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Achieving Regulatory Policy Objectives: An Overview and Comparison of U.S. and EU Procedures

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Abstract

This paper aims to provide a descriptive analysis of procedural differences in regulatory development between the United States and the European Union to serve as a factual basis for understanding the regulatory challenges and opportunities for transatlantic trade. It summarizes regulatory procedures in each jurisdiction, dividing the process for establishing regulations into four stages: 1) agenda setting, 2) regulatory development, 3) final determination and opportunities for challenge, and 4) implementation and enforcement. After presenting the procedures in the U.S. and EU, the paper compares how the shared goals for achieving a regulatory system that is evidence based, transparent, and accountable are achieved in the two jurisdictions.

This draft paper has been produced with the assistance of the European Union. The contents of this paper are the sole responsibility of the authors and can in no way be taken to reflect the views of the European Union.

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Susan E. Dudley & Kai Wegrich¹

The quality and extent of government regulation is “a major determinant of prosperity.”² As the World Bank observes, “a thriving private sector—with new firms entering the market, creating jobs and developing innovative products—contributes to a more prosperous society,”³ “promotes growth and expands opportunities for poor people.”⁴

The United States and the European Union, along with other “OECD high-income economies continue to have the strongest legal institutions and the least complex and costly regulatory processes on average”⁵ according to the World Bank’s annual *Doing Business* survey.

All the top countries [in the Bank’s survey] regulate, but they do so in less costly and burdensome ways. And they focus their efforts more on protecting property rights than governments in other countries.⁶

As the U.S. Office of Management and Budget has noted, these “results are also consistent with economic theory, which predicts that economic growth is enhanced by regulatory policies that promote competitive markets, secure property rights, and intervene to correct market failures rather than to increase state influence.”⁷

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² World Bank 2003. *Doing Business in 2004: Understanding Regulation*. Washington, DC: World Bank Group.

³ World Bank. 2013. *Doing Business 2014: Understanding Regulations for Small and Medium-Size Enterprises*. Washington, DC: World Bank Group. The Bank notes that the 8 economies that joined the European Union in 2004 have “largely continued on a path of comprehensive and ambitious economic and institutional reforms.”

⁴ World Bank 2003.

⁵ World Bank 2013.

⁶ World Bank 2004. *Doing Business in 2005: Removing Obstacles to Growth*. Washington, DC: World Bank Group.

⁷ U.S. Office of Management and Budget. *2006 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities*.

Well-reasoned regulatory policies and practices that are not excessively burdensome can not only facilitate economic growth and public welfare within countries, but they can support international trade and investment, which raises standards of living across jurisdictions.

Recognizing this, the Transatlantic Trade and Investment Partnership (T-TIP) between the EU and the U.S. aims to be “an ambitious and comprehensive trade agreement that significantly expands trade and investment between the United States and the EU, increases economic growth, jobs, and international competitiveness, and addresses global issues of common concern.”⁸

While recognizing that Europe and the U.S. have an “immensely successful economic relationship,” officials on both sides of the Atlantic hope to “do more to strengthen the contribution of trade and investment to fostering jobs, growth, and competitiveness in both economies.”⁹

The success of T-TIP depends on strengthening EU-U.S. regulatory coherence, and reducing regulatory barriers to transatlantic trade and investment. As our economies become more global, and the EU and U.S. work to reduce tariffs and explicit trade barriers, regulations are emerging as more important and significant barriers to trade.¹⁰ Not only can poorly designed or conflicting regulations inhibit transatlantic trade and investment, but differences in regulatory policy and procedural approaches may continue to challenge economic partnerships between the EU and U.S.¹¹ While forward-looking (horizontal) regulatory cooperation efforts have been relatively successful, and may offer more opportunities than efforts to change existing regulations, they also face significant challenges.¹² In particular, procedural differences in how regulations are

⁸ Office of the U.S. Trade Representative, “U.S. Objectives, U.S. Benefits In the Transatlantic Trade and Investment Partnership: A Detailed View” March 2014. <http://www.ustr.gov/about-us/press-office/press-releases/2014/March/US-Objectives-US-Benefits-In-the-TTIP-a-Detailed-View>

⁹ Final Report of the EU-US High Level Working Group on Jobs and Growth, February 11, 2013. Available at http://trade.ec.europa.eu/doclib/docs/2013/february/tradoc_150519.pdf.

¹⁰ Thomas J. Bollyky, “Better Regulation for Freer Trade,” Center on Foreign Relations, Policy Innovation Memorandum No. 22, June 2012. <http://www.cfr.org/trade/better-regulation-freer-trade/p28508>

¹¹ Céline Kauffmann, “The OECD Perspective on Good Regulatory Practices and International Regulatory Cooperation.” November 2014. <http://regulatorystudies.columbian.gwu.edu/oecd-perspective-good-regulatory-practices-and-international-regulatory-cooperation>. Anne Meuwese, “EU–US horizontal regulatory cooperation: Mutual recognition of impact assessment?” In D. Vogel, & J. Swinnen (Eds.), *Transatlantic Regulatory Cooperation: The Shifting Roles of the EU, the US and California*. (pp. 249-264). Cheltenham: Edward Elgar Publishing. 2011.

¹² The EU-US High-Level Regulatory Cooperation Forum has been successful in advancing cooperation and discussion among EU and U.S. regulators. http://www.whitehouse.gov/omb/oira_irc_europe

analyzed, developed, and enforced must be understood if regulatory cooperation is to be achieved.

Thus, one of the goals of the T-TIP negotiations is to agree upon:

Cross-cutting disciplines on regulatory coherence and transparency for the development and implementation of efficient, cost-effective, and more compatible regulations for goods and services, including early consultations on significant regulations, use of impact assessments, periodic review of existing regulatory measures, and application of good regulatory practices.¹³

Achieving this goal requires both policy research to identify and analyze key challenges, and public debate to develop politically-feasible solutions. This paper aims to provide a descriptive analysis of procedural differences in regulatory development to serve as a factual basis for understanding the regulatory challenges and opportunities for transatlantic trade.

The sections below summarize regulatory procedures in each jurisdiction, dividing the process for establishing regulations into four stages: 1) agenda setting, 2) regulatory development, 3) final determination and opportunities for challenge, and 4) implementation and enforcement. After presenting the procedures in the U.S. and EU, we compare how the shared goals for achieving a regulatory system that is evidence based, transparent, and accountable are achieved in the two jurisdictions.

Summary of U.S. Regulatory Procedure

The United States is a federal republic, comprising 50 states and the District of Columbia. The U.S. Constitution divides federal regulatory power among three branches. It grants the *legislative branch* (a bicameral body made up of a Senate and House of Representatives) the power to pass laws; it tasks the *executive branch* (headed by the President) with administering and enforcing those laws; and it makes the *judicial branch* responsible for settling conflicts

¹³ Final Report of the EU-US High Level Working Group on Jobs and Growth, February 11, 2013. This objective is reiterated in the Initial EU Position Paper “Trade Cross-cutting disciplines and Institutional Provisions,” July 2013. Available at <http://trade.ec.europa.eu/doclib/html/151622.htm>

arising from those laws.¹⁴ This “separation of powers” and the corresponding “checks and balances” that each branch provides on the others, are central to the U.S. approach to regulation.

Figure 1, below, illustrates the key steps in the regulatory process.

Stage 1 – Agenda Setting

Under the Constitution, it is the legislative branch that must provide the authority underlying all regulations. This bicameral body enacts legislative statutes by majority vote of both houses, followed by the signature of the President. Over the course of each two-year “Congress,” many draft laws or “bills” may be introduced, but only a small fraction of them actually become laws.

To become law, a bill goes through several steps. First, a Member of Congress must “sponsor” it, at which point it is given a number (e.g., H.R. 1 or S. 25), and referred to a committee. While anyone can draft a bill, only members of Congress can introduce it. Some bills are introduced at the request of the President.¹⁵ The chair of the committee to which the bill is referred decides whether it will receive committee consideration. If not, it will not proceed. With permission of the chair, the committee will hold public hearings, after which it may vote to send a “marked up” bill to the full chamber (Senate or House). That chamber’s leadership then decides whether to allow debate on the floor among the full membership. This debate is governed by different rules in the two houses, but is also public.

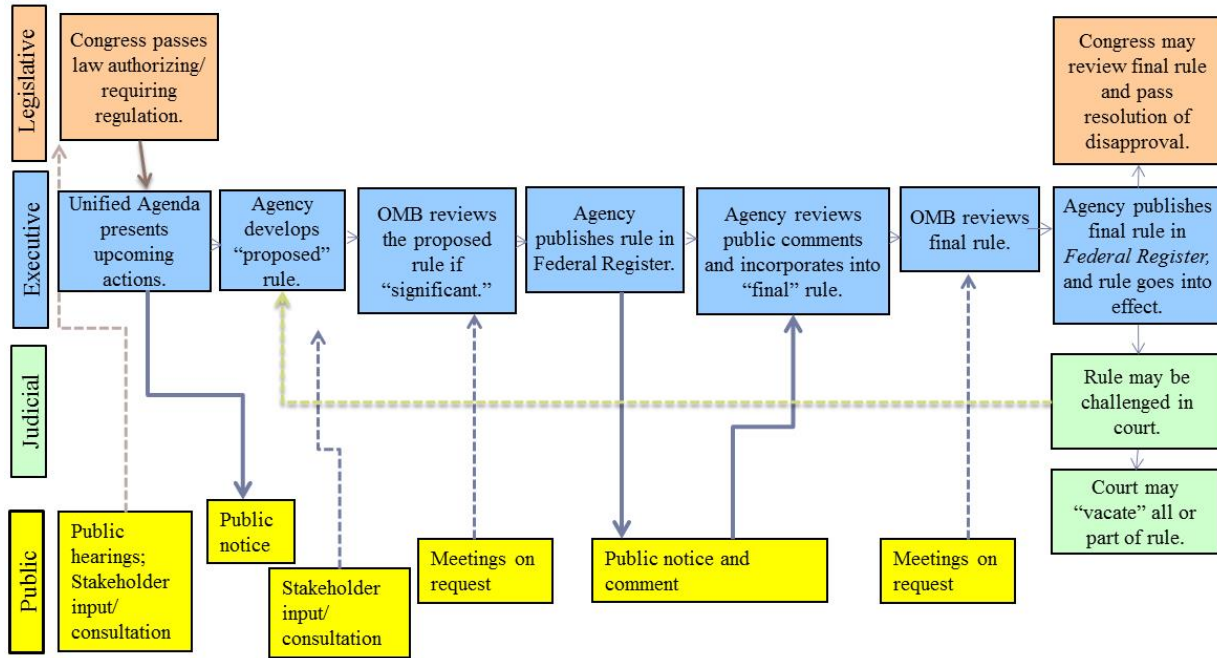
If one chamber votes to pass a bill, it is sent to the other chamber unless that chamber already has a similar measure under consideration. If either chamber does not pass the bill, it will not proceed. Often, the two chambers pass different bills, which must be reconciled during a Conference Committee comprising Members from both chambers. Once they reach a compromise, the final bill goes back to each chamber for a vote.

¹⁴ According to the Tenth Amendment to the Constitution, “Powers not delegated [to a branch of the federal government] are reserved to the states... or to the people.”

¹⁵ For example, the annual fiscal budget is introduced each year at the request of the President. During the legislative process, these bills and others undergo significant changes.

