

Towards Effective Regulatory Cooperation under TTIP: A Comparative Overview of the EU and US Legislative and Regulatory Systems

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Abstract

The aim of this report is to inform the EU-US Transatlantic Trade and Investment negotiations on enhanced regulatory coherence and cooperation, by providing negotiators, stakeholders and the public with a comparative overview of the US and EU legislative and regulatory processes in their current form, highlighting differences and similarities.

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Executive Summary

The EU and US legislative and regulatory systems are highly dissimilar in many respects, yet close analysis reveals that they share common features, including a concern with promoting public transparency and participation (albeit with different levels of emphasis at different stages in the process), and a commitment to notifying stakeholders, including trading partners, of emerging legislation and regulations that may affect them (though this commitment has been realised only imperfectly to date).

The main steps in the legislative and regulatory process described herein are illustrated side-by-side in brief, schematic form in the Annex to this Report.

A. Comparison of the EU and the US legislative systems

Laws in the United States and European Union emerge from different kinds of institutions following quite distinct processes.

In the United States the principal legislative actor is the US Congress, consisting of a House of Representatives comprised of representatives elected directly from districts of equal population in the 50 states; and a Senate comprised of two Senators from each state.

In the EU, the nature of the institutions involved in the legislative process is driven by the supranational character of the Union. The principal actors are the Commission representing the interests of the Union; the Council representing the interests of Member States; and the European Parliament (hereinafter 'EP'), the only institution whose members are elected by direct universal suffrage. The Commission is accountable to the European Parliament: its President is elected by the EP and the Commission as a body is appointed by the European Council with the consent of the EP. The design of the legislative and regulatory processes in the EU thus strikes an 'institutional balance', not between three coordinate branches of power (as in the US), but rather among the Union as a supranational entity, the Member States as sovereign nation, and the European Parliament representing the European citizenry in the process.

On both sides of the Atlantic, the legislative process may be divided, conceptually, into two main stages: (1) the formative stage, in which ideas for legislation are developed in concept

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and embodied in draft bills, and (2) the deliberative stage, in which the bill is amended, debated and, in some cases, voted into law.

1. *The formative stage*

In the European Union, only the EU Commission can propose legislation to Parliament and Council, though the Commission may derive the inspiration for such legislation from any number of sources.

The EU pre-legislative process typically offers significant opportunities for consultation with relevant stakeholders (as guided by the EU's "minimum standards for consultation").¹ Major legislation that goes from the EU Commission to the European Parliament and Council is the product of an elaborate administrative process that generally will include early warnings in the form of public Commission Roadmaps, extensive stakeholder consultations, fully-fledged Impact Assessment (IA), Impact Assessment Board (IAB) review, Inter-Service Consultation (ISC), and final adoption by the EU College of Commissioners.²

In the US, by contrast, draft legislation *may* in rare cases be fully considered and developed in an inter-agency process culminating in a proposed bill that is then submitted by the Administration to a friendly Member for introduction and sponsorship in Congress. But this is the exception rather than the rule and there is no requirement or even customary expectation that legislation will originate in this way. In fact, any Member of either the House of Representatives or the Senate can propose legislation that may be drafted by his or her staff, possibly with the help of outside interests and/or each House of Congress's Office of Legislative Counsel. There is no Impact Assessment of draft bills, and no required process of stakeholder consultation prior to introducing the bill. As a result, the process used to develop legislation for introduction in either the House or the Senate is usually quite opaque to the public.

2. *The deliberative stage*

In the US, all bills introduced in either house of Congress (House of Representatives or Senate) are published online, and the Library of Congress maintains a website, www.Congress.gov (scheduled to replace www.Thomas.loc.gov by the end of 2014), that compiles these bills in full text form along with much additional information.

A bill introduced in the US Congress normally (though not necessarily) goes through a hearing and 'mark-up' or amendment process in one or more relevant committees in each chamber. These hearings and committee mark-ups generally will be open to the public with a transcript made of the proceedings. However, participation in these meetings is limited to a handful of invited witnesses (hearings) and to committee members (mark-ups). Once a bill is reported out of Committee it goes to the 'floor' of the House or Senate, where once again there is a public debate and amendment process.

¹ Communication from the Commission of 11 December 2002 on the collection and use of expertise by the Commission: principles and guidelines – "Improving the knowledge base for better policies", COM(2002) 713 final.

