frameworks and deregulation had been seen as associated with renewed economic growth (Radaelli and De Francesco 2007). As in the US, regulatory oversight has achieved a kind of bipartisan consensus in the EU: The EU Better Regulation initiative and the IA process have been supported through several presidencies of the Commission, including Presidents Romano Prodi (a progressive) José Manuel Barroso (a conservative), and Jean-Claude Juncker, and have also been endorsed by the Council of the EU.<sup>6</sup> Under President Juncker, Better Regulation has been elevated to one of the Commission's top political priorities.

### 2.3 Other examples of ROBs

These trends have been mirrored in many other countries and jurisdictions, spreading across almost all OECD countries (OECD 2015). For example, the UK has had a Regulatory Impact Unit, followed by a Better Regulation Executive, with an advisory body called the Better Regulation Task Force; these were succeeded by the Better Regulation Commission in 2006, and in turn by the Risk and Regulation Advisory Council in 2008, and now the Regulatory Policy Committee (RPC), as well as accompanied by additional scrutiny from the National Audit Office, the Panel for Regulatory Accountability, and the House of Commons. The Netherlands program to reduce administrative costs was overseen by the Inter-Ministerial Project Team (IPAL) in the Ministry of Finance, with external scrutiny by the Advisory Board on Administrative Burdens (ACTAL) (OECD 2007b). Countries such as Mexico, with COFEMER following on to the previous example of UDE, and Korea have also set up ROBs, influenced by examples in other OECD countries and by advice from the OECD. At the EU level, the European Court of Auditors (an institution created to audit the EU budget) has also indicated some interest in performing a role in regulatory oversight. Beyond the 35 members of the OECD, several other countries have established or are creating ROBs (Renda and Castro 2016; Wiener 2013; Wiener and Ribeiro 2016).

### 3. Structure: constitutional and institutional design of the US and EU ROBs

In the US, the location of the main ROB, OIRA, is in the Executive Office of the President. The OIRA Administrator is appointed by the President, with confirmation by the Senate. The OIRA Administrator reports to the Director of Office of Management and Budget (OMB), and then to the President. From this center-of-government location, OIRA oversees regulation by all federal agencies – and although it has historically limited its RIA oversight authority to 'executive' agencies and taken a more deferential approach to 'independent' agencies (Mendelson and Wiener 2014: 449, 459-460), that stance may be evolving toward more inclusive oversight as Presidents (as indicated in EO 13579) and scholars (Datla and Revesz 2013; Bubb 2015) increasingly favor OIRA oversight of RIA by historically 'independent' agencies. OIRA's oversight role is nested among other White House offices also interested in shaping policy (such as the Council on Environmental Quality [CEQ], which can review agencies' environmental impact assessments), potential judicial review in the courts, and potential further legislative action by the Congress. The distinct regulatory systems of the 50 states may help administer federal regulations, and may have their own ROBs to review state agencies' regulations. Meanwhile, OIRA's location in the executive branch and the separation of powers structure of the US government means that OIRA review

<sup>&</sup>lt;sup>6</sup> Council of the European Union, Conclusions of the Competitiveness Council on Better Regulation, December 3-4, 2009.

occurs after legislation has been enacted by the Congress, and typically after the agency has developed and proposed a new regulation to implement that legislation (Parker ad Alemanno 2015) (although OIRA has sought to play a role earlier in agencies' development of their regulations, see Graham 2007a).

The US has no IA process nor ROB to oversee Congressional enactment of primary legislation itself. Compared to the courts and the executive branch, Congress has played a smaller role in regulatory review. Some comment on some proposed legislation may occur through Congressional committee hearings, debates among members of Congress, input and analysis from the White House and agencies, and analyses by Congressionally established bodies such as the General Accountability Office (GAO), the Congressional Budget Office (CBO), and the Administrative Conference of the US (ACUS). But, in general, after having created OIRA, Congress has not strongly favored regulatory oversight – especially of its own legislative enactments<sup>7</sup>. Congress has no ROB of its own equipped to carry out such a function.

In the EU, the structure of principals and agents is more fragmented and interwoven across several institutions. The European Commission, akin to an executive branch, nonetheless has the sole authority to propose new legislation to be enacted by the legislative European Parliament and European Council (with possible amendments). Thus the IAB/RSB, established within the Commission, is reviewing the IAs conducted on DGs' proposals for new primary legislation, before enactment. If amendments are considered to such legislative proposals, further IA may be conducted by the European Parliament's own Impact Assessment Unit. And when such legislation is later implemented in the member states, the member states' ROBs may conduct their own IAs of their implementation policies.