Figure 1. Key Steps in U.S. Regulatory Development Process

U.S. Rulemaking Process



www.RegulatoryStudies.gwu.edu

Source: Susan E. Dudley, "Opportunities for Stakeholder Participation in U.S. Rulemaking," GW Regulatory Studies Center. <http://regulatorystudies.columbian.gwu.edu/opportunities-stakeholder-participation-us-regulation>

The Congressional Budget Office (CBO) produces formal estimates of the budgetary costs of all bills (except appropriations bills) once they are approved by a full committee of either House of Congress. Congressional leadership may also ask CBO to produce formal and informal cost estimates of legislative proposals at other stages of the legislative process. Pursuant to the Unfunded Mandates Reform Act, CBO also assesses the cost of legislative "mandates" that would increase expenditures by state, local, and tribal governments or the private sector.¹⁶

Once a bill passes both the House and Senate, it is sent to the President, who may sign it – at which point it becomes law – or he may veto it. A two-thirds majority vote of both houses can override a Presidential veto. Any bill not passed and signed by the President expires at the

¹⁶ Unfunded Mandates Reform Act of 1995, Public Law 104-4

conclusion of the 2-year Congressional session (although bills can be reintroduced in a subsequent Congress and the procedure starts again).

Fewer than 5 percent of bills introduced actually become law.¹⁷ During the 113th Congress (2013-2014), 10,524 bills were introduced (6,812 in the House and 3,712 in the Senate).¹⁸ Of those, only 296 (or less than 3 percent) were enacted into law, and only about 10 percent of those laws address regulatory matters.¹⁹

However, those that do confer new regulatory authority and responsibility on executive branch agencies can lead to numerous rulemakings over many years. The length, significance, and specificity of the authority these statutes grant executive departments and agencies varies significantly. A statute may direct an executive branch department or agency to conduct rulemaking by assigning deadlines by which regulatory actions should be taken, or the frequency by which regulatory decisions should be updated. For example, the Patient Protection and Affordable Care Act of 2010 assigned agencies such as the Department of Labor and Department of Health and Human Services deadlines by which dozens of regulations were to be promulgated.²⁰ Often, statutes will grant broad authority to departments or agencies within the executive branch to develop and issue regulations. For example, the Clean Air Act of 1970 directed the U.S. Environmental Protection Agency (EPA) to establish national standards to “protect public health” with an “adequate margin of safety,” which grants the agency not only wide latitude in setting the standards but an ongoing responsibility to update them periodically based on new information.²¹

Thus, while all regulatory action must be authorized by legislation enacted by Congress, a particular regulation may be triggered by other actions. The executive branch may identify the

¹⁷ Alexander Furnas and Lee Drutman. “Why Congress might be more productive and less partisan than you think. The Sunlight Foundation. January 16, 2014. <http://sunlightfoundation.com/blog/2014/01/16/congress-in-2013/#gplus>

¹⁸ Information on bills introduced and laws enacted is available at [Thomas.loc.gov](http://thomas.loc.gov).

¹⁹ The count of laws that address regulatory issues is based on authors’ review of enacted laws. Other laws deal with such matters as naming post offices and bridges, appropriations, etc.

²⁰ Sam Batkins and Dan Goldbeck, “Analysis Finds Obamacare Already Missed Nearly Half of Its Regulatory Deadlines.” <http://americanactionforum.org/research/analysis-finds-obamacare-already-missed-nearly-half-of-its-regulatory-deadl>.

²¹ http://www.law.cornell.edu/wex/clean_air_act_caa.

need for a regulation that is consistent with broad authority already delegated to it by statute.²² Sometimes, non-governmental parties will petition for a new regulation, or sue an agency to regulate pursuant to its statutory authority.²³

Tracking legislative initiatives

The online resource, “Congress.gov,” managed by the U.S. Library of Congress, tracks the progress of bills from introduction to enactment.²⁴ It is updated daily to reflect legislative activity, including the full text of bills introduced and subsequent amendments, and contains advance search functions that allow users to search for particular bills or by phrases contained in legislation. Members of the public can subscribe to RSS feeds or e-mails to receive regular updates. Nongovernmental websites (such as OpenCongress.org) also provide tools for tracking legislative activity, and include topic area search and subscription functions that may be useful for foreign regulators or other entities interested in actions that may have international trade or investment effects.²⁵

Within the Executive Office of the President (EOP), the Legislative Reference Division (LRD) of the Office of Management and Budget (OMB) tracks and coordinates administration positions on major bills being considered for legislative action.

For major bills scheduled for House or Senate floor action in the coming week, LRD will prepare “Statements of Administration Policy (SAPs)” in coordination with other parts of OMB, the affected agency or agencies, and other EOP units.²⁶ Once a SAP has received clearance from

²² For example, while Congress has not enacted legislation to address climate change, the EPA is able to issue regulations restricting emissions of greenhouse gases, pursuant to existing authority in the Clean Air Act to take action to address pollutants that may endanger public health or welfare.

²³ Biber, E and Berry, B. “Officious Intermeddlers or Citizen Experts? Petitions and Public Production of Information in Environmental Law.” 58 UCLA L. REV. 321 (2010-2011)

²⁴ Library of Congress. Congress.gov

²⁵ OpenCongress.org is a project of the Sunlight Foundation. Among other things, it allows users to “find bills by more than 4,000 issue areas using the classification system designed by the Congressional Research Service.” <http://www.opencongress.org/issues>

²⁶ Office of Management and Budget, “The Mission and Structure of the Office of Management and Budget,” Available at http://www.whitehouse.gov/omb/organization_mission

the relevant agencies and offices, OMB sends it to Congress, and publishes it on its public website.²⁷

LRD also coordinates within the executive branch once Congress has passed a bill and sent it to the President. It gathers the recommendations of interested agencies and offices as to whether the President should approve or disapprove the bill, and whether approval should include a signing statement.²⁸

Tracking regulatory initiatives

Tracking the regulations that federal agencies and departments have under development is facilitated by the semi-annual *Unified Agenda of Federal Regulatory and Deregulatory Actions*, an on-line list of all forthcoming and ongoing regulatory actions that is updated twice a year. Its publication is coordinated by the Office of Information and Regulatory Affairs (OIRA) in OMB, and the General Services Administration.²⁹ The *Unified Agenda* lists for every rule under consideration a title, abstract, legal authority, timeline (including expected publication dates for notices, regulations, public comment periods, etc.), whether the rule is expected to affect small entities or international trade and investment, its economic significance, and contact information for the responsible agency personnel. An annual *Regulatory Plan*, published once a year with the fall *Unified Agenda*, provides more detail on each agency's priorities and significant planned regulatory actions.

Stage 2 – Regulatory Development

Agencies often spend years developing a regulation before beginning to draft a proposal. (The *Unified Agenda* divides regulations into “Active Actions,” which are expected to involve notices within the upcoming 12 months, and “Long Term Actions.”) For an extreme example, the

²⁷ The Obama administration issued 152 SAPs during the 113th Congress. Some of these support legislation (such as the endorsement of S. 2569, which according to the SAP “would encourage companies to invest in the United States and bring jobs back while preventing companies from receiving tax breaks for shipping jobs overseas.” Others state that the President’s senior advisors would recommend veto if the bill were passed. http://www.whitehouse.gov/omb/113/legislative_sap_date_2014

²⁸ Office of Management and Budget, “The Mission and Structure of the Office of Management and Budget.”

²⁹ Office of Information and Regulatory Affairs, “Current Unified Agenda of Federal Regulatory and Deregulatory Actions,” Available at <http://www.reginfo.gov/public/do/eAgendaMain>

Occupational Safety and Health Administration (OSHA) announced in 1998 that crystalline silica was among its top regulatory priorities, but did not issue a proposed rule for public comment until 2013.³⁰ At EPA, there are generally two years between the initiation of a regulatory action and publication in the *Federal Register* of a notice of proposed rulemaking.³¹

In preparation for issuing a proposal, agencies prepare supporting analyses as required by statute and executive order, including technical support documents, a risk assessment, and regulatory impact analysis.³² They may also consult with stakeholders at this stage,³³ including occasionally through advanced notices of proposed rulemaking (ANPRM). Some agencies are required by statute to follow transparent procedures for engaging small businesses when developing regulations that are expected to affect a significant number of small entities³⁴ and some actions must be accompanied by environmental impact analyses.³⁵

Presidential Executive Order 13609, issued in May 2012, focuses on international regulatory cooperation, noting that “in meeting shared challenges involving health, safety, labor, security, environmental, and other issues, international regulatory cooperation can identify approaches that are at least as protective as those that are or would be adopted in the absence of such cooperation [and] reduce, eliminate, or prevent unnecessary differences in regulatory requirements.”³⁶ Further, when considering new “significant regulations that the agency

³⁰ Susan Dudley, “OSHA’s Long Awaited Crystalline Silica Rule,” *Regulation*, Vol. 37, No. 1. p. 7. Spring 2014. <http://www.cato.org/regulation/spring-2014>

³¹ Cornelius M. Kerwin and Scott R. Furlong, “Time and Rulemaking: An Empirical Test of Theory,” *Journal of Public Administration Research and Theory*, Vol. 2, No. 2 (April 1992), pp. 113-138.

³² Susan E. Dudley and Jerry Brito. *Regulation: A Primer*. The George Washington University Regulatory Studies Center and the Mercatus Center at George Mason University. August 2012. https://regulatorystudies.columbian.gwu.edu/sites/regulatorystudies.columbian.gwu.edu/files/downloads/RegulatoryPrimer_DudleyBrito.pdf.

³³ Esa L. Sferra-Bonistalli, “*Ex Parte* Communications in Informal Rulemaking,” (Report prepared for the consideration of the Administrative Conference of the United States, Washington, D.C., June 5-6, 2014).

³⁴ Small Business Administration Office of Advocacy, “The RFA in a Nutshell: A Condensed Guide to the Regulatory Flexibility Act.” October 2010. <https://www.sba.gov/advocacy/rfa-nutshell-condensed-guide-regulatory-flexibility-act>.

³⁵ Such analyses are required by the National Environmental Policy Act of 1969, as amended (Pub. L. 91-190, 42 U.S.C. 4321-4347, January 1, 1970, as amended by Pub. L. 94-52, July 3, 1975, Pub. L. 94-83, August 9, 1975, and Pub. L. 97-258, § 4(b), Sept. 13, 1982). http://ceq.hss.doe.gov/laws_and_executive_orders/the_nepa_statute.html.

³⁶ Barack Obama, Executive Order 13569, “Promoting International Regulatory Cooperation.” May 1, 2012. <http://www.whitehouse.gov/the-press-office/2012/05/01/executive-order-promoting-international-regulatory-cooperation>

identifies as having significant international impacts,” E.O. 13609 directs agencies to “consider, to the extent feasible, appropriate, and consistent with law, any regulatory approaches by a foreign government that the United States has agreed to consider under a regulatory cooperation council work plan.”

At this stage in the regulatory process, the regulating agency will draft the text of the proposed rule, and a preamble that describes the rationale and analysis supporting the proposed option and lays out alternative options for consideration.

For regulations that are considered significant,³⁷ executive agencies³⁸ send the draft regulatory text along with preamble and supporting documents to OIRA for review under E.O. 12866.³⁹ This review can last 90 days (and sometimes more, although on average reviews take around 60 days), and during this time interested parties may request a meeting with OIRA and the issuing agency.⁴⁰

Once a draft regulation has passed these reviews, the originating agency may publish the rule preamble and text in the *Federal Register* and the public has an opportunity to comment on it along with all supporting analysis and documentation. This public comment step has been a central element of U.S. regulatory procedure since it was required by the Administrative Procedure Act (APA) of 1946.⁴¹ Agencies must consider the public comment and prepare a response to comment document, although they need not address or reply to comments individually.

³⁷ Executive Order No. 12866, 58 Federal Register 190 (Oct. 4, 1993)

³⁸ A few U.S. agencies are considered “independent regulatory agencies,” which though part of the executive branch, are more independent of the President than executive departments and agencies. Dudley & Brito, 2012.