² According to the 2009 Commission Impact Assessment Guidelines (currently under revision), IAs are necessary for "the most important Commission initiatives and those which will have the most far-reaching impacts". This will be the case for all legislative proposals of the Commission's Legislative and Work Programme (CLWP) and for all non-CLWP legislative proposals that have clearly identifiable economic, social and environmental impacts (with the exception of routine implementing legislation). See European Commission, Impact Assessment Guidelines, SEC(2009) 92.

In order for a bill to become law in the United States, an identical bill must be approved by both House and Senate and sent to the President, who signs it as well. If the President vetoes a bill, it can nevertheless be enacted by a two-thirds vote of each House, though this rarely happens. If the House and Senate enact different bills, initially, they must either ‘ping-pong’ amended bills between chambers (with passage dependent upon a majority vote in favour of identical bills in each Chamber) or they must convene a conference committee to negotiate a compromise package that then wins majority assent in each chamber.

In the US Congress, as in the European Parliament, debates are public, as are proposed amendments to draft legislation. The Council and the Parliament engage in a deliberative interaction that is roughly analogous to that of the US House of Representatives and Senate, with the Parliament considering the Commission proposal and sending the (possibly amended) draft legislative proposal – if passed by majority vote – to the Council. Council and Parliament as co-legislators may ‘ping-pong’ amended proposals back and forth through two rounds of exchange until at last, if no final agreement is reached to either accept or reject the measure, a Conciliation Committee is convened (analogous to the US Congress’s conference committees) to try to craft a mutually agreeable compromise. If the Conciliation Committee succeeds in reaching agreement on common draft text, it will forward that text to the Council and Parliament for review and vote on an up-down basis with no amendments allowed.

Once the legislative proposal is pending before EP and Council (the process of “co-legislation”), throughout this process the Commission participates in ‘trilogues’ with the EP and Council co-legislators aimed at achieving voluntary consensus on a common position. It also expresses its position on amendments.³ The Commission retains the option of withdrawing the proposal – until the proposal is adopted by the Council and EP.

In both the US and EU systems, a legislative proposal becomes a law only if its text is approved in identical form by two separate bodies – by Parliament and Council in the EU, by the House and Senate in the US – and is then signed by the Presidents of the European Parliament and Council (in the European Union) or by the US President (in the United States). However, signature by the Presidents of the European Parliament and Council is largely ceremonial, whereas the US President’s signature requires a discretionary decision.

3. Regulatory notification of trade partners in the legislative process

Both the US and the EU and its Member States have committed - in the framework of the WTO Agreements - to notify their trading partners of emerging laws and rules that impact their trading partners, and both have established enquiry points for that purpose.

Under the WTO Agreement on Technical Barriers to Trade (TBT), for example, the EU notifies relevant legislative drafts (draft regulations and directives) to the WTO once they are adopted by the College of Commissioners. By contrast, the US does not notify draft Congressional bills, perhaps because of the sheer number of bills in the hopper at any given time. In excess of 7,000 bills are currently pending in the 113th Congress. Of these it is expected that fewer than 5 percent will become law.⁴ This poses a dilemma: at what stage in the process is a bill a serious enough contender to be worth worrying about?

One solution might involve the Office of Management and Budget’s (OMB’s) Office of Legislative Information (OLI), which monitors developments on Capitol Hill on behalf of the

³ In the rare cases that the Commission does not agree with the amendments, the Council must vote unanimously to adopt a legislative act; otherwise a qualified majority voting applies.

⁴ See www.govtrack.us.

Administration, and coordinates the Administration's response to bills that in OLI's judgment merit careful attention. This suggests that OLI might serve as a useful contact point in any future notification arrangement, working through the OIRA-led Regulatory Working Group established under Exec. Order 12,866.⁵

Another difference is that EU Member States directly notify draft legislation in non-harmonised areas. In the US, by contrast, the federal government is responsible for ensuring that TBT-relevant state legislation is notified, though, in practice, it seems that this is done relatively rarely (e.g., 35 notifications between 2011 and 2013).

B. Comparison of US and EU regulatory systems

Comparison of the US and EU regulatory systems is complicated at the outset by the fact that US agencies and the EU Commission are delegated rather different kinds of power by their respective legislatures. In the US, agencies have no power to modify congressionally enacted legislation. They can only implement it. In the EU, by contrast, non-legislative acts promulgated by the Commission divide into two categories: *delegated acts* can modify primary legislation in 'non-essential' ways, while *implementing acts* merely enable implementation of basic legislation where uniform conditions for implementation across Member States are needed.