Compared to US OIRA review of RIAs on agency regulations after legislation is enacted, the EU IAB/RSB review of proposals for legislation occurs much earlier in the policy cycle (for more detail and a useful flow chart, see Parker and Alemanno 2015; and cf. Alemanno and Meuwese 2013 on the possibilities of EU review of post-legislative implementing actions). In the EU, most legislation is then implemented not by the EU institutions (such as the Commission and its DGs), but by the member states through their national governments, whereas in the US most Congressional legislation is then implemented by the federal agencies. Hence the early EU IAB/RSB review of IAs occurs before further amendments and before the details of implementation are worked out (perhaps before the policy details are fully clear), while the later US OIRA review of RIAs occurs after primary legislation (hence after some options may already have been mandated or prohibited in the enacted legislation). And the IAB/RSB oversight role is nested among other bodies, including the European Court of Justice, the European Court of Auditors (which reviews the budget), and the European Ombudsman (which can investigate 'maladministration') (Lindseth, Aman & Raul 2008, Alemanno 2009).

These different approaches to the structure of oversight in the US and EU systems stem in part from the different structures of governance on each side of the Atlantic. In the US, legislation begins in the Congress, a political body, which enacts statutes and can thereby create regulatory agencies and delegate tasks to these agencies. The agencies possess technocratic expertise that the Congress lacks, and Congress often relies on the agencies to determine essential issues such as the appropriate level of protection of health and environment. OIRA in turn is also a highly technical body, staffed by professional experts, that reports to the President. The heads of the agencies and the head of OIRA are all

<sup>&</sup>lt;sup>7</sup> The EU TTIP proposal for Chapter : Good Regulatory Practices, notably Article 2 (a) and Article 8, requires both the EU and the US 'planned regulatory acts' (which encompass both legislative and regulatory acts) to be subject to RIA. Available at http://trade.ec.europa.eu/doclib/docs/2016/march/tradoc\_154380.pdf 7

appointed by the President, but nonetheless it is sometimes a challenge for the presidency to steer the policy direction of the agencies, each of which has its own constituencies among the public and in Congressional committees, and some of whose heads are legally shielded from being easily removed by the President (Bubb and Warren 2014). Regulatory oversight through OIRA is one means for the president to manage this multi-headed regulatory state (E. Kagan 2001). Thus in the US, OIRA is a politically accountable body that exercises technocratic review of regulatory power delegated by Congress to the federal agencies.

In the EU, by contrast, legislation begins exclusively in the Commission, which is mainly a technical executive body, although the political accountability and authority of the Commission's president is growing (Alemanno 2015a). (The Commission's president is not popularly elected like the US president, but rather is nominated by the European Council and elected by the European Parliament.) 'Agencies' such as the European Environment Agency or European Food Safety Authority exist in the EU, but, being judicially barred from exercising delegated regulatory authority,<sup>8</sup> their main function is to engage in preparatory research and deliberation under Commission oversight. Regulatory power is exercised by the Commission's DGs (such as DG Environment), subject to their proposals for legislation being proposed by the full Commission, and enacted by the Council and the Parliament. The Council is made up of the relevant ministers of the member states – a kind of legislature composed of elected representatives, seated by party not by member state. The adage is that 'the Commission proposes, the Council disposes.' These institutions operate in a complex relationship of delegation and cooperation.

Moreover, within the Commission and its DGs, many staff and observers point to a tradition of collaborative harmony or collegiality rather than adversarial or hierarchical relations; the 'College of Commissioners' (each from a different member state, and appointed together as a slate) makes its decisions in a consensual style. This emphasis on harmony and collegiality may derive from several factors, among them the original purpose of the European Community to heal and unify the continent. This may also be related to the substantially smaller and more close-knit size of the Commission (about 25,000 staff) compared to the larger US multi-agency administration (several hundred thousand staff in the civilian agencies; EPA alone has about 15,000 staff, while the Departments of Agriculture, Interior, and Transportation range from about 60,000 to 100,000 each). This collegiality within the Commission stands in contrast to the more hierarchical relationship in the US executive branch between OIRA (and the White House generally) and the federal agencies it oversees.

Thus in the EU, the IAB/RSB is a multi-member body (drawn from its own DGs) that is reviewing proposals from its own DGs, before those proposals go to the legislative branches for assent and then often to the member states for implementation. The structural role of regulatory 'oversight' is thus different in the EU, where legislation comes initially from the technical branch and where the Commission internally follows a collegial structure and style, than it is in the US. In the US, legislation comes initially from the most political branch, to be implemented through delegated power by the agencies, subject to review by the President. In the US, where the President may be held politically accountable by voters for the successes and failures of the regulatory agencies implementing Congressional statutes, the

<sup>&</sup>lt;sup>8</sup> Although the European Court of Justice recognised the need for delegated legislation in *Meroni* (case 9/56, *Meroni v. High Authority*), it limited significantly the possibility of delegating regulatory authority. The idea is that agency decisions should not entail any use of regulatory discretion beyond a purely technical evaluation of the applications against fixed criteria. For a recent critique of the 'Meroni doctrine' see Majone (2010). 8

ROB (OIRA) is a mechanism for the presidency to manage the administrative state through technocratic expertise in a hierarchical structure (Breyer 1993; E. Kagan 2001).