³⁹ Dudley & Brito, 2012.

⁴⁰ OIRA’s policy is to meet with any party interested in discussing issues on a rule under review. Following procedures set forth in Executive Order 12866, meetings on regulatory actions must be conducted by the OIRA Administrator or a specific designee, and a representative of the regulatory agency is invited. OIRA maintains a log of such meetings and other communications at http://www.whitehouse.gov/omb/oira_default/.

⁴¹ Steven J. Balla and Susan E. Dudley, “Stakeholder Participation and Regulatory Policymaking in the United States.” October 2014 draft report for the OECD. <http://regulatorystudies.columbian.gwu.edu/node/264>

Stage 3 – Final Determination and Opportunity for Challenge

After reviewing public comment, agencies develop a final regulation and accompanying analysis, which executive agencies submit to OIRA for review. Once OIRA concludes review, a final rule can be published in the *Federal Register*.

Regulations do not typically take effect for at least 30 days after final publication (60 days for major rules).⁴² When publishing a final rule, agencies must also submit it to the Government Accountability Office (GAO) and Congress.⁴³ Congress has an opportunity to issue a joint resolution of disapproval after a final regulation has been published, although it has only done so once.⁴⁴

Affected parties may also seek redress from the courts on final regulations, and pursuant to judicial review, regulations are often remanded to agencies for reconsideration. The APA allows courts to set aside agency actions that are “(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; (B) contrary to constitutional right, power, privilege or immunity; (C) in excess of statutory jurisdiction [or]... (D) without observance of procedure required by law ...”⁴⁵ This judicial review looks to the administrative record developed by the regulating agency, including its analysis of the facts and its response to public comment.⁴⁶ Thus,

⁴² Executive Order 12866 defines a “meaningful opportunity” to comment as a period of “not less than 60 days.” (<http://www.archives.gov/federal-register/executive-orders/pdf/12866.pdf>) President Obama has reaffirmed this, calling for comment periods to last for “at least 60 days.” (Barack Obama, “Improving Regulation and Regulatory Review.” (<http://www.whitehouse.gov/the-press-office/2011/01/18/improving-regulation-and-regulatory-review-executive-order>))

⁴³ According to former Congressional analyst, Curtis Copeland, agencies do not always comply with this requirement. See “Congressional Review Act: Many Recent Final Rules Were Not Submitted to GAO and Congress.” <http://www.washingtonpost.com/r/2010-2019/WashingtonPost/2014/07/25/National-Politics/Advance/Graphics/CRA%20Report%200725.pdf>

⁴⁴ Susan E. Dudley, “Improving Regulatory Accountability: Lessons from the Past and Prospects for the Future,” forthcoming in 65 *Case Western Reserve Law Review* (2015) <http://regulatorystudies.columbian.gwu.edu/improving-regulatory-accountability-lessons-past-and-prospects-future>

⁴⁵ APA Sec. 706

⁴⁶ Parker and Alemanno point out that while this encourages agencies to develop a full and robust record to defend the rule in court, ironically, it may constrain agencies’ ability to take international trade impacts into consideration if the enabling statute does not mention those factors. Richard Parker and Alberto Alemanno, “Towards Effective Regulatory Cooperation under TTIP: A Comparative Overview of the EU and US Legislative and Regulatory Systems.” European Commission, Brussels, May 2014

the administrative record, which includes all supporting documentation and public comment, is an important element of accountability and transparency.⁴⁷

Stage 4 – Implementation and Enforcement

In general, regulatory agencies are responsible for regulatory implementation and have dedicated enforcement offices responsible for ensuring that regulated parties comply with their regulations and standards. They can work with regulated parties to ensure they understand and meet their regulatory obligations; they can bring civil proceedings against non-compliant entities; and they can, in some cases, work with the U.S. Department of Justice to criminally prosecute certain violations.

While some federal statutes, such as the Clean Air Act, envision a role for states in compliance and enforcement, they usually provide federal agencies (e.g., EPA) authority to ensure that their standards are met. Almost all major U.S. environmental statutes also include provisions that allow private citizens to sue violators in federal court.⁴⁸

* * *

In summary, under the U.S. Constitution, all federal regulations are written under authority delegated to executive branch agencies by legislatively-enacted statutes. They are constrained by a) authorizing statutory language, b) executive principles for regulatory analysis, and c) procedural rules regarding consideration of public comment. Generally, agencies must solicit and consider public comment on draft regulations before they are issued in final form. Most regulations become effective after final publication, and the issuing regulatory agency is responsible for monitoring and enforcing compliance.

⁴⁷ Dudley & Brito, 2012. Pp 48-50.

⁴⁸ See Air Pollution Prevention and Control (Clean Air) Act, 42 U.S.C. § 7604(a) (1994); Federal Water Pollution Control (Clean Water) Act, 33 U.S.C. § 1365(a) (1994); Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), 42 U.S.C. §9659(a) (1994); Emergency Planning and Community Right to Know Act (EPCRA) 42 U.S.C. §11046(a)(1) (1994); Resource Conservation and Recovery Act (RCRA) 42 U.S.C. § 6972 (1994); Safe Drinking Water Act, 42 U.S.C. § 300j-8 (1994 & Supp. IV 1998); Toxic Substances Control Act, 15 U.S.C. § 2619 (1994). The one major environmental statute without a citizen-suit provision is the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136 et seq. (1994).

Summary of EU Regulatory Procedure

The EU is a political union of 28 member states. The member states have delegated sovereign powers to the EU under two principal treaties, the Treaty on the European Union (TEUR) and the Treaty on the Functioning of the European Union (TFEU) which empower the EU institutions to adopt laws. The Treaties also define the balance of powers between the EU and its member states, by laying out areas of exclusive EU competence, shared competence with the member states, and supportive competence (i.e. where legislation from the EU level is precluded). The laws (regulations, directives and decisions) are binding for national authorities and take precedence over national law. At the same time, the EU competences are limited by the principles of subsidiarity and proportionality (Art 5 TFEU). The constitutional set-up of the European Union, its institutions and their jurisdiction, is stipulated in a set of international treaties signed by the European Union member states. The EU institutions are the European Commission, the Council of the European Union, the European Council (the Heads of member states), the Court of Justice of the European Union, the European Central Bank, the Court of Auditors, and the European Parliament. The EU Commission, the Council of the European Union (referred to as the Council below) and the EU Parliament are the key institutional pillars in the legislative and rule-making process. The European Parliament is elected every five years by EU citizens. The European Commission is the executive institution of the European Union, but also has a central position in the legislative process. The Council of the European Union is the institution representing the EU member states' governments.

The specific character of the EU as a polity is also reflected in the types of EU law that are “made” by these institutions. Beyond the treaty articles, which are the primary law in the EU context and have constitutional character, standard legislative acts come in three types, namely regulations, directives and decisions. **Regulations** are the most direct type of EU secondary legislation. A regulation is similar to national statutory law. EU regulations are binding in all member states and no further action by national legislators is required to transpose the regulation into national law. **Directives**, in contrast, in general⁴⁹ require transposition into national law to

⁴⁹ The caveat refers to conditions under which individuals can directly rely on directives, namely a) their governments do not transpose a directive in time or b) where a directive is transposed incorrectly.

become effective. They usually define a broader framework to achieve a policy objective, which national legislators can fill in (somewhat) different ways. Finally, **decisions** are EU laws relevant for specifically mentioned persons or organizations. Decisions do not require transposition into national law but they are limited in scope.

The most recent amendments to the TFEU established a new distinction between **legislative** and **non-legislative acts**. All acts that have been adopted by the ordinary legislative procedure or a special legislative procedure are considered “legislative acts.” Through a legislative act, the Commission can be empowered to adopt non-legislative acts, either “to supplement or amend certain non-essential elements of the legislative act” (Art 290 TFEU) (so-called **delegated acts**) or to create uniform conditions for the implementation of EU law (so-called **implementing acts**, Art 291 TFEU). Two main elements differentiate delegated and implementing acts. The first is the extent to which the act amends or departs from existing legislation. Delegated acts may amend as long as they do not alter “essential elements”; implementing acts are not meant to substantively change anything but rather to fill out (or in the words of the Treaty ensure “uniform implementing conditions for”) the substance of the legislative act (for example in the field of limiting greenhouse gas emissions from cars, the implementing acts set the precise CO₂ levels within the framework of the legislative act). The second main difference is the form of post-legislative control, which involves committees of member state representatives (see below on “Comitology”) for implementing acts but not for delegated acts (for which Council and EP have rights of revocation and objection. Figure 2 illustrates the stages of the ordinary legislative procedure.

Stage 1 – Agenda Setting

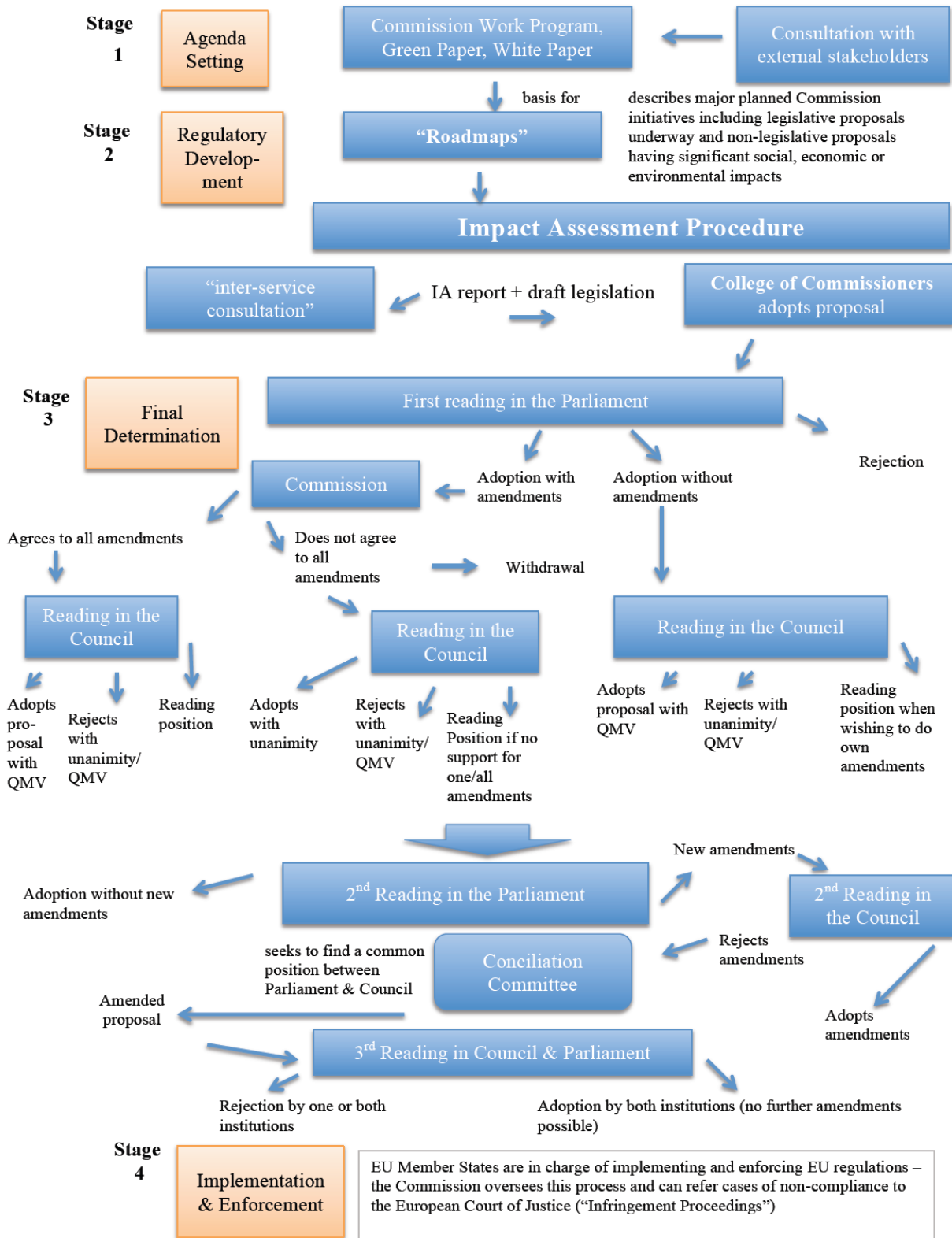
Formally, the European Commission is the sole initiator of EU legislation and policy (with few exceptions). In the EU legislative process, more specifically in the so-called “ordinary legislative procedure” (which was called “codecision” procedure before the abovementioned changes came into force in 2009), the Commission is the only body that can initiate a legislative process. Note, however, that in a number of important areas the Council remains the agenda setter, the most important being foreign affairs. And in areas of shared competence with the member states, particularly economic governance, a kind of “dual executive” has developed. The European

Council is adopting conclusions regarding the priorities of the EU for the next five years and setting the general policy direction (see the task force of the President of the European Council on economic governance). In other words, the European Council is becoming more relevant as an agenda-setter in these key policy areas.