In the US, federal rule-making is in the exclusive remit of regulators. Congress cannot amend or veto regulations duly enacted by agencies except through the passage of a new statute *de novo*, a cumbersome process which requires passing the identical bill in each chamber and securing the signature of the President.

In the EU, however, the Commission's draft delegated acts are subject to the oversight (review with veto power) of the European Parliament and Council, each of which has two months (extendable upon request by another two months) after adoption of a delegated act by the Commission to review the act in question. Either the Parliament (by absolute majority vote) or the Council (by Qualified Majority Vote) can reject the delegated act at any time within the 2-4 month review period.

Likewise, the Commission may enact an 'implementing act' only after receiving a formal opinion from an Examination Committee comprised of Member State representatives. In the (rarely used) advisory procedure, the Commission merely consults the Committee before it adopts the implementing act. In the much more widely used examination procedure, the Examination Committee may, by Qualified Majority Vote, block the Commission from adopting the implementing act in question. Moreover, in sensitive policy areas (including taxation, consumer health, food safety, and protection of the environment) and in cases where the basic legislation so provides, the Commission may adopt its draft measure only with the active concurrence of the Examination Committee, via affirmative Qualified Majority Vote.⁶

If it is blocked by the Examination Committee, the Commission may submit its (possibly amended) draft to an Appeals Committee made up of more senior Member State

⁵ Of course, most bills that come to the OLI's attention do not raise trade or regulatory cooperation concerns, and OLI is not well-placed to make that judgment in any case. So any notification scheme involving OMB/OLI would have to supply an additional mechanism for identifying and responding to the small subset of bills that affect the trade or regulatory interests of the trans-Atlantic partners.

⁶ See Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers.

representatives. The Commission can then adopt its draft unless the Appeals Committee either amends or rejects the measure by Qualified Majority Vote.

1. Transparency and public participation in the early, formative stage of rulemaking

In the formative stage of rulemaking – the stage at which a proposed rule is being drafted and initially analysed and weighted against alternatives – the situations in the EU and the US are broadly similar, in practice, in terms of transparency and public participation. Prior to the publication of a Notice of Proposed Rulemaking (NPRM), US agencies *may* choose to consult advisory boards and stakeholder groups, hold public hearings, and issue early questionnaires and notices that signal their current thinking, etc. But nothing in US law *requires* them to do so, apart from (perhaps) the spectre of judicial review on the merits. There are no formal restrictions on *ex parte* contacts between stakeholders and the agency staff at this stage, but by the same token there is no requirement to disclose or transcribe communications between stakeholders and the agency. Likewise, on the European side: unless an impact assessment is required for the proposed delegated or implementing act, regulators consult stakeholders as needed to gather information relevant to the proposed delegated or implementing act, but they do so through an informal process that is not subject to detailed procedural requirements, and is not particularly transparent.

The special case of ‘negotiated rulemaking’ – currently practised only in the United States, and then rather rarely – offers some additional transparency and involvement with stakeholders at the pre-analysis and rule-formation stage. In this process an outside convenor and mediator is brought in to convene, and preside over negotiations with, a balanced group of representative stakeholders – public interest groups, industry and government regulators, usually a group of no more than 25 – as they analyse data, examine the issues and try to negotiate a text, or the main terms, of a proposed rule. Although not all agencies have used negotiated rule-making (as it remains optional) several US agencies – including the Environmental Protection Agency, the Department of Energy, and the Department of Transportation – have used it, including in the US-Canada context (e.g. parking spaces for the disabled). Even if the process does not lead to consensus, experience suggests that a well-done collaborative process very often improves the agency’s analysis while building support for – or at least minimising resistance to – the final decision.