Science advisory bodies and public comment can also provide influential advice to regulators (Jasanoff 1990, Morgan & Peha 2003, Graham 1991). ROBs themselves may have external advisory bodies. For example the UK Better Regulation (BR) Executive has had its BR Task Force, which then became the BR Commission, and then the Risk and Regulation Advisory Council (OECD 2007a, chapter 3). Neither the US OIRA nor the EU IAB has a standing external advisory body, but such an external body has been called for by some members of the Commission<sup>9</sup> and the European Parliament.<sup>10</sup> The addition of three 'independent' members of the RSB reflects this interest in external expert input. Such calls could be amplified if the European courts conduct judicial review of the EU institutions' compliance with Better Regulation procedures.<sup>11</sup>

#### 4. Powers

The mandate of any ROB is usually set forth in its enabling document. The powers accorded to an ROB may depend importantly on the source of its authority, that is, on the institution that created the ROB, and the structure of governance in which the ROB operates. Depending on their powers, ROBs may perform a variety of functions or tasks. Neither OIRA's nor IAB/RSB's missions are limited to assessing the quality of analysis in RIAs. Their powers include:

(a) Inhibiting undesirable policies

OIRA has the power to inhibit the adoption of undesirable policies (such as those whose benefits do not 'outweigh' or 'justify' the costs), including by sending 'return' letters to the federal agencies, under EO 12291 and EO 12866. Initially, unlike OIRA, the IAB had no veto power over the IAs or policy proposals from the Commission DGs. The IAB could ask the relevant DG to resubmit a revised version of the original IA. Thus, while the IAB could not formally veto a flawed IA draft, its (negative) opinion could influence the outcome of the quality control process. Then in 2010, President Barroso required new regulatory proposals to obtain a positive opinion from the IAB before going forward (European Commission 2010a), thereby giving the IAB an authority more akin to OIRA's return letter power than the IAB had previously had<sup>12</sup>. Strikingly, while the IAB returned for resubmission only 9 percent of the DGs' regulatory proposals in 2007, by 2010 it was returning 42 percent, and its resubmission rate ranged between 33 and 48 percent in each year from 2008 to 2014 (European Commission, 2015a, Table 1). It remains to be seen how the new RSB will operate. Further, the Commission has required that new or revised legislation should be based on an expost evaluation of the existing policies, through a program to evaluate "regulatory fitness" called "REFIT" (European Commission 2014b; Alemanno 2015a).

The question is then how far ROBs may go in inhibiting undesirable policies. OIRA can issue return letters, but under EO 12866, the agency can then appeal to a more senior

<sup>&</sup>lt;sup>9</sup> Keynote Speech by Commissioner G. Verheugen, 'Better Legislation in the EU', delivered at the European Conference on Subsidiarity during the Austrian Presidency, 19 April 2006 ('what we need is the independent validation of impact assessment').

<sup>&</sup>lt;sup>10</sup> Report on Better Regulation in the European Union prepared by the Committee on Legal Affairs of the European Parliament (Rapporteur: Katalin Levai, 2007/2095(INI)) as a motion for an EP Resolution. See A6-0273/2007, para 6.

<sup>&</sup>lt;sup>11</sup> For example, in Spain v. Council (2006), the European Court of Justice held that failure to produce an IA to support a regulatory decision may lead to a violation of the 'proportionality' principle of EU law. See Case C-310/04, Kingdom of Spain v. Council of the European Union (2006); see Alemanno (2009).

<sup>&</sup>lt;sup>12</sup> This has been confirmed by the 2015 Impact Assessment Guidelines, para 3.15.

administration official (such as the Vice President or the White House Chief of Staff). Can the ROB go to court, or be challenged in court? In the US, courts usually do not enforce Presidential executive orders against executive agencies, or hear disputes between agencies and OIRA, i.e. within the executive branch. Revesz and Livermore (2008: 172) have proposed that OIRA's issuance of key oversight guidelines should be subject to judicial review, similar to rulemaking by regulatory agencies. US courts will require agencies to abide by Congressional statutes, which may affect regulatory oversight in various directions (including enforcing legislative requirements to conduct IA, enforcing legislative prohibitions on some types of analysis in rulemakings under some statutes, and enforcing legislative time limits on agency action notwithstanding ongoing OIRA review). The US Supreme Court has authorized agencies to conduct benefit-cost analysis under a statute using the term 'best' (Entergy v. Riverkeeper, 2009), and required agencies to conduct some version of benefit-cost analysis under a statute using the term 'appropriate' (Michigan v. EPA, 2015) (where the dissent also agreed that 'reasonable' regulation requires consideration of pros and cons). But these decisions interpret statutory language, not presidential EOs or OIRA guidelines. An open question is whether courts should give some kind of deference or nod to OIRA review of agency benefit-cost analysis, such that, for example, a favorable OIRA review would help the agency survive a challenge in court asserting that the agency's rule is 'arbitrary' or violates a statutory requirement such as 'appropriate' or 'reasonable' (Mendelson and Wiener 2014: 519).