In practice, the formal initiation of a legislative procedure by the European Commission is preceded by a range of coordination activities involving the other key EU institutions and other stakeholders. The **Commission Work Programme (CWP)** sets out how the multiannual goals, as stipulated by the President of the European Commission, are supposed to be realized by legislative measures and policies. The CWP is updated every year, with multiannual strands. A key input to the work programming, and hence to the subsequent legislative activity, are the conclusions of the European Council (consisting of the Heads of State or Government of the member states, together with its President and the President of the Commission), which is responsible for providing general guidelines to EU policy. The CWP lists all major initiatives adopted by the Commission but pending final adoption by the legislator, as well as new initiatives (plus measures to consolidate and simplify existing legislation, so called “REFIT actions”⁵⁰). Finally, the CWP also lists legislative proposals that have been withdrawn (and notes the reasons for withdrawals) and those EU laws becoming effective in the respective year.

⁵⁰ REFIT” is the European Commission’s “Regulatory Fitness and Performance” program. “Action is taken to make EU law simpler and to reduce regulatory costs, so contributing to a clear, stable and predictable regulatory framework supporting growth and jobs.” (http://ec.europa.eu/smart-regulation/refit/index_en.htm). REFIT is the current incarnation of ex post regulatory simplification with a focus on reducing administrative burden for business.

Figure 2: Ordinary Legislative Procedure



Agenda-setting activities of the European Commission also include the launch of Green Papers and White Papers and other non-legislative items such as Communications, Guidelines and Action Plans. Green Papers are designed to stimulate a broader discussion of a topic at the European level; they are combined with a broad consultation procedure. White Papers follow-up on the public comments on the Green Paper and outline the envisaged policy responses by the Commission. The pre-legislative stage of developing regulatory proposals can take a long period of time, and involves discretionary consultation of external stakeholders. The EU Commission when preparing legislative and non-legislative proposals, relies on a variety of sources, including studies commissioned from research organizations and consultancies, expert group advice, stakeholders' input etc. For interested organizations and other stakeholders, this is the key stage at which to influence EU policy making, i.e. via liaising with research organization and consultancies. The EU Commission also relies on expert groups for the preparation of legislative and non-legislative acts. According to Register of Commission Expert Groups and Other Similar entities,⁵¹ 833 of such expert groups exist in September 2014 (this does not include the committees of the so-called Comitology procedure, see below). According to an analysis by Falke,⁵² most of the expert groups (517 out of 839 active groups in February 2014) have been established for coordination purposes with member states, 377 support the Commission in preparing legislative initiatives and 101 assist in the preparation of implementing acts. Expert groups are consultative entities, the role of which is to provide advice and expertise to the Commission in relation to different tasks: (1) the preparation of legislative proposals and policy initiatives, (2) the preparation of delegated acts and/or (3) the implementation of existing EU legislation, programmes and policies. Expert groups never take binding decisions and the Commission remains totally independent regarding the way it takes into account the expertise gathered.

⁵¹ <http://ec.europa.eu/transparency/regexpert/>

⁵² Josef Falke Comitology after Lisbon: What is left of Comitology as we have praised it? In: Christian Jorges and C. Glinski (eds) *The European Crisis and the Transformation of Transnational Governance*, Oxford: Hart Publishing (forthcoming 2014), p. 7 (manuscript version).

Stage 2 – Regulatory Development

The initiation of the individual legislative proposal lies with the European Commission. On the basis of the CWP, the initiative usually starts with the publication of a “**Roadmap**.” A roadmap gives a first, not too detailed description of a planned Commission initiative. Roadmaps are required for Commission initiatives that may have significant direct economic, social or environmental impacts, including legislative proposals, non-legislative initiatives (white papers, action plans, financial programmes, negotiating guidelines for international agreements) “which define future policies,” implementing measures, and delegated acts.

The roadmap outlines the underlying policy problem, the objectives and the policy options considered. Basic parameters for the subsequent Impact Assessment are outlined and initial assessments of potential impacts are provided, if possible. Also the planned role for stakeholders, i.e. consultation procedures, is outlined in the roadmap.

The next step in the regulatory development is the preparation of the **Impact Assessment (IA)**. Compared to the U.S., the EU’s impact assessment regime is of relatively recent origin; based on a number of sectoral impact procedures that have existed in parallel since the 1980s and 90s, an integrated IA system has been developed since 2002 and fully implemented (with IA guidelines) in 2005.

This is a complex process, encompassing a public consultation, the analysis of evidence and the drafting of the IA report and the legislative proposal.⁵³ The draft IA report is subject to a quality control by the Impact Assessment Board (IAB) of the European Commission. The IA process is carried out by the Directorate General (DG) that is responsible for the initiative. Other DGs are involved via an Impact Assessment Steering Group (IASG) consisting of the Directorates General who are likely to be affected by the initiative, and the Secretariat General (SG), which has a coordinating role. According to the IA guidelines of the European Commission (which are

⁵³ On the details of the IA procedure, see European Commission, IA Guidelines 2009, SEC(2009)92. The guidelines are currently in a process of revision. However, the draft of the revised guidelines suggests a lot of continuity.

currently, in Fall 2014, in the process of revision), the normal duration of the process is about 52 weeks.

The public **consultation** procedure is an integral part of the IA process and can target important aspects of the initiative on which stakeholders should be consulted, i.e. the problem definition, the subsidiarity analysis, the description of the possible options and their impacts. The EU Commission's minimum standards for consultation, adopted in 2002, prescribe that the public consultation must have a minimum duration of eight weeks and a single access point showing a list of consultations planned, in progress and closed.⁵⁴ Initially, the Commission had intended to establish a minimum of only six weeks, but due to the critical feedback it got during the consultation procedure in preparation of its minimum standards, the Commission finally changed it to a minimum of eight weeks.⁵⁵ Subsequently, in 2012, this minimum duration was then extended to twelve weeks.⁵⁶ Beyond that, public consultations can take a variety of forms, from online consultations to stakeholder and expert workshops. Today, online consultations are standard practice, and allow for any interested party to participate. Information on the initiative is provided in a "consultation document" that is based on the Roadmap and likewise presents different policy options (those that will also be subject to the IA).

In general, the full draft of the regulatory proposal is not available at this stage, nor is the draft IA (as in the U.S.). Instead the policy options under consideration are presented and the comments are used as an input to the IA and the further drafting and development of the act/policy. Note, however, that the practice varies with the character of the initiative. The consultation itself often takes the form of a semi-open questionnaire asking participants to assess the different elements of the proposal (for example the different options considered). In other words, while the framework suggest a particular sequence of steps (roadmap → consultation →

⁵⁴ The "Your Voice in Europe" web portal is http://ec.europa.eu/yourvoice/consultations/index_en.htm.

⁵⁵ Communication from the Commission: Towards a reinforced culture of consultation and dialogue – General principles and minimum standards for consultation of interested parties by the Commission (COM(2002) 704 final), p.8; p. 12; p. 21

⁵⁶ European Commission – Press Release: Have a bigger say in European policy-making: Commission extends public consultations to 12 weeks and creates new 'alert service'. Retrieved from http://europa.eu/rapid/press-release_IP-12-1_en.htm?locale=en (20 October 2014).

IA → draft act), the practice varies considerably, also reflecting the divergent character of legislative and non-legislative initiatives launched by the EU Commission.⁵⁷

While public comments should be reflected in the IA report, there is no precise requirement that the draft legislative proposal include the public comments or the responses of the Commission to these comments (which is different from the U.S.). However, comments are generally published on the Commission's website.

The consultation of stakeholders is an important input to the IA, which in turn is considered as an aid to political decision-making and not as a mode of decision-making that replaces political choices. And while the **assessment of costs and benefits** of the different policy options under consideration is at the core of the EU Commission's IA regime, the application of the methods of economic analysis is less common than in the U.S. This is a result of the scope of IA which is designed to assist the legislative process (rather than delegated rule-making as in the U.S. case). As such, IAs are not only carried out for narrow technical regulations but also for packages of combined measures that are distinguished according to the type of regulation (regulation, directive, recommendation, open method of coordination).⁵⁸ Second, IAs should consider economic, social and environmental consequences of EU initiatives in a balanced way. Quantifying all dimensions of impact across different policy packages is often difficult, if not impossible. Hence, the practice of IA in the EU Commission is characterized by a more flexible use of analytical methods, including cost-benefit analysis but also more qualitative methods (such as "multi-criteria analysis").⁵⁹ As a result, regulatory and policy choices in the EU place less emphasis on a positive net-benefit estimate than in the U.S. In terms of evidence, the responsible units in the DGs rely on their own expertise, the expertise of other units in the Commission, EU agencies, and member states, but they also commission targeted analyses from

⁵⁷ As an example consider the different scope of two initiatives for which consultation procedures are running at the time of writing: a) "The urban dimension of EU policies – key features of an EU Urban Agenda," http://ec.europa.eu/regional_policy/consultation/urb_agenda/index_en.cfm, and b) "Second draft of the new Block Exemption Regulation applicable to the fishery and aquaculture sector," http://ec.europa.eu/dgs/maritimeaffairs_fisheries/consultations/block-exemption-regulation-2/index_en.htm.

⁵⁸ For example, the Impact Assessment for an Action Plan on Organ Donation and Transplantation considers four options: 1) the do-nothing option, 2) a non-regulatory approach, 3) a 'flexible' directive and 4) a 'stringent' directive. See, http://ec.europa.eu/health/ph_threats/human_substance/oc_organ/docs/organs_action_en.pdf

⁵⁹ European Commission, IA Guidelines 2009, SEC(2009)92, 47

research organizations and consultancies. As has been mentioned above, the bulk of evidence is often generated before the initiative has formally started, for example through research commissioned by the responsible DG and via expert committees. But it is also standard practice for DGs to commission research that generates input to IAs.