2. Transparency and public participation in later stages of rulemaking

After publication of the Notice of Proposed Rulemaking (NPRM), the US notice-and-comment process becomes a bit more open (or rather more reliably open) than its EU counterpart. The US Administrative Procedure Act (APA) requires that all agency rules that carry the force and effect of law must go through a notice and comment process, which involves:

- Publishing a draft regulation (other laws require that it be supported, in the case of ‘significant’ rules, by a draft Regulatory Impact Analysis)
- Inviting comment for a specified period
- Reviewing the comments that come in
- Revising the draft rule as needed to reflect the comments, and
- Issuing a final rule supported by responses to comments and an explanation of why of the agency adopted the rule as opposed to alternatives (including the option of no regulation) that the agency considered and rejected.⁷

⁷In the United States the Administrative Procedure Act (APA) applies to virtually all federal regulatory agencies and provides a common legal and policy framework for the conduct of rulemaking and

Some, though not all, US agencies restrict (or require disclosure of) *ex parte* communications between stakeholders and agency staff after the opening of the comment period, and an even greater number of agencies restrict (or require disclosure of) *ex parte* contacts with the public after the close of the comment period.

In the EU, Impact Assessment with regard to draft delegated or implementing acts is carried out when these acts are expected to have significant economic, environmental or social impacts.

In the EU, transparency is enhanced for delegated acts by a Register of Expert Groups and Other Similar Entities that has been set up by the Commission to provide an overview of the consultative entities that help it in the preparation of, *inter alia*, delegated acts. For each group, the register provides standard information such as the Commission department running the group, as well as the group's mission, tasks and membership.

For implementing acts, transparency is enhanced by a 'Comitology Register' containing a list of all comitology committees (including the Appeal Committee), agendas of committee meetings, summary records of the meetings and the lists of authorities representing the Member States, draft implementing acts submitted to committees, the results of voting, the final draft implementing acts following delivery of the opinion of the committees, information concerning the adoption of the final draft implementing acts by the Commission as well as statistical data on the work of the committees.

In the US, a centralised portal, www.regulations.gov, provides a similar function for US regulations, collecting proposed rules, comments, supporting analyses, and final rules and preambles for easy public access.

3. Regulatory notification of trading partners in the regulatory process

Pursuant to the TBT and SPS Agreements, WTO Member States – including both the EU and its Member States and the US – are obliged to notify the WTO secretariat of all draft national (technical) regulations and conformity assessment procedures that might affect the trading interests of other WTO members. Such notifications are supposed to take place at a draft stage, when the (technical) regulation or conformity assessment procedure is not yet adopted and amendments can still be introduced and comments from other WTO Members can still be taken into account. In current practice there is significant variance on both the frequency and the timing of the notification.

On the US side, for example, Executive Order 13,609 (2012) established an OIRA-led Regulatory Working Group charged with promoting international regulatory cooperation. Under current practice, notification to the WTO of draft rules coincides with the launch of the domestic public stakeholder consultation through publication of a Notice of Proposed Rulemaking (NPRM). Other WTO members, including the EU, are treated as any other stakeholder.

enforcement across many agencies. However, the APA is itself a broad framework that allows for significant variations of practice among agencies. Likewise, there are considerable variations across sectors in the processes followed in the EU. This being the case, the needs of brevity and the very strict time limits for this paper will not permit exploration of agency- and sector-specific variations in depth here. This study focuses on the broad contours of the regulatory process on each side, leaving the detailed variations to be explored at a later time, perhaps in the context of sector-specific TTIP negotiations.

On the EU side, draft delegated and implementing acts are generally notified to the WTO Secretariat either before their adoption (as is the case for TBT-relevant measures), or afterwards.

C. Judicial review of laws and regulations

Although EU delegated acts and implementing acts must be considered as more vulnerable to *legislative* veto than their US regulatory counterparts prior to enactment, they are far less prone to *judicial* reversal afterwards. On one hand, US statutes are judicially reviewed only for conformity to the Constitution and are rarely overturned. However, US agency rules are frequently challenged in court, with complaints ranging from illegality (non-conformity to US law or the Constitution) to abuse of discretion (the so-called ‘arbitrary and capricious’ test) to failure to follow proper procedures.

Moreover, the prospect of searching judicial review – review that is conducted exclusively on the basis of the record created by the agency in its rulemaking process – often prompts US agencies to offer more notice, more hearings, more workshops, and more opportunity for comment than the bare words of the APA and/or the enabling statute would seem to require.

In the EU, both legislative and regulatory acts are likewise subject to judicial review. However, largely due to the strict rules on *locus standi* and the rather deferential standard of review exercised by EU courts, only a few acts – be they legislative or non-legislative – are challenged and struck down by courts every year.