In the EU, the European Courts may be starting to enforce such requirements.<sup>13</sup> Indeed, despite the Commission's efforts to dismiss any attempt to legalize the Better Regulation requirements, these requirements, by dictating a more informed and more inclusive method of decision-making, are expected to influence public expectations, thus encouraging stakeholders to act in order to ensure their implementation by the Commission. Not only are private parties willing to challenge the correctness of IAs carried out by the Commission services but it may be that the ECJ is ready to rely on IAs to determine a possible breach of a general principle of law, such as the principle of proportionality (Alemanno 2009).

(b) Promoting desirable policies

In its first two decades, OIRA did not have an institutional mechanism for using benefit-cost analysis to promote desirable new regulations. Then in 2001, OIRA Administrator John Graham began to issue 'prompt' letters to promote desirable new policies (see Graham 2007a).<sup>14</sup> Rather than being sent in response to the regulators' submission of a draft rule for ROB review, a 'prompt' letter is sent on the ROB's own initiative, and contains a suggestion for how the regulator could improve its regulations. The prompt letter, at least as developed by OIRA, does not mandate agency action; it only suggests a prima facie case for action based on an initial benefit-cost assessment showing that such new agency action could increase net benefits. For example, one of OIRA's first prompt letters was to the US Food and Drug Administration (FDA), asking FDA to consider a new rule requiring the listing of trans-fat content on the nutrition labels on packaged foods (which FDA subsequently promulgated).

Yet the issuance of prompt letters by OIRA has been episodic. OIRA issued about a dozen such letters under Graham between 2001-2006. There is not yet a system in place to help OIRA generate prompt letters routinely, much as OIRA currently reviews agency proposals and potentially issues return letters. One option would be an external advisory body

<sup>&</sup>lt;sup>13</sup> Case C-310/04, Kingdom of Spain v. Council of the European Union (2006) (holding that failure to conduct an IA is a breach of the proportionality principle), see Alemanno (2009).

<sup>&</sup>lt;sup>14</sup> OIRA posts its prompt letters online at <u>http://www.reginfo.gov/public/jsp/EO/promptLetters.jsp</u> (visited 24 April 2016).

to OIRA, or a new panel of the National Academy of Sciences, or both, that would generate candidate prompt letters.<sup>15</sup> An interagency working group could play a similar role. Another option would permit nongovernmental organizations to appeal to OIRA to issue a prompt letter if an agency denies a rulemaking petition (Revesz and Livermore 2008).

In Europe, the IAB's original Mandate and Rules of Procedure also speak of 'prompt' letters, but, unlike in the US context, they are prompts to conduct an IA, not to develop a regulation.<sup>16</sup> IAs are required for all Commission initiatives that are likely to have significant economic, environmental or social impacts, including legislative and regulatory proposals.<sup>17</sup> Following the establishment of the RSB, DGs are supposed to establish as early as possible in the policy planning/political validation process whether an IA is required on the basis of the associated Roadmap. If it is established that an IA will be carried out, the Roadmap should be developed and presented as an Inception IA.

(c) Information burdens

The ROB may also oversee the administrative burden of governmental requests for information. This was the objective of the US Paperwork Reduction Act of 1980 that created OIRA. It is also the objective of the efforts at Administrative Burden Reduction by many European governments. OIRA also oversees agency requests to collect information, such as through surveys. Meanwhile, the ROB may also oversee the accuracy of information produced by government agencies, as under the US Information Quality Act of 2001.<sup>18</sup>

(d) Quality of analysis

Both OIRA and the IAB/RSB are instructed to help agencies and DGs conduct better IAs. They may perform this task by issuing guidelines on how to conduct IA.<sup>19</sup> They may engage in early collaboration with agencies to shape the rule toward increasing net benefits – not just waiting to receive the proposed rule and then critiquing it.<sup>20</sup> They may act as 'information aggregators' to ensure that the views of all agencies are heard on each important rule (Sunstein 2013). Unlike the IAB, the mission of the RSB has been widened to include major retrospective evaluation and fitness checks of existing EU policies and legislation<sup>21</sup>.