According to the EU Commission's rules, an **IA report** should always start with the definition of the problem and the formulation of the objectives of the proposal. Next, the policy options to achieve these objectives should be developed and economic, social and environmental impacts assessed. Next, the different options are assessed individually in terms of their impact and then compared. Finally, the plans for monitoring and evaluation should be outlined. The responsible DG must submit the draft report to the IAB, which exercises a quality control function. Created in 2006, the IAB is composed of high-level officials from various DGs chaired by the Deputy Secretary General responsible for "Smart Regulation." The officials are supposed to act in an independent expert capacity, not as agents of their DG. While the IAB's role is limited to an assessment of the quality of the analysis, a positive opinion from the board is in principle needed for an initiative to proceed to the next step in the regulatory process, the submission to the college of Commissioners for adoption of the proposal. The Board issues opinions on all the Commission's draft IAs. In 2012 and 2013, 47% and 41% of IAs, respectively, received a revise and resubmit type of decision, i.e. they were referred back to the responsible DG, which had to revise the IA report. The opinion accompanies the draft initiative together with the IA throughout the Commission's political decision-making. All IAs and all IAB opinions are published once the Commission has adopted the relevant proposal.

The IA report, together with the draft legislation (or non-legislative measure), go into the internal coordination process within the European Commission, called "inter-service consultation." The final stage in the regulatory development is the adoption of the proposal by the college of Commissioners. The next stage in the legislative procedure is the submission of the proposal to the EU Parliament (see below) and the Council of the EU.

The process of regulatory development differs for **non-legislative acts** (implementing and delegated acts). While the internal procedure for the development of non-legislative acts within the Commission is rather similar to those of legislative acts – the responsible DG unit develops a

proposal by consulting with external stakeholders, other Commission units and EU agencies, and submits the draft to inter-service consultation – the limited scope of non-legislative acts comes with a reduced level of legislative control. For implementing acts, the member states are involved in the decision-process through committees composed of Member State experts, which adopt opinions on draft implementing acts, the so-called “**comitology**” process, which is a means of member states’ (and increasingly, the EU Parliament’s) control of the Commission. “Comitology committees” assist the Commission in executing its implementing powers by giving an opinion on draft implementing measures before they are adopted. They include representatives from all EU member states and are chaired by a Commission official. The notion of “Comitology,” which is not an official term, is derived from the high number of existing committees. According to the EU Commission’s 2013 report on the working of committees,⁶⁰ 302 committees were working in 2013 (compared to 271 in 2012). According to Falke, these committees are involved in the preparation of 1,800 implementing acts every year, which equals 65 per cent of the European Union’s legislative output.⁶¹

For delegated acts, a new category of non-legislative acts established in the Lisbon Treaty (Article 290 TFEU), draft acts are submitted directly to the European Parliament and the Council without any comitology procedure. The legislator may hereby delegate the power to adopt acts amending non-essential elements of a legislative act to the Commission. For example, delegated acts may specify certain technical details or they may consist of a subsequent amendment to certain elements of a legislative act. The legislator can therefore concentrate on policy direction and objectives without entering into overly technical debates. However, this delegation of power has strict limits. In effect, only the Commission can be authorized to adopt delegated acts. Furthermore, the legislator sets the conditions under which this delegation may be implemented. Article 290 TFEU specifies that the Council and the Parliament may revoke a delegation or limit its duration. Moreover, the delegated act will only enter into force if no objection has been expressed by the European Parliament or the Council within a period set by the legislative act (right of objection).

⁶⁰ COM(2014) 572 final

⁶¹ Josef Falke Comitology after Lisbon: What is left of Comitology as we have praised it? In: Christian Jorges and C. Glinski (eds) *The European Crisis and the Transformation of Transnational Governance*, Oxford: Hart Publishing (forthcoming 2014), p. 1 (manuscript version).

The new procedure involving direct transmission without intermediary control via member state committees means the Council and Parliament have limited time or resources to scrutinize Commission decision-making on these matters.

Until recently, non-legislative acts have not been subject to IA rules and guidelines, but this is gradually changing and “rule-making IAs” are of increasing significance in the EU.⁶² Since the adoption of the 2009 IA guidelines, IAs should be carried out for Commission initiatives expected to have “significant direct economic, social or environmental impacts,” including “non-legislative initiatives (white papers, action plans, financial programmes, negotiating guidelines for international agreements) that define future policies” and “implementing measures and delegated acts.”⁶³ Moreover, the monitoring role of the IAB also applies to non-legislative acts. From the “significant impact” criteria, it follows that most legislative proposals fall under the requirement to carry out an IA, but not all non-legislative acts. And while various stakeholders, including the Parliament, Council and industry representatives, have demanded that IAs be carried out for individual non-legislative acts, the practice is sporadic. IAs are carried out for an increasing number of non-legislative acts, based on the IA guidelines principle that IAs should be carried out for any initiative with significant impact. This principal-based approach has been criticized as lacking a set of rules for deciding if a “rulemaking IA” should be carried out, nor how it should be carried out.⁶⁴ While the IA guidelines offer some instructions for IAs for non-legislative acts, in particular to focus on operational dimensions in the assessment, it is debatable if the other procedural rules of the EU Commission’s IA regime also apply (concerning consultation, the time frame etc.). If non-legislative acts have significant impact, other procedural rules apply. In general, IAs should be proportionate to the problem and character of the initiative.⁶⁵ Alemanno and Meuwese⁶⁶ argue that “rulemaking IAs” should have a more prominent role, given the reduced level of member state control for delegated acts developed by the Commission outside the Comitology regime.

⁶² 2009, IA Guidelines, 17

⁶³ http://ec.europa.eu/smart-regulation/impact/index_en.htm; note that the terminology changed after the reform of the Comitology system after the adoption of the Lisbon Treaty.

⁶⁴ Alberto Alemanno and Anne Meuwese “Impact Assessment of the EU Non-Legislative Rulemaking: The Missing Link in the ‘new Comitology’,” *European Law Journal*, Vol 19, No 1 (January 2013), pp. 76-92

⁶⁵ The ongoing revision of the Impact Assessment guidelines will address the issue of proportionality of analysis.

⁶⁶ Ibid.

Stage 3 – Final Determination and Opportunity for Challenge

On the basis of the draft developed by the EU Commission, the EU Parliament and the Council jointly decide on the adoption of the proposal and amendments to it. In the so-called “ordinary legislative procedure,” also known as the community method, this process includes up to three readings of the draft by both institutions. The process starts with the first reading in the Parliament (including deliberations in a committee of the Parliament), which results in the rejection or adoption of the proposal, with or without amendments. In the subsequent first reading in the Council, this co-legislator develops a position regarding the Parliament’s decision (and any particular amendments). The Council may either adopt the proposal with qualified majority voting (QMV) if the Parliament has not made any amendments, adopt the proposal by unanimity if the Commission does not endorse all amendments (the idea being to raise the threshold for agreements among EP and Council without the Commission’s assent), or adopt a so-called reading position if it does not support all amendments by the Parliament or wishes to introduce its own amendments. In practice, the Council may also reject the proposal by QMV at this stage, even though this is not explicitly laid down in the Treaty.

The letter text is sent to Parliament for a second reading. If Parliament suggests amendments to the Council’s first reading position, the modified proposal is sent to the Council for a second reading, as well as to the Commission to comment on the amendments. If Council does not approve the amendments to the proposal, a Conciliation Committee between the two institutions is composed and seeks to find a common position. An amended proposal from the Conciliation Committee goes to a third reading in both co-legislators, with no further amendments possible. At all stages of the process, a rejection of the proposal is an option for both institutions, either *de jure* or *de facto*. In other words, both institutions have veto-power, but rely on each other for a proposal to be successful. Informal consultations between all three institutions – Commission, Parliament, and Council – have become a common practice in order to smooth the consensus seeking process (so-called “trilogues” or “trialogues”). These trilogues are in fact ongoing from the very beginning of the legislative process, and this consensual approach to legislation resulted in a substantial number of proposals (between 85 and 90 percent) being adopted at the first reading stage. It should also be noted that the Commission may withdraw its proposals from the decision process, hence allowing the Commission to reset the legislative process if it does not

endorse amendments. The power of withdrawal therefore gives the Commission a somewhat stronger position than is apparent from the official procedure.

With regard to non-legislative acts, the role of the Parliament and the Council depends on the type of act. For implementing acts, Parliament and Council may pass a non-binding resolution in case they consider the draft implementing act to go beyond the delegated powers stipulated in the respective legislative act. If a (Comitology) committee adopts no opinion (i.e. there is no qualified majority for or against the draft) the Commission can adopt or withdraw the implementing act under consideration (unless there is a simple majority against the draft implementing act). This is, however, not the case in the areas taxation, financial services, health and safety or trade. If there is a qualified majority in the committee against the draft, the Commission may refer the draft act to an Appeal Committee composed of high-ranking member state representatives and the Commission, entitled to amend the draft. Again, the act is adopted with a qualified majority. For delegated acts, Parliament and Council may not amend the acts nor do they need to approve them to take effect, but the co-legislators can veto them (objection) or revoke the power of the Commission to issue a delegated act altogether within the timeframe defined by the basic act.

Stage 4 – Implementation and Enforcement

The European Union is often named a “Regulatory State” because its capacity to influence developments in the member states is limited to regulatory measures – since the direct delivery of public services is not done by EU institutions and because the EU lacks the financial capacities to rely on spending programs to a large extent. But also in its capacity as a regulatory state, the EU has to rely on its member states for implementation and enforcement. Each member state is responsible for policy implementation, such as adopting implementing measures and their correct application. The Commission is, according to Article 258 of TFEU, responsible for safeguarding that EU law is correctly applied and enforced by member states. When a member state fails to comply with EU laws, the Commission has powers to intervene (so-called action for non-compliance) and can refer the case to the European Court of Justice. In the so-called “**Infringement proceedings**,” the Commission demands that the member state comply with the EU law requirement within a set timeframe. In particular, when the infringement proceeding

responds to a complaint, the process starts with an investigation by the Commission. Referral by the Commission to the Court of Justice opens the litigation procedure.

Since EU directives require member states to adapt national laws to implement the objectives and requirements of the directive (so-called “national implementing measures”), the “transposition” of directives into national law is subject to monitoring by the Commission. Each directive comes with a deadline by which national laws must be adapted according to the directive, typically two years. EU directives are particularly common in matters that affect the operation of the single market. In areas like competition, large corporations are especially likely to litigate under EU law to force either national governments or their competitors to adapt to EU regulation.

While there is a growing number of EU agencies, which get increasingly involved in setting regulatory standards, they are generally not directly involved in the implementation and enforcement of EU law. Most of them have important advisory and expert functions and play a role in coordinating national agencies, but are not supervisory bodies to these national agencies.

* * *

To summarize, there are two major types of EU regulation which follow specific decision procedures. EU legislative acts are comparable to statutory law enacted by national parliaments. They are enacted in a complex procedure involving the Commission, the European Parliament and the Council. The decision process is increasingly dominated by largely informal consultation among these institutions with the aim of reaching a policy consensus. EU non-legislative acts are roughly comparable to delegated rule-making in a national setting, however unlike in the U.S. context, EU agencies⁶⁷ do not play a major role in EU level rulemaking.

The enactment process for implementing acts in particular is characterized by a strong member state involvement in the comitology process, thereby effectively producing a counterweight to

⁶⁷ EU agencies are distinct bodies from the EU institutions – separate legal entities set up to perform specific tasks under EU law. There are over 40 agencies, divided into 4 groups: decentralised agencies, executive agencies, EURATOM agencies, European Institute of Innovation and Technology (EIT) (http://europa.eu/about-eu/agencies/index_en.htm).

the supranational-oriented Commission. The Commission has to consult the public and stakeholders before submitting a proposal for a legislative act, and it has increasingly done so for non-legislative acts. The same applies for regulatory impact assessment, although its application to delegated and implementing acts is still evolving. With few exceptions, in particular competition policy, the Commission is not in charge of implementing EU law, which is delegated to the member states and their bureaucracies, but the Commission is in charge of overseeing the implementation process.