D. Impact Analysis in the EU and US legislative and regulatory processes

Both the US and EU employ various forms of Impact Assessment (EU) or Regulatory Impact Assessment (US) to aid in the evaluation of alternative approaches to regulation. However, Impact Assessment (IA) is applied at quite different stages in the two systems, making use of rather different methodologies and processes.

Differing points of application. IA is widely used in the pre-legislative phase in the EU, but rather rarely applied to delegated acts or implementing measures that follow such legislation.⁸ In the US, by contrast, Impact Assessment is almost *never* applied to draft legislation, but is required for all ‘significant’ rules, apart from those developed by independent regulatory commissions.⁹

Differing methodologies. Besides applying the assessments at different points in the process, the US and EU also use rather different methodologies of assessment. In the US, assessors focus on providing a quantitative and (to a far lesser degree) qualitative analysis of the costs and

⁸ According to the EU’s 2009 Impact Assessment Guidelines, non-legislative acts with significant economic, social or environmental impacts also need to be accompanied by an IA. Nonetheless, use of formal IA in the development of delegated and implementing acts remains rare in practice, though its use is increasing. When used for a non-legislative measure or a delegated/implementing act, non-legislative IA has to follow the same procedure and requirements as any other IA, though the level of analysis should be “proportionate” to circumstances such as the economic stakes of the measure and the degree to which the measure raises issues not already addressed in an Impact Assessment previously conducted for the basic legislation authorising the measure. See A. Alemanno and A. Meuwese (2013), “Impact Assessment of EU Non-Legislative Rulemaking: The Missing Link of ‘New’”, *European Law Journal*, Vol. 19, No. 1, January.

⁹ Generally speaking, ‘significant’ rules are those expected to impose more than \$100 million per year in compliance costs, or which raise significant and novel legal or policy issues in the judgment of the Office of Management and Budget’s Office of Information and Regulatory Affairs (OIRA). See Executive Order No. 12,866.

benefits of the proposal compared with anticipated costs and benefits of adopting certain salient alternatives to the rule, including the alternative of no regulation. The Commission's approach to Impact Analysis, by contrast, favours a more holistic approach integrating the features of regulatory impact assessment, sustainable impact assessment and other types of *ex ante* policy evaluations, such as cost-benefit analysis (CBA), cost-effectiveness analysis (CEA), and multi-criteria analysis (MCA).

Differing consultative processes. In the US, the RIA is published in draft form with the publication of the Notice of Proposed Rulemaking, giving the public the opportunity to comment on the draft assessment as well as the proposed rule.

The EU generally builds into each Impact Assessment a public consultation process that identifies the problem, along with various policy options for responding to the problem, and solicits public comment on those options and their impacts. EU practice is not to publish the text of the draft act itself, or the Impact Assessment supporting it, before the act is adopted by the College of Commissioners and sent along to the EP and Council for review. But the policy options are thoroughly aired at the draft proposal stage, comments are sought relatively early so that they have a real chance to shape policy development, and all comments are made public on the Commission's website. Once the draft act is sent forward, the Impact Assessment is not updated post-proposal by the Commission. In principle, the European Parliament and Council should conduct a form of Impact Assessment of any significant amendments they propose.

Differing external review processes. In the EU, the Commission makes use of an Impact Assessment Board (IAB) to review the quality of Impact Assessments prepared by the DGs and to advise on issues on methodology and procedure. In principle, in cases where an Impact Assessment is prepared, a positive opinion from the IAB is needed before a proposal can be put forward for decision by the College of Commissioners. By contrast, the US Office of Management and Budget's Office of Information and Regulatory Affairs (OIRA) is empowered to both review the quality of agencies' impact assessments, and to return for reconsideration those assessments that OIRA finds to be not adequately supported by sound analysis, or otherwise not in keeping with the President's policy agenda.¹⁰

Conclusion

Overall, both sides offer the key element of transparency and public participation, but they do so to differing degrees at different stages in the process. Clearly, the EU legislative drafting process is more transparent, rigorous and inclusive of stakeholders in the formative stages of legislation. This is largely due to the Impact Assessment/public consultation system that is applied to the vast of majority of significant policy initiatives proposed by the EU Commission.

With regard to transparency of deliberations within the EU Parliament/Council and the US Congress, while we have not found any specific comparative analyses, we suspect that the legislative processes on either side of the Atlantic are roughly comparable in transparency terms.