### 5. Rules of procedure

To fully exercise its tasks and discharge its mandate, any oversight body must act within the framework of a set of procedural rules. The specific rules of procedure of a ROB can be important in determining its effectiveness, quality, and perceived legitimacy (Rose-Ackerman 1995). US OIRA follows rules of procedure established in EO 12866, including rules regarding the timetable to review agency IAs, the transparency of OIRA's contacts with outside parties, and the opportunity for an agency to appeal an OIRA decision. EO 12866 (1993) significantly changed OIRA's rules of procedure, notably by requiring much greater transparency than under EO 12291 (1981). The European Commission's IAB had rules of

<sup>&</sup>lt;sup>15</sup> See Committee of Past Presidents, Society for Risk Analysis (SRA), Recommendations to OMB on Regulatory Review, March 16, 2009, Recommendation number 7, p.9, available at <a href="http://sra.org/OMB\_regulatory\_review.php">http://sra.org/OMB\_regulatory\_review.php</a> .

<sup>&</sup>lt;sup>16</sup> IAB Mandate, point 4 and Article 6 of the IAB Rules.

<sup>&</sup>lt;sup>17</sup> Impact Assessment Guidelines, 2015, p. 17.

<sup>&</sup>lt;sup>18</sup> Information Quality Act of 2001, Pub. L. No. 106-554, § 515, codified at 44 U.S.C. 3516 (Note) (directing OMB to issue guidelines that 'provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information ... disseminated by Federal agencies'). OMB issued its guidelines in December 2001, see 67 Fed. Reg. 8452 (republication of Feb. 22, 2002).
<sup>19</sup> See OIRA Circular A-4 (Sept. 2003), and the EU IAB Mandate 2005, point 6.

<sup>&</sup>lt;sup>20</sup> See Graham (2007); IA Guidelines 2009; IA Guidelines 2015; IA Rules of procedure, Art. 5.3.

<sup>&</sup>lt;sup>21</sup> European Commission, Regulatory Scrutiny Board, Mission, tasks and staff, p. 2.

procedure issued in early 2007, governing the composition and voting of the five-member IAB, the timing of reviews of IAs, transparency of IAB deliberations, and sources of internal and external expertise. The RSB has new procedures as of 2016. In addition, US OIRA has guidelines for impact assessment, mainly in Circular A-4, Sept. 2003, as does the European IAB/RSB, mainly in its IA Guidelines of 2009 and 2015. OIRA also issued guidelines for good risk analysis (jointly with Office of Science and Technology Policy [OSTP] in September 2007).

# 5.1 Staffing

As noted above, US OIRA is headed by a single Administrator, appointed by the President, who is assisted by about 40 career staff members (down from about 80 in the 1980s). By contrast, the EU IAB was a five-member board, and the RSB has seven members, chaired by one of the Deputy Secretaries-General. The number of permanent staff at the IAB/RSB is small. It remains to be seen whether a seven-member board (four from the DGs, and three 'independent' experts) can operate effectively to review IAs, compared to OIRA's single Administrator and permanent staff (Alemanno 2015a).

# 5.2 Time to review

Under EO 12866, OIRA review of RIA is supposed to take no more than 90 days, and has typically averaged about 50 days, but in early 2013 the average rose to more than 140 days (Copeland, 2013). In the EU IAB/RSB, the time to review is 12 weeks before inter-service consultation begins. Too short a time period may make meaningful review of complex IAs difficult or impossible. But too long a time period may impose unwarranted delay on needed new rules and may undermine morale.

# 5.3 Who can participate in review

The EU rules expressly allow the IAB/RSB to solicit advice from outside experts, and its impact assessment system foresees a 12-week internet-based public consultation.<sup>22</sup> OIRA can receive communications from parties outside government (so long as they are identified in its docket), and sometimes solicits peer reviewers on its own publications, but does not seem to have the standard practice of soliciting advice from outside experts on agency RIAs. Both the IAB/RSB and OIRA have processes of inter-service (or interagency) consultation on proposed rules (Sunstein 2013). EO 12866 calls for the agency proposing the rule to be invited to have a representative present whenever OIRA staff meet with an outside party about the rule.

## 5.4 Appeals to higher authority

EO 12866 provides that disputes over a return letter could be appealed to a cabinet-level committee chaired by the Vice President. In the EU, no formal appeal proceeding is foreseen against an IAB/RSB opinion or Secretariat-General decision.

# 5.5 Influence of statutory deadlines

In the US, a statutory deadline or a court-ordered deadline for rulemaking will force the agency to act (e.g., to publish a rule) even if OIRA has not yet completed its review. A similar constraint does not exist in the EU, where IA is conducted on the Commission's own proposals for legislation, without such deadlines (see Alemanno 2009).