Cross-Cutting Disciplines on Regulatory Coherence and Transparency: A Comparison of U.S. and EU Approaches

As the above descriptions show, regulatory policies and procedures in the U.S. and EU are governed by different institutions and influenced by different cultures and circumstances, yet they both recognize the importance of a transparent regulatory framework that promotes the public interest. As noted above, a goal of T-TIP is to agree on “cross-cutting disciplines on regulatory coherence and transparency for the development and implementation of efficient, cost-effective, and more compatible regulations for goods and services, including early consultations on significant regulations, use of impact assessments, periodic review of existing regulatory measures, and application of good regulatory practices.”⁶⁸

To support discussion of potential cross-cutting disciplines that could lead to more compatible regulation,⁶⁹ this section examines how regulatory practices in the U.S. and EU:

- 1) Generate **evidence** to evaluate alternative regulatory options,
- 2) Facilitate **unbiased input** into the regulatory development process from external stakeholders,
- 3) Ensure **accountability** of agencies and bureaucrats to citizens and democratic institutions, and

⁶⁸ Final Report of the EU-US High Level Working Group on Jobs and Growth, February 11, 2013. T Initial EU Position Paper “Trade Cross-cutting disciplines and Institutional Provisions,” July 2013.

⁶⁹ Kauffmann (2014) outlines ways in which good regulatory practices contribute to regulatory convergence and compatibility.

- 4) Support the **legitimacy** of final regulatory decisions and their general acceptance.

In the following sections, we use these four criteria to compare the “performance” of the two regulatory systems. While both the U.S. and EU are committed to these objectives in principle, the two jurisdictions’ regulatory procedures differ, and these objectives are often met in different ways at different times. Hence, the two regulatory systems might have particular strengths and weaknesses that follow from their respective institutional structures.

Evidence Generation

The generation and use of evidence is an essential element in developing and evaluating efficient, cost-effective, and more compatible regulations. The key instrument to achieve this is Regulatory Impact Analysis (RIA) in the U.S and Impact Assessment (IA) in the EU. Both these approaches rely on the systematic and structured application of tools of (economic) policy analysis to evaluate the likely consequences of alternative regulatory approaches. The OECD encourages members to

- Integrate Regulatory Impact Assessment (RIA) into the early stages of the policy process for the formulation of new regulatory proposals.
- Clearly identify policy goals, and evaluate if regulation is necessary and how it can be most effective and efficient in achieving those goals.
- Consider means other than regulation and identify the tradeoffs of the different approaches analysed to identify the best approach.⁷⁰

Both the EU and the U.S. have institutionalized strong impact assessment systems. However, they differ in two fundamental ways. First, the U.S., which has a longer tradition of impact analysis as part of the regulatory process,⁷¹ puts more emphasis on measurement and

⁷⁰ OECD, 2012, *Recommendation of the Council on Regulatory Policy and Governance* (<http://www.oecd.org/gov/regulatory-policy/49990817.pdf>)

⁷¹ Fabrizio De Francesco, “Diffusion of Regulatory Impact Analysis Among OECD and EU Member States.” *Comparative Political Studies* October 2012 vol. 45 no. 10 1277-1305. Claudio Radaelli, “Whither better regulation for the Lisbon agenda?” *Journal of European Public Policy* 2007 vol. 14 no 2, 190-207. Meuwese observes that in the U.S. “‘regulation of regulation’ had already been underway for longer [than in the EU]: for

quantification of costs and benefits. Related to this is the role “precaution” plays in regulatory decisions. The second difference, which may be more important, relates to the stage at which the impact assessments are developed in the regulatory process.

Quantified Impacts

In both jurisdictions, regulatory analysis is viewed as tool to inform decision making, rather than as the sole factor in developing rulemaking. In the U.S., OMB’s RIA Primer states: “The purpose of the RIA is to inform agency decisions in advance of regulatory actions and to ensure that regulatory choices are made after appropriate consideration of the likely consequences.”⁷² But it goes a step further to say, “To the extent permitted by law, agencies should proceed only on the basis of a reasoned determination that the benefits justify the costs (recognizing that some benefits and costs are difficult to quantify).” In the EU, IAs “evaluate the potential economic, social and environmental consequences” of new initiatives,⁷³ without a strict rule that benefits should justify costs or guidance on how to evaluate tradeoffs between policy outcomes (e.g. weighing non-monetized social benefits against qualitative environmental harms). The IA guidelines offer methodological guidance on how to conduct cost-benefit analysis, cost-effectiveness analysis and multi-criteria analysis, but only stipulate that “the balance of positive and negative impacts associated with the preferred option and possible alternatives” should be the basis for ranking the different options under consideration (along with the “performance of different policy options in achieving the defined policy objective”).⁷⁴

many decades the broad regulatory powers delegated to federal agencies have been accompanied by heavy procedural protection, both judicial (review) and non-judicial (hearings and regulatory impact analysis) in nature.” “EU–US horizontal regulatory cooperation: Mutual recognition of impact assessment?” Executive Order 12044, issued by President Jimmy Carter in 1978, required regulatory analysis for rules that “may have major economic consequences for the general economy, for individual industries, geographical regions or levels of government.” It required regulatory analysis to “involve a careful examination of alternative approaches early in the decisionmaking process.” <http://www.presidency.ucsb.edu/ws/?pid=30539> In 1981, President Ronald Reagan included more widespread and quantitative regulatory impact analysis requirements in Executive Order 12291. <http://www.presidency.ucsb.edu/ws/?pid=43424> (For a table of U.S. executive orders requiring analysis and review, see the George Washington University Regulatory Studies Center’s Regulation 101 page: <http://regulatorystudies.columbian.gwu.edu/regulation-101>.)

⁷² U.S. Office of Information and Regulatory Affairs. *Regulatory Impact Analysis: A Primer* (2011) available at http://www.whitehouse.gov/sites/default/files/omb/info/reg/regpol/circular-a-4_regulatory-impact-analysis-a-primer.pdf

⁷³ http://ec.europa.eu/smart-regulation/impact/index_en.htm

⁷⁴ IA guidelines 2009, p. 48.

In 2002, the European Commission released a *Communication from the Commission on Impact Assessment* to provide guidance on conducting IAs.⁷⁵ It lists five questions to ask while conducting an impact assessment:

- (1) what issue is the policy/proposal expected to tackle; what would be the Community added value;
- (2) what main objective is the policy/proposal supposed to achieve;
- (3) what are the main policy options available to achieve the objective;
- (4) what are the impacts—positive and negative—expected from the different options identified; and
- (5) how can the results and impacts of the policy/proposal be monitored and evaluated?⁷⁶

In many respects these guidelines resemble the requirements of U.S. Executive Order 12866, which instructs regulatory agencies to identify the problem their regulation is intended to solve, identify alternative options for addressing the problem, and estimate the benefits and costs of those alternatives.⁷⁷ Also similar to the U.S., the Commission recommends consideration of policy alternatives, including the alternative of no policy action.⁷⁸

Despite these guidelines, both jurisdictions face criticism for lack of objective analysis. For example, some observers find that “European regulatory policy, especially in the chemicals and environmental sectors, is not as predictable, evidence-based, risk-informed, or clear as it could be.”⁷⁹ In the U.S. a bipartisan panel of experts suggested that agencies should be required to:

spell out genuine alternative regulatory policies when proposing guidance or a rule. Although this approach is embodied in some federal decision processes (e.g.,

⁷⁵ At the time, these assessments were called “Extended Impact Assessments,” but have since been re-termed as “Impact Assessments.”

⁷⁶ Commission of the European Communities, *Communication from the Commission on Impact Assessment, 2002* (Brussels, Belgium: COM(2002) 276 Final), pg. 13. Available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2002:0276:FIN:EN:PDF>

⁷⁷ U.S. Office of Information and Regulatory Affairs, *Regulatory Impact Analysis Primer*. (2011)..

⁷⁸ Commission of the European Communities, *Communication from the Commission on Impact Assessment 2002*.

⁷⁹ Ragnar Lofsted, “A possible way forward for evidence-based and risk-informed policy-making in Europe: a personal view.” *Journal of Risk Research* 2014.

those under the National Environmental Policy Act), the approach is not uniformly applied, and the alternatives proposed can be less than genuine.⁸⁰

In 2008, Cecot et al. compared the quality of RIAs in the EU and the U.S. and found that the EU's RIAs have improved, but many are still missing important economic information, such as monetized benefits and calculation of net benefits.⁸¹ This is contrary to the guidance provided by the Commission, which recommends that impacts be “expressed as concretely as possible in qualitative, quantitative, and where possible, monetary terms.”⁸² While Cecot et al. find that the U.S. RIAs initially seem to outperform EU IAs by a wide margin, the authors find that rules of similar impact (e.g. greater than \$100 million in effect) have roughly equivalent quality RIAs. However, it should be noted that the U.S. RIAs that were scored by Cecot et al. were only derived from major rules from a single agency—the Environmental Protection Agency—which is not necessarily representative of U.S. RIAs generally.⁸³

The Role of Precaution

The perception is that Europe is more precautionary than the U.S., yet closer examination suggests the reality may be more nuanced.⁸⁴ The TFEU states that “Union policy on the environment shall ... be based on the precautionary principle and on the principle that preventive action should be taken...”⁸⁵ However, the TFEU also calls for a balancing of risks and benefits, stating that “the Union shall take account of available scientific and technical data,...[and] the

⁸⁰ Bipartisan Policy Center. *Improving the Use of Science in Regulatory Policy*. p. 16. August 5, 2009.

⁸¹ Cecot, C., Hahn, R., Renda, A. and Schrefler, L. (2008), “An Evaluation of the Quality of Impact Assessment in the European Union with Lessons for the US and the EU,” *Regulation & Governance*, Vol. 2, Issue 4: 405–424

⁸² Commission of the European Communities, *Communication from the Commission on Impact Assessment, 2002*.

⁸³ In 2010, Ellig and Morrall used a scorecard system to evaluate the quality of U.S. RIAs from 2009 and found that EPA ranked fifth out of nine agencies in overall quality. In 2008, the quality of EPA's RIAs was ranked more highly—second out of twelve agencies—but the quality of these analyses decreased by 7% between 2008 and 2009. Ellig, J., Morrall, J., “Assessing the Quality of Regulatory Analysis: A New Evaluation and Data Set for Policy Research,” *Mercatus Center Working Paper No. 10-75* (2010)

⁸⁴ For different analyses and explanations of the evolving patterns of risk regulation in the two jurisdictions, see: David Vogel “The Politics of Precaution: Regulating Health, Safety, and Environmental Risks in Europe and the United States” *Princeton and Oxford: Princeton University Press* and Brendon Swedlow, Denise Kall, Zheng Zhou, James K. Hammitt and Jonathan B. Wiener “Theorizing and Generalizing about Risk Assessment and Regulation through Comparative Nested Analysis of Representative Cases” *Law & Policy* Vol. 31, No. 2, April 2009, pp. 237-268

⁸⁵ Article 191 paragraph 2.

potential benefits and costs of action or lack of action,” among other factors.⁸⁶ The U.S., as noted above, has embraced benefit-cost analysis and not explicitly adopted a precautionary principle, yet several of its statutes do envision a precautionary approach to health and environmental risk.⁸⁷ A recent analysis finds:

a complex pattern of regulation of multiple risks, with general parity between the US and Europe, punctuated by the selective application of precaution to specific risks on both sides – sometimes manifesting greater European precaution since 1990, but sometimes greater US precaution since 1990, and no major aggregate shift.⁸⁸

Timing of Impact Analysis

In the U.S., RIA is conducted by regulatory agencies as part of the delegated rulemaking process, after legislation has established broad themes and purposes. In the EU, IA occurs earlier in the process, as part of the development of policy proposals by the European Commission. As a result, EU IAs often examine broad (framework) policy proposals before detailed regulatory options are identified, while U.S. RIAs accompany a particular draft regulation and attempt to quantify estimated benefits and costs of specific required actions.