¹⁰ OIRA cannot alter statutes. Therefore, OIRA cannot legally force an agency to miss a statutory deadline for enacting a rule, nor can OIRA over-ride a statutory delegation of authority to an agency to make a final decision based on statutory decision criteria. However, OIRA can exert considerable pressure on agencies to exercise their (often broad) statutory discretion in ways that seem appropriate to OIRA, or to the White House in cases that come to the attention of White House staff or the President.

In the formative (pre-notice) stage of rulemaking both sides' processes allow, in principle, free-wheeling and candid off-the-record communications in support of agencies' efforts to gather the often extensive information needed to craft an effective rule.

Finally, in the deliberative stage of rulemaking stakeholder consultations tend to be less formalised and thus somewhat less predictably open in the EU than in the United States. All US federal agencies must publish all proposed rules, accept comments, and respond to comments when issuing the final rule. However, Impact Assessment and its associated consultation process is not required as a matter of course for delegated and implementing acts in the EU, although the involvement of Member States experts is often required and the consultation of stakeholders is a common practice.

In sum, it would appear that *both* the EU and the US quite reasonably nurture the hope of identifying more effective ways to learn about, and respond to, practices or emerging proposals on the other side of the Atlantic side that might affect their key trade or regulatory interests.

TTIP negotiators may find it useful to examine sectors of particular interest with an eye to ascertaining specifically what would be needed to achieve desired levels of compatibility/alignment of TTIP-relevant regulations in those sectors. This is the 'in-built agenda' of TTIP, and it may be useful to consider launching a few pilot projects to try out different approaches to regulatory cooperation – including multi-stakeholder collaborative approaches – to guide negotiators' thinking about how to design or refine the regulatory cooperation chapter (the so-called "horizontal chapter") to TTIP.

Overview of the legislative and regulatory processes of the EU

Regulatory policy development in the EU follows two main processes: legislation proposed by the EU Commission and enacted by the European Parliament (EP) and Council (hereinafter, the EU legislative process), and non-legislative measures or rulemaking through implementing acts (traditionally called “comitology”) and delegated acts, both performed by the EU Commission under the control of Member States and of the EP and Council respectively (hereinafter, the EU regulatory process). Legislative and significant regulatory proposals are normally subject to Impact Assessment. This section will examine each of these procedures – legislative and regulatory – in turn.

Overview of the EU Legislative Process

1.1 The source of EU legislative powers

EU legislative bodies have no inherent powers, and wield only the powers assigned to them by the EU Member States in EU Treaties.¹¹ Moreover, whereas the US Constitution’s “Commerce Clause” gives Congress plenary authority to regulate all activities involved in “interstate and foreign commerce” – an authority that encompasses most activities of interest to TTIP negotiators – the EU Treaties enumerate legislative authority sector by sector. According to the principle of conferral,¹² unless the EU Treaties provide a legal basis for action at the EU level – by means of a specific Treaty article allowing the EU to intervene in a certain area - then only Member States may take action in that area.

The Treaties distinguish between four general categories of Union “competences” (or authorities) to enact binding legislation:

- Exclusive competences (i.e. only the EU may act);
- Shared competences (i.e. both the EU and the Member States may act);
- Coordinating competences (i.e. the EU may frame national action) and
- Complementary competence (still largely undefined).

Thus, for instance, agriculture (Article 38), transport (Article 91), workers’ protection (Article 153), consumer protection (Article 169) represent shared competences, whereas commercial policy (Article 207) belongs to the exclusive competence of the EU.

In areas of exclusive competence, the EU alone “may legislate and adopt legally binding acts”¹³ and Member States may act only “if so empowered by the Union or for the implementation of Union acts”.¹⁴

¹¹ The “EU Treaties” refer to the Treaty on European Union (TEU) and the Treaty on the Functioning of the European Union (TFEU).

¹² Article 2(1) TFEU.

¹³ Article 2(1) TFEU.

¹⁴ Id.