# 5.6 Public access to information about the review

Rules of procedure not only dictate each stage of the examination undertaken by the ROB, but also introduce transparency requirements. In the US, agency rulemaking is already public, pursuant to the APA, with requirements for notices of proposed rulemaking, proposed rules, and final rules all to be published in the Federal Register and now also online, and opportunities for public comment to which the agency must respond. EO 12866 added transparency provisions to ensure public awareness of the OIRA process, including a record of those who met with OIRA regarding each rule. Under John Graham in 2001-06, OIRA

<sup>&</sup>lt;sup>22</sup> Impact Assessment Guidelines, 2015, p. 16.

went further than required by EO 12866 and posted all of its return letters, prompt letters, guidelines, and almost all other important documents on its public web site, a practice it continues.<sup>23</sup>

In the EU, the location of IAB/RSB review in the regulatory process limits the transparency of its activities. Article 16 of the IAB Rules of Procedure seemed to ensure transparency to the extent that it requires the Board to make available its draft agendas, meeting records, opinions, prompt-letters, and notes signed by the Chair on behalf of the IAB as quickly as possible to all Commission departments. At the same time, it ensures public access to the Board's documents by subjecting them to principles and conditions as laid down in Regulation 1049/2001 regarding public access to European Parliament, Council and Commission documents<sup>24</sup>. Although all IAB/RSB opinions must be available to all Commission services,<sup>25</sup> they are released, through a publication on the RSB page within the Europa website, only when the Commission has adopted the corresponding legislative proposal. Thus the public does not have an opportunity to see and comment on the draft proposals and draft IAs before they are final. The lack of publication of the draft IA report combined with the delayed disclosure of its final version make it difficult to determine whether the IA actually influenced the proposal, and difficult for the public to comment on the draft proposal.

### 6. Scope of oversight

### 6.1. Timing: ex ante and ex post

Both US OIRA and EU IAB/RSB have focused on *ex ante* impact assessment of new regulations. Both are now also trying to increase their attention to retrospective *ex post* IAs of existing rules (through EO 13563 and the REFIT program, respectively, as discussed above). Retrospective review can be useful to identify needed policy revisions, and to assess and improve the accuracy of *ex ante* IAs (Harrington et al. 2000; Coglianese 2013; Sunstein 2014; OECD 2015: ch. 5, 119-140; Wiener 2006; Wiener 2013; Wiener and Ribeiro 2016).

### 6.2 Scope of impacts

Both US and EU regulatory oversight systems seek integrated assessment of all important policy impacts, including economic, environmental and social. EO 12866 calls for attention to qualitative as well as quantitative impacts, to distributional as well as aggregate impacts, and to ancillary as well as intended impacts. Ensuring attention to ancillary impacts (both harms and benefits) is especially important to overcome agencies' incentives to focus narrowly on their own domains, and to enable prospective and retrospective evaluation of the full portfolio of policy impacts on overall social well-being (Graham and Wiener 1995; Revesz and Livermore 2008; Wiener and Ribeiro 2016).

Some ROBs focus on reducing the administrative burden of existing rules (Renda and Castro 2016: sec. 3.1, p.18); in the US, EO 13563 and EO 13610 emphasize reducing the burden of existing regulation, as does REFIT in the EU. Despite the widespread enthusiasm for cutting red tape, it is not always obvious that cutting administrative burdens is desirable. Subjecting administrative burdens to a benefit-cost test (as for other regulations) would be superior to simply enforcing arbitrary administrative burden reduction targets. Regulations imposing information collection burdens can be warranted, such as to enable information disclosure and labelling rules that are more cost-effective than prescriptive technology-forcing

<sup>23</sup> See the OIRA website at <u>https://www.whitehouse.gov/omb/oira</u> (visited 24 April 2016) and the OIRA Letters page at <u>http://www.reginfo.gov/public/jsp/EO/letters.jsp</u> (visited 24 April 2016).

<sup>&</sup>lt;sup>24</sup> Regulation 2001/1049 of the European Parliament and of the Council of 30 May 2001, OJ L 145, p. 43.

<sup>&</sup>lt;sup>25</sup> Article 6 of the Rules.

rules, or to support benefit-cost analysis itself (OECD 2007b, Hamilton 2005; Sand 2010; Wiener 2006: 500-01). The European Commission recognised this in its 2006 revised IA Guidelines (stating in Box 11 that 'The fact that one option would impose lower administrative costs is *not* in itself a sufficient reason to prefer it. ... a measure ... likely to impose relatively fewer administrative costs ... could give manufacturers less flexibility and could reduce consumer choice, [so that] its overall costs may be higher than the 'administrative' requirement to display data ...').

## 6.3 Topical areas of regulation

In principle, an ROB could oversee all regulation, covering all topics. In practice, ROBs often focus on health, safety, security and environmental regulations (sometimes called 'social regulation' or 'risk regulation') while sometimes having curtailed powers or less emphasis in the area of banking, finance, competition, trade, and other 'economic regulation.'