Thus, the systematic generation of evidence can occur earlier in the regulatory process in the EU than in the U.S. (since IAs are part of the legislative process). They are designed to inform the (political) choice between different policy options that are compared in the IA report. The European Commission has sole responsibility for initiating the legislative process (although based on agenda setting activities of the other institutions, and in particular the European Council), and uses Green and White Papers – along with consultation procedures and a high number of expert committees – to gather input for agenda building. Recently, the EU IA has

⁸⁶ Article 191 paragraph 3.

⁸⁷ For example, laws governing pharmaceuticals, pesticides, and toxic substances task agencies with the role of “gatekeeper,” which leads to regulations that are precautionary in that they require affirmative approval of new products before they can be introduced.

⁸⁸ Jonathan B. Wiener, “The Politics of Precaution, and the Reality,” *Regulation & Governance* (2013) 7, 258–265 (discussing the results of research presented in Jonathan B. Wiener, Michael D. Rogers, James K. Hammitt, & Peter H. Sand, *The Reality of Precaution. Comparing Risk Regulation in the United States and Europe*. (2011) RFF Press/Earthscan/Routledge, Washington, DC and London.

been expanded to non-legislative acts, but it is too early for statements about the characteristics of IAs in this context. While the European Parliament has traditionally acted on legislation initiated in the Commission without conducting additional analysis, in 2012 it set up its own Impact Assessment unit charged with screening Roadmaps accompanying the Commission's Work Programme, conducting an initial or detailed appraisal of a Commission IA and conducting impact assessment on substantive amendments being considered by the Parliament (carried out by external experts).

In the U.S., the elected legislature establishes the authority for subsequent executive branch regulation and through statutes defines the factors that agencies can and cannot consider when developing new regulations. While longstanding U.S. regulatory policy requires that regulations be based on evidence of the need for the rule and analysis of impacts, those requirements apply only "to the extent permitted by law."⁸⁹ While many authorizing statutes grant regulatory agencies wide leeway with respect to the form and substance of regulations, including permitting or requiring an assessment of impact or need for particular regulatory requirements, the legislature itself does not generally conduct quantitative analysis of the impact of its laws or the regulations they enable.

Because it is conducted later in the process, U.S. RIAs tend to be more specific and quantitative, as noted above. Further, in the U.S., established law requires that decisions be based on the evidence available in the "administrative record"; if not, they could be overturned in court. This encourages regulatory agencies to present the evidence supporting their regulations clearly in the public docket for the rulemaking.

Each of these approaches has merit. Applying analytical tools early in the process (as in the EU) can help decision-makers understand the problem, and gather information on a range of available alternative options before choosing a particular path.⁹⁰ On the other hand, analysis of concrete

⁸⁹ E.O. 12866 Section 1(b)

⁹⁰ Carrigan and Shapiro suggest that shorter RIAs conducted earlier in the regulatory development process could improve regulatory outcomes in the U.S. Christopher Carrigan and Stuart Shapiro, "What's Wrong with Back of the Envelope? A Call for Simple (and Timely) Benefit-Cost Analysis," GW Regulatory Studies Center Working Paper. October 7, 2014. <http://regulatorystudies.columbian.gwu.edu/whats-wrong-back-envelope-call-simple-and-timely-benefit-cost-analysis>

options allows decision makers and the public to consider in a disciplined way the consequences of different approaches before regulations are issued. Policy makers should be aware of the different rationales for RIAs and IAs in the two jurisdictions, and may want to consider practices that take advantage of the merits of each approach.

Unbiased Input

The OECD has emphasized the importance of gathering unbiased input and recommended that its members:

Adhere to principles of open government, including transparency and participation in the regulatory process to ensure that regulation serves the public interest and is informed by the legitimate needs of those interested in and affected by regulation. This includes providing meaningful opportunities (including online) for the public to contribute to the process of preparing draft regulatory proposals and to the quality of the supporting analysis. Governments should ensure that regulations are comprehensible and clear and that parties can easily understand their rights and obligations.⁹¹

In both jurisdictions, discretionary and informal consultation shapes the early stages of the regulatory process before the initiative is formally launched. Both jurisdictions solicit expert input when developing regulations, and, particularly at the agenda-setting stage, may consult with “stakeholders” who may have a particular interest in the design of regulatory approaches. However, regulation can confer competitive advantage on some parties at the expense of others, and economic theory and empirical evidence have shown that regulations often benefit well-organized interests with strongly-felt preferences at the expense of larger, less well-coordinated groups with weakly-felt preferences.⁹² To counter this interest group influence, broader opportunities for engagement as well as impact analysis are important.

⁹¹ OECD, 2012, *Recommendation of the Council on Regulatory Policy and Governance* (<http://www.oecd.org/gov/regulatory-policy/49990817.pdf>)

⁹² For a summary of this literature, see chapter 2 of Dudley & Brito. *Regulation: A Primer*. (2012) For more detail, see Stigler G. 1971, Peltzman, S. 1976. Carpenter, D. and Moss, D. 2013.

As noted above, the U.S. notice-and-comment procedures (in place since 1946) provide an opportunity for anyone to review and provide input on draft regulations and all supporting analysis. Regulatory agencies must consider and respond to those comments before issuing a final rule.

Procedures for consultation in the EU are less formalized, and are specified by the Commission at the initiation of a legislative act. The Commission has established minimum standards for consultation, but they have the status of internal rules and guidelines, rather than mandatory law and leave room for discretion to individual DGs. The EU Commission relies more on external experts and stakeholders to inform regulatory decisions. As with the IA, consultation procedures such as the widely-used online questionnaires occur early in the regulatory development process. They are used to gather feedback on broad policy options that are presented in a “consultation document.” The public is generally not given an opportunity to comment on actual draft regulation but on regulatory options and their specific impact. When publishing the IA together with the proposed regulation the Commission explains the considerations which led to the adoption of one particular proposal, in light of comments received, though with less specificity than a U.S. response-to-comment document.

An area where unbiased input is particularly important is in support of policies to address public health risks. In the EU, risk-based regulatory decisions are often supported by risk assessments conducted by a staff of experts who are separate from the risk management decision, whereas in the U.S., the scientific basis for decisions is often developed by the same staff who draft the policies to manage that risk. Both jurisdictions recognize the importance of distinguishing between analysis needed to assess risks and analysis needed to manage risks. The Bipartisan Policy Center (a non-profit U.S. organization) observed:

Distinguishing between science and policy is not always easy or straightforward, and scientists may make choices based on values in the course of their work. Nonetheless, policy debate would be clarified and enhanced if a systematic effort were made to distinguish between questions that can be resolved through scientific judgments and those that involve judgments about values and other matters of policy when regulatory issues comprise both. This transparency would

both help force values debates into the open and could limit spurious claims about, and attacks on science.⁹³

Some scholars find that the EU approach to distinguishing between science and policy via separate institutions yields superior outcomes to those of the U.S., where risk assessment and risk management are housed within single agencies. For example, Marchant observes that the structure of the European Food Safety Authority (EFSA) “is explicitly based on separating science-based risk assessment and policy-based risk management into separate institutions.” He concludes that “while the EFSA has not been without some controversy, it has generally been perceived as responsible for restoring credibility and public trust to the European regulation of food safety after a series of European food controversies.” He concludes that “the primary reason for EFSA’s success is an institutional commitment to scientific objectivity, as seen by the commitment in its Mission Statement ‘to the core standards of scientific excellence, openness, transparency, independence and responsiveness.’”⁹⁴

Controlling Bureaucracy

The OECD encourages members to “commit at the highest political level to an explicit whole-of-government policy for regulatory quality,” and to “establish mechanisms and institutions to actively provide oversight of regulatory policy procedures and goals, support and implement regulatory policy, and thereby foster regulatory quality.”⁹⁵

Oversight of regulatory bodies, procedures, and policies are accomplished in different ways. Both jurisdictions rely to a certain extent on publicly-elected officials to ensure regulations developed by career experts are responsive to citizens. In the U.S., this is done at the agenda-

⁹³ Bipartisan Policy Center. (2009).

⁹⁴ Gary E. Marchant. Written testimony before the Subcommittee on Energy and the Environment of the United States House of Representatives Committee on Science Space and Technology Fostering Quality Science at EPA: Perspectives on Common Sense Reform. Nov. 30, 2011. Citing: European Food Safety Administration, Management Plan of the European Food Safety Authority for 2008 7 (2007), available at http://www.efsa.europa.eu/cs/BlobServer/DocumentSet/mb_managementplan2008-adopted,3.pdf?ssbinary=true. Referenced in Marchant 2011. https://science.house.gov/sites/republicans.science.house.gov/files/documents/hearings/113011_Marchant.pdf.

⁹⁵ OECD, 2012, *Recommendation of the Council on Regulatory Policy and Governance* (<http://www.oecd.org/gov/regulatory-policy/49990817.pdf>)

setting stage when Congress passes legislation that authorizes agency action. In the EU, the Council and Parliament must approve legislation drafted by the Commission. These inter-institutional mechanisms of control and coordination are very important in the EU. For legislative acts, this involves the co-legislators' strong role during the process, for non-legislative acts the "comitology" assures a control by member states. However, the reform of the comitology system has reduced the level of control of delegated rulemaking for so-called delegated acts.

Both jurisdictions also maintain institutions to oversee regulatory development. In the EU, the IAB reviews of the IAs generated in support of proposed legislative acts are an effective tool for quality control of IAs, but since delegated and implementing acts are not yet routinely subject to IAs, this element of control is absent there. In the U.S., OIRA reviews executive branch RIAs as well as draft regulations before they are proposed or issued in final form, however it does not have the same oversight role for "independent regulatory agencies."⁹⁶ In addition, the courts provide an oversight function to ensure that regulations comply with APA procedures and statutory requirements.⁹⁷

Weiner and Alemanno have emphasized the growing importance of regulatory oversight bodies, such as OIRA in the U.S. and the IAB in the EU, stating:

Wherever states deploy regulation, demand arises for oversight of the regulatory system to reduce the costs and side effects of regulation, promote efficiency in standard-setting and instrument choice, encourage consistency and transparency, ensure accountability, and improve the overall social outcomes of regulation. Regulatory oversight, particularly oversight by a centralized governmental body, has increasingly been seen as an effective mechanism for improving regulation.⁹⁸

⁹⁶ Dudley 2015.

⁹⁷ Dudley 2015.

⁹⁸ Jonathan B. Wiener & Alberto Alemanno, "Comparing Regulatory Oversight Bodies Across the Atlantic: The Office of Information and Regulatory Affairs in the U.S. and the Impact Assessment Board in the EU," *Comparative Administrative Law* (Susan Rose-Ackerman & Peter Lindseth eds., Edward Elgar, 2011)

In 2004, Hahn and Litan encouraged the U.S. to broaden the scope of existing regulatory review, for OIRA to conduct its own analysis instead of relying on agencies' numbers, and for the EU to embrace strong centralized regulatory oversight grounded in economic efficiency. However, as Weiner and Alemanno point out, "the salient differences between OIRA in the U.S. and IAB in Europe derive in part from the different U.S. and EU constitutional contexts, and from the different purposes of their respective IA systems."⁹⁹

Legitimacy

For regulated entities to accept and comply with regulations, they must be viewed as legitimate. This can be particularly important when regulatory authority is delegated to "non-majoritarian" institutions, including DGs and regulatory agencies, such that mechanisms of democratic legitimacy are not fully in place.¹⁰⁰ Elected members of the legislature in the U.S. delegate regulatory authority to agencies, and European states "delegate" sovereign powers to a supranational authority. Regulatory practices, such as transparency, public consultation, and regulatory impact analysis, are all important to the overall legitimacy and ultimate acceptance of regulatory law.¹⁰¹

In the U.S., the APA procedures and opportunity to challenge regulations in the courts adds an additional layer of legitimacy to agency actions. In the E.U. the fact that elected officials—the Council and the Parliament—must approve legislative acts and exercise political control over the Commission (through budgets, etc.) grants democratic legitimacy and accountability to the process. Further, the control by member states (in the comitology procedures), as well as experts and representatives of the Parliament, is an important mechanism for creating legitimacy.