Table 1. Overview of Union competences

Exclusive competence (see Article 3 TFEU)	Shared competence (see Article 4 TFEU)	Competence to support, coordinate or supplement actions of the member states (see Article 6 TFEU)	Competence to provide arrangements within which EU member states must coordinate policy (see Article 5 TFEU)
▪ customs union ▪ the establishing of the competition rules necessary for the functioning of the internal market ▪ monetary policy for the member states whose currency is the euro ▪ conservation of marine biological resources under the common fisheries policy ▪ common commercial policy ▪ concluding international agreements ◦ when their conclusion is required by a legislative act of the EU ◦ when their conclusion is necessary to enable the EU to exercise its internal competence ◦ in so far as their conclusion may affect common rules or alter their scope.	▪ internal market ▪ social policy, limited to the aspects defined in the TFEU ▪ economic, social and territorial cohesion ▪ agriculture and fisheries, excluding the conservation of marine biological resources ▪ environment ▪ consumer protection ▪ transport ▪ trans-European networks ▪ energy ▪ area of freedom, security and justice ▪ common safety concerns in public health matters, limited to the aspects defined in the TFEU ▪ research, technological development and space ▪ development cooperation and humanitarian aid	▪ protection and improvement of human health ▪ industry ▪ culture ▪ tourism ▪ education, vocational training, youth and sport ▪ civil protection ▪ administrative cooperation <i>Legally binding EU acts in these areas cannot imply the harmonisation of national laws or regulations.</i>	▪ economic policy ▪ employment ▪ social policies

Unless the Treaty provides otherwise, a Union competence is shared. However, in areas of shared competence Member States and the Union are prohibited from acting concurrently. The Member States may only legislate in those areas of shared competence which the EU has not (yet) entered.

In areas of “coordinating competence” – such as economic policy, employment policy and social policy under Article 5 TFEU – the EU is empowered to provide arrangements for the Members States to exercise their national competences in a coordinated manner. The Union’s coordination may include the adoption of “guidelines” and “initiatives to ensure coordination”, but cannot consist of any form of harmonisation.

In addition to the sectoral policy competences reviewed above, the Union enjoys two legal bases that authorise it to act horizontally across policy areas: (a) Article 114 TFEU, like the “Commerce Clause” in the US Constitution, empowers the EU to replace divergent national laws with a common rule applicable across the whole territory; (b) Article 352 TFEU, which is comparable to the “Necessary and Proper Clause” in the US Constitution,¹⁵ allows the Union to act when it is “necessary, within the framework of all the policies defined in the Treaties, and the Treaties have not provided the necessary powers”. This residual legislative

¹⁵ Article I, Section 8, Clause 18 of the US Constitution.

competence enshrined in Article 352 TFEU may be used either: (i) in a policy in which the EU has already been conferred some competence, but where the latter is deemed insufficient to achieve a specific objective; or (ii) to develop policy in an area that is not specifically encompassed within the existing text of the Treaties. However, Article 352 TFEU does not empower the EU to harmonise in areas where the Treaties expressly exclude such harmonisation (e.g. public health) nor to legislate in pursuit of objectives pertaining to a common foreign and security policy.¹⁶ Although the powers conferred by Articles 114 and 352 appear quite broad, they are constrained by the principles of subsidiarity and proportionality discussed in the next section.

1.2 The limits to the exercise of legislative powers

Once it has been established that the EU has the competence to act, it becomes necessary to determine whether it should exercise its powers. The principles of subsidiarity and proportionality constrain EU action.

The subsidiarity principle requires that the EU – in all areas of shared competence – may act only “if and insofar as the objectives of a proposed action cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale or effects of the proposed action, be better achieved by the Community.”¹⁷

The proportionality principle requires that EU intervention – regardless of the competence it is relying upon – should not go beyond what is necessary to achieve the objectives pursued.¹⁸

While this latter principle is frequently litigated, the former is not, largely due to the reticence of the European Court of Justice to make it actionable through a meaningful test.

1.3 Legislative procedures

The actors involved in the EU legislative process are depicted in Figure 1 below, arrayed in the so-called “institutional triangle”: the EU Commission’s role is limited to proposing a bill to the co-legislators, the EP and the Council, which they may enact if and when they both agree on a common text.

The European Commission’s role is similar to that of a government for the Union. It consists of one national of each Member State, the commissioner, chosen “on the ground of their general competence and European commitment from persons whose independence is beyond doubt”,¹⁹ for a term of five years. Following nomination by the European Council, the President of the Commission is elected by the European Parliament. The other commissioners are selected by the Council on the basis of nominations by the Member States and subject “as a body to a vote of consent by the European Parliament”.²⁰ It is on the basis of this election that the Commission is appointed by the European Council as a College.²¹ Each commissioner is

¹⁶ Article 352(4) TFEU.