Expanding the ROB's scope could bring the benefits of oversight to those areas and could also help correct the misimpression that oversight tools, such as benefit-cost analysis, are biased against the subjects of their current narrow application. For example, extending benefit-cost analysis beyond social regulation to cover economic regulation and government-funded projects would help demonstrate that benefit-cost analysis need not be biased against health or the environment. Benefit-cost analysis would then be deployed to assess environmentally damaging projects such as dams, deforestation and power plants – as it had been in its early uses decades ago (Kneese 2000, Hufschmidt 2000).<sup>26</sup> Early in the modern environmental movement, benefit-cost analysis was seen as a useful tool for environmental protection when applied to evaluate projects in the US and elsewhere.<sup>27</sup>

At the same time, expanding the scope of oversight could stretch ROBs' capacity. And it could bring ROBs into conflict with other institutions already active in those areas. A lively debate has arisen over whether benefit-cost analysis should be required of US financial agency regulation (Coates 2015), and if so, whether it should be overseen by OIRA (Bubb 2015). In another area, OIRA could expand its mandate to oversee international treaty commitments (via impact assessments); the US State Department has recently proposed requiring agencies to consult with OMB/OIRA on the regulatory impacts of pending new international agreements,<sup>28</sup> and the State Department already requires agencies to consult with OMB before making new budgetary commitments in international agreements.<sup>29</sup> Section 201 of the Trade Act of 1974, 19 USC 2251(a), calls for benefit-cost analysis of trade measures, but this law has not been overseen by OIRA.<sup>30</sup>

### 6.4 Types of legal action

As noted above, the IA system in the European Commission applies to proposals for legislation and regulatory acts (ie. delegated and implementing acts), whereas the RIA system in the US occurs only after enactment of legislation at the stage of administrative

http://www.whitehouse.gov/omb/assets/regulatory matters pdf/sg-omb final.pdf .

<sup>&</sup>lt;sup>26</sup> See the Federal Flood Control Act of 1936 (requiring that the 'benefits to whomsoever they may accrue are in excess of the estimated costs,' 33 USC 701(a)).

<sup>&</sup>lt;sup>27</sup> See e.g. Berkman and Viscusi (1973) (using BCA to critique federal dams); Calvert Cliffs Co-ordinating Committee v AEC, 449 F 2d 1109 (DC Cir 1971) (finding that the Environmental IA provision in NEPA section 102(2)(C) requires benefit-cost analysis of federal projects such as nuclear power plants, in order to take into account their previously neglected environmental costs), cert denied, 404 US 942 (1972).

<sup>&</sup>lt;sup>28</sup> 71 Fed Reg 28831 (18 May 2006).

<sup>&</sup>lt;sup>29</sup> See 22 CFR § 181.4(e).

<sup>&</sup>lt;sup>30</sup> See on this point, Review of the application of EU and US Regulatory Impact Assessment Guidelines on the Analysis of Impacts on International Trade and Investment, Final Report and Conclusion, prepared by the OMB and Secretariat-General of the EU Commission, available at

implementation (Parker and Alemanno 2015). The EU Parliament has added an IA Unit to assess amendments (although it also reviews the Commission's IAs), and EU member states have their own ROBs. To the extent that US agency regulations warrant oversight, in many cases much of their costs and benefits derives from the underlying legislation. Perhaps the US Congress could create a new ROB, to oversee IA of legislation proposed in the Congress. Such a system would need a screening method to select which proposals warrant review, and staff with relevant expertise.

## 6.5 Selection of which regulations to review

Any ROB with limited oversight resources (staff, funding, time) must have some criteria for selecting which regulations to review. In the US, section 3(f) of EO 12866 sets a threshold for "economically significant," requiring an IA for any regulation imposing \$100 million or more in impacts (and for those interfering with the plans of another agency, or raising novel legal issues). With inflation, this threshold has come to cover more rules over time (Mendelson and Wiener 2014: 483-85). In Circular A-4 (2003), OIRA added the criterion that any regulation posing an impact exceeding \$1 billion should be accompanied by an IA using formal probabilistic scenarios to assess its impacts.

The EU IA Guidelines do not set a quantitative threshold, but instead employ the concept of 'proportionate analysis,' meaning that the degree of analysis should be greater where the potential impacts of the regulation are larger. This approach avoids potential errors or gaming around the cut-off line. OIRA and the Office of Science and Technology Policy (OSTP) endorsed the concept of proportionate analysis in 2007, saying 'The depth or extent of the analysis of the risks, benefits and costs associated with a decision should be commensurate with the nature and significance of the decision.'<sup>31</sup>

#### 6.6 Analytic methods

As discussed above, ROBs can employ a variety of analytic methods in their reviews, and can ask agencies to use these methods in their regulatory IAs. Statutory restrictions sometimes limit the type of analysis that an agency may use in making its regulatory decisions. For example, the US Congress has in some statutes prohibited (or the courts so infer from statutory language) agencies to use benefit-cost analysis in developing rules, but in some other statutes Congress has required or authorized agencies to use benefit-cost analysis.<sup>32</sup> In cases where BCA is prohibited under the statute, the agency can still prepare an RIA using BCA for OIRA review under the EO, but the agency is not supposed to refer to or base its decisions on that analysis when it sets standards in the rule itself.<sup>33</sup> In the early 1990s, Congress considered but did not enact a law including a 'supermandate' to require benefit-cost analysis. A different option would be a legislative 'superauthorization,' permitting but not requiring agencies to use benefit-cost analysis in major rules notwithstanding prior statutory restrictions on such analysis. This approach was taken by Congress in the 1996 amendments to the Safe Drinking Water Act, but has not yet been employed more broadly.