⁹⁹ Wiener & Alemanno, 2011.

¹⁰⁰ Giandomenico Majone, "The Regulatory State and its Legitimacy Problems" *West European Politics* Vol 22, No. 1 (January 1999), pp. 1-24

¹⁰¹ Ragnar Löfstedt & David Vogel, "The changing character of regulation: A comparison of Europe and the United States." *Risk Analysis*, 2001; 21:399-406.

Challenges and Opportunities

The U.S. and EU share many similarities in their approaches to regulation. Nevertheless, there are important differences between the jurisdictions in both the procedures and policies for developing and implementing regulation. While some of these differences are inherent in the different constitutional foundations of the EU and U.S., making direct procedural alignment unlikely, there may be opportunities for greater regulatory coherence and mutual recognition. The above comparison of regulatory practices suggests a few challenges and opportunities.

Who Regulates

One difference relates to who does the regulating. In the U.S., executive branch agencies, accountable to the President, develop and implement regulation pursuant to rulemaking powers delegated by Congress (via legislation). In the EU, regulation is a process driven by the executive (EU Commission) but ultimately decided by the other EU political institutions: the Council and the Parliament. Rulemaking powers are delegated to the European Commission (not to regulatory agencies), and there is a stronger role for independent expert bodies (CEN, ETSI) in technical regulation (under broad policy principles defined at EU level).

While negotiations between the European Commission and the U.S. Administration may not be able to bind the U.S. legislature and the European Parliament, principles of mutual recognition may facilitate trade and investment between Europe and the U.S. even when laws are not aligned. Routine sharing of regulatory agendas between the Commission and the Administration can be valuable for alerting trading partners to developing policies with potential consequences. The European Commission produces an annual Work Programme that “presents the major political priorities of the Commission [and] identifies concrete actions either legislative or non-legislative that translate these priorities into operational terms.”¹⁰² This Work Programme is less detailed and specific than the semiannual *Unified Agenda of Regulatory and Deregulatory Actions* in the U.S., partly reflecting the earlier stage of the legislative/regulatory process.

¹⁰² http://ec.europa.eu/taxation_customs/common/about/work_program/index_en.htm

To address the concern that it can be difficult for entities without a Washington presence to engage effectively with U.S. legislators when new bills are being considered, the Legislative Reference Division of OMB, as part of its analysis and tracking of pending bills, might be able to share with trading partners information on bills that may have international trade or investment impacts. Additionally, the increased availability of data on-line (such as through Congress.gov) and applied programming interfaces may facilitate third-party analysis of legislative elements relevant for trading partners.¹⁰³

The Role of Consultation

While stakeholder consultation is an important element of both regimes, the mode, timing, and role of consultation differ. In the U.S. consultation is a means to gather input and increase accountability of delegated agency rulemaking. It allows interested parties to voice concerns, and has a long tradition of transparency concerning procedures and the role of comments in decision making. Both regulatory text and supporting analysis are available for review and comment.

In the EU, consultation is a means of gathering input and evidence for the assessment by politically accountable decision-makers of policy options. Stakeholder input is solicited earlier in the rulemaking process to develop and support the IA and identify options, but is generally not invited on the IA or regulatory text.

There are merits to early consultation, in that public input can provide valuable evidence for the design of policy options. For regulations with particularly significant effects, particularly on international trade and investment, U.S. regulatory agencies might consider issuing advanced notices of proposed rulemaking to solicit input from trading partners and interested parties domestically and internationally on a range of possible policy options.

There are also benefits to public consultation (as distinguished from selected stakeholder consultation which runs the risk of regulatory capture) on specific proposals and their supporting analyses. The European Commission has been clarifying its consultation procedures for

¹⁰³ For example, see OpenCongress.gov.

individual policies and might consider developing clear consultation guidelines for rulemaking processes (implementing and delegated acts) broadly.

The Role of Impact Analysis/Assessment

While both jurisdictions emphasize the importance of ex ante assessments of the impacts of alternative regulatory options, the role of these analyses differ. In the U.S., RIA is a means to inform policy choices and establish accountability in delegated rulemaking, thus there is a strong emphasis on ensuring that regulations offer net benefits, and hence on benefit-cost analysis. In the EU, IA as a means to inform policy choices and political decisions, thus there is a stronger emphasis on comparative assessments of different policy options earlier in the process.

In the U.S., RIAs are often very detailed, running into thousands of pages, but have been increasingly criticized for being used to justify a selected regulatory option, rather than to inform decisions.¹⁰⁴ In some cases, public comment occurs after major decisions regarding regulatory approach have been made.¹⁰⁵ To address this concern, some have suggested that U.S. agencies should conduct simpler, exploratory analysis of broad themes and alternatives early in the process, and solicit public comment on broad questions, in addition to conducting analysis and engaging public comment on actual draft text.¹⁰⁶

In the EU, a single IA framework is used for a variety of types of legal acts (legislative and non-legislative acts, including delegating and implementing acts). The IA guidelines suggest that the scope of the analysis should be commensurate with the importance of the problem addressed, and the magnitude of the expected impacts. For example, the IA analysis for a legislative proposal in an area never covered before by EU legislation should differ from that required for an implementing act. While in both cases an IA should inform political decision making, the depth and focus of the analysis as well as the scope of the related public consultation should differ.

¹⁰⁴ Wagner WE (2009) The CAIR RIA: Advocacy Dressed Up as Policy Analysis. In: Harrington W, Heinzerling L, Morgenstern R (eds) *Reforming Regulatory Impact Analysis*, pp. 56–81. Resources for the Future Press, Washington, DC.

¹⁰⁵ Parker & Allemano 2014.

¹⁰⁶ Carrigan and Shapiro 2014

In both jurisdictions, the distinctions between policy judgments and scientific facts are often blurred. The U.S. could consider how to implement the recommendations of the Bipartisan Policy Center to “distinguish between questions that can be resolved through scientific judgments and those that involve judgments about values and other matters of policy”¹⁰⁷ and perhaps experiment with institutional separation of risk “assessment” and risk “management.” The EU could clarify how the precautionary principle relates to its impact assessment principles.

Retrospective Evaluation of Existing Regulation

While horizontal or forward-looking initiatives have often been more successful than efforts to modify existing regulations to comport with trading partner objectives, the growing interest in improving evaluation of the effects of existing regulations may offer opportunities not only for making regulatory policies more effective and less burdensome domestically but for opening doors to more transatlantic trade and investment. The EU REFIT program is mainly about reducing unnecessary and burdensome provisions from the stock of regulation, and can be seen as a successor to previous programs of this kind (which had limited success). While in recent years there has been increased emphasis on regulatory ex post evaluation and they are widely practiced in the EU, the emphasis in terms of streamlining practices has been on the impact assessment system, i.e. ex ante evaluations.

The situation is similar in the U.S., where President Obama has asked agencies to “consider how best to promote retrospective analysis of rules that may be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned.”¹⁰⁸ However, retrospective regulatory review, including both analysis and stakeholder participation, is far less robust than established practices for the initial development of regulations.¹⁰⁹

¹⁰⁷ Bipartisan Policy Center 2009. P. 15.

¹⁰⁸ <http://www.gpo.gov/fdsys/pkg/FR-2011-01-21/pdf/2011-1385.pdf>.

¹⁰⁹ Susan Dudley, “A Retrospective Review of Retrospective Review,” George Washington University Regulatory Studies Center, May 07, 2013.

<http://regulatorystudies.columbian.gwu.edu/sites/regulatorystudies.columbian.gwu.edu/files/downloads/20130507-a-retrospective-review-of-retrospective-review.pdf>. As Coglianese observed “retrospective review is today where prospective analysis was in the 1970s: ad hoc and largely unmanaged.” Cary Coglianese “Moving Forward with Regulatory Lookback,” *Yale Journal on Regulation*, Vol. 30 (2013), p. 59

The renewed emphasis in both jurisdictions on retrospective review may offer opportunities for the transatlantic dialogue. As governments improve their ability to evaluate the effects of their regulations, including effects on international trade and investment, doors may open to alternatives that minimize regulatory burdens and regulatory barriers. The U.S. E.O. 13609, issued in May 2012, directs agencies to consider “reforms to existing significant regulations that address unnecessary differences in regulatory requirements between the United States and its major trading partners” noting that “in meeting shared challenges involving health, safety, labor, security, environmental, and other issues, international regulatory cooperation can identify approaches that are at least as protective as those that are or would be adopted in the absence of such cooperation...[and] reduce, eliminate, or prevent unnecessary differences in regulatory requirements.”¹¹⁰ The Administrative Conference of the United States recently issued recommendations for improving retrospective review that would target for review regulations where disparities exist between U.S. regulatory approaches and those of key international trading partners, among other things.¹¹¹

Smarter Regulation

Empirical cross-country analyses repeatedly find that excessive, poorly designed regulation can hinder economic growth and well-being.¹¹² “Intentionally or not, regulation can impose rigidities and distort the incentives for factor reallocation, capital accumulation, competition, and innovation.”¹¹³

Regulations that respect property rights and address public needs (rather than cater to particular interests) while encouraging competition, entrepreneurship and innovation not only facilitate economic growth within countries, but can open doors to international trade and investment, which further raise standards of living and well-being across jurisdictions. A “thriving private

¹¹⁰ Barack Obama, Executive Order 13569, “Promoting International Regulatory Cooperation.” May 1, 2012.

¹¹¹ Administrative Conference of the United States Recommendation 2014-5, “Retrospective Review of Agency Rules.” December 4, 2014. https://www.acus.gov/sites/default/files/documents/Recommendation%25202014-5%2520%2528Retrospective%2520Review%2529_1.pdf

¹¹² OMB’s annual reports to Congress summarize empirical research. For example, see U.S. Office of Management and Budget, “2008 Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities”

¹¹³ Norman V. Loayza, Ana Maria Oviedo & Luis Servén, “The impact of regulation on growth and informality - cross-country evidence,” Policy Research Working Paper Series 3623, The World Bank. 2005.

sector—with new firms entering the market, creating jobs and developing innovative products—contributes to a more prosperous society,”¹¹⁴ “promotes growth and expands opportunities for poor people.”¹¹⁵

When regulation is necessary, well-designed regulations that target an identified problem while maintaining freedom of choice (such as warnings, default rules, and disclosure requirements) can achieve public goals while minimizing burdens. Regulations that establish realistic performance goals, rather than technology or procedural standards, can also encourage innovation and experimentation. Both EU and U.S. policies encourage consideration of such regulatory alternatives, which are also more conducive to mutual recognition across jurisdictions than those that specify the behavior or manner of compliance that regulated entities must adopt.

¹¹⁴ World Bank, *Doing Business 2014: Understanding Regulations for Small and Medium-Size Enterprises*. Washington, DC: World Bank Group. (2013)

¹¹⁵ World Bank, *Doing Business 2004*. (2003)