In the EU, where legislation is initiated by the Commission, and the Commission has committed itself to conduct impact assessments, there are no restrictions in particular pieces of legislation on the use of impact assessments. The EU Commission's IA Guidelines require analysis of 'positive and negative impacts', without imposing any specific methodology. The

<sup>&</sup>lt;sup>31</sup> OMB/OIRA and OSTP Memorandum on Updated Principles of Risk Analysis, Sept. 19, 2007, p. 4.

<sup>&</sup>lt;sup>32</sup> See Whitman v. American Trucking Assns., 531 U.S. 457 (2001) (BCA prohibited); Entergy v. Riverkeeper, 556 U.S. 208 (2009) (BCA authorized); Michigan v. EPA, 576 U.S.--- , 135 S.Ct. 2699 (2015) (BCA required).

<sup>&</sup>lt;sup>33</sup> For example, for national ambient air quality standards under section 109 of the Clean Air Act. See Whitman v. American Trucking Assns., 531 U.S. 457, 471 n.4 (2001). But employing BCA could actually lead to stronger protections of ambient air quality and public health than avoiding BCA, see Revesz and Livermore 2014.

2009 Lisbon Treaty on the Functioning of the European Union, Article 191, expressly calls for analysis of benefits and costs in setting environmental standards.<sup>34</sup>

#### 7. Conclusions

As governments seek better policy making, they establish Regulatory Oversight Bodies to supervise the quality of regulatory analysis and action. Our review of US and EU practice indicates that ROBs are structured to fit the constitutional framework of governance, and yet that institutional housing can shape and limit an ROB's powers and effectiveness.

The US and EU have now created generally similar systems of RIA and ROBs, with powers to review policies and impact assessments, to return and to prompt. But differences remain between OIRA in the US and the IAB/RSB in Europe, deriving in part from the different US and EU constitutional contexts. Impact assessment in the US and the EU is conducted and reviewed at different stages in the policy cycle, with different powers and limitations. In the US, Congress enacts statutes instructing agencies to regulate; the President then requires agencies to conduct RIAs to accompany proposed rules, and empowers OIRA, a body created by statute, to oversee rules and to review the RIAs. In the EU, IAs are conducted by the Commission, on its own legislative proposals, and largely for its internal use; the IAs are then reviewed by the IAB/RSB within the Commission to support its own policy decisions. Further, OIRA has a single high-level administrator and a sizable (though declining) permanent expert staff, whereas the IAB/RSB is a multi-member board with fewer staff. And a year after the May 2015 announcement revising the IAB into the RSB, the three independent members of the RSB have still not been named, raising questions about its capacity to be effective. Meanwhile, both OIRA and the IAB/RSB are seeking to increase the role of retrospective ex post RIA, in order to evaluate actual impacts, revise existing policies, and improve the accuracy of ex ante RIA. Both may also exercise a sort of 'soft power' to strengthen the overall culture of regulatory quality, consistent with the view that 'to be effective, a system of regulation must create compliance incentives for regulated parties, rather than rely on corrective action and oversight.' (Elliott 1994).

The emergence of ROBs in both the US and, more recently, the EU, demonstrates the transatlantic consensus on the desirability of regulatory oversight, at least at the centers of government. An open question deserving further study is how effective the ROBs are at improving the quality of IAs and of regulatory policies. Does 'better regulation' actually yield better regulation?<sup>35</sup> By studying the variation in origins, structures, powers, procedures and scope, along with associated outcomes, each polity can learn from the other's experience to improve its performance. Differences can be sources of insight and learning if their impacts are monitored, evaluated and shared over time. In that way, the US and EU can use the parallel development of their ROBs to engage in a 'transatlantic policy laboratory' that yields better regulatory results for both (Wiener and Alemanno 2015).

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<sup>&</sup>lt;sup>34</sup> As a result, the IA conducted by DG Environment on the Clean Air for Europe (CAFÉ) policy – the EU counterpart of the US EPA's national ambient air quality standards – included an extensive analysis of benefits and costs that many regard as one of the best quality IAs prepared by the Commission to date. See <a href="http://ec.europa.eu/environment/archives/cafe/general/keydocs.htm">http://ec.europa.eu/environment/archives/cafe/general/keydocs.htm</a>.

<sup>&</sup>lt;sup>35</sup> For an appraisal of the research needs in Europe, see Alemanno 2015. Empirical assessments of the impact of OIRA oversight, finding modest but beneficial influence, include Croley (2003) and Hahn & Muething (2003). 16

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