¹⁷ See Article 5(2) TFEU and the Protocol on the Application of the Principles of Subsidiarity and Proportionality, annexed to the TFEU.

¹⁸ See Article 5(2) TFEU. According to established case law, an EU act is proportionate when it is suitable and necessary to achieve its declared goal. See Case 11/70, Internationale Handelsgesellschaft mbH v. Einfuhr- und Vorratsstelle für Getreide und Futtermittel, 1970 ECR 1125.

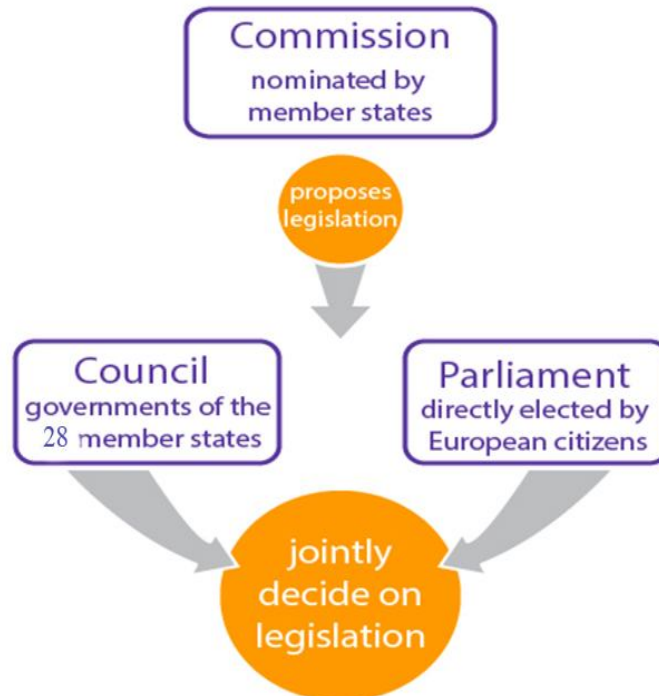
¹⁹ Article 17(3) TFEU.

²⁰ Article 17(3) 2 indent.

²¹ Article 17(3), 3 indent.

entrusted a specific policy area by the President (e.g. internal market, competition, taxation, environment, etc.) and is supported at technical level by a directorate-general (DG).

Figure 1. The EU 'institutional triangle'



The European Parliament represents the only directly elected EU institution. Over time, it has transformed itself from an assembly of national parliamentarians into a directly elected parliament. It is composed of 751 representatives of the Union's citizens. These representatives are elected every five years in elections taking place on the very same date and according to similar modalities in each Member State of the Union.²² It is the European Council that must decide on the national quotas for the Union's parliamentary representatives.

Within the European Union, the Council is the institution of the Member States. It consists of a ministerial-level representative of each Member State. This representative may commit the government of the Member State in question and cast its vote. While there is formally one single Council, there are ten different thematic configurations, ranging from economic and social affairs to environment, education, and justice and home affairs.

At the head of the EU institutional triangle lies the European Council. It consists of the Heads of State or Government of the Member States plus the Commission's President, and is chaired by a permanent President who is elected by the members of the EU Council itself. Its task is "to provide the Union with the necessary impetus for its development and shall define the general political directions and priorities".²³

²² While relatively large in comparison with the US House of Representatives, the EP is smaller than the British House of Lords, which number, at present, 829 members.

²³ Article 15(1) TEU.

1.3.1 The six steps of ordinary legislative procedure

The most common form of legislative procedure, called “ordinary”, proceeds in six stages:²⁴

1.3.1.1 Proposal

The EU Commission enjoys – with minor exceptions²⁵ – the exclusive right to initiate legislative action, and to submit a legislative proposal.²⁶

But the legislative process starts much earlier, when the Commission first puts an initiative in its Annual Work Programme (Commission Legislative Work Programme) and publishes a Roadmap. On this basis the Commission then carries out an impact assessment and public consultation, which play a particularly significant role for all stakeholders concerned by the proposed legislation. Given its complexity and its common structure for both legislative and rulemaking procedures, this important pre-legislative phase is covered in a separate section below, entitled *Ex ante analysis of EU policymaking: impact assessment*.

1.3.1.2 First reading

The Commission proposal goes first to the European Parliament, which is empowered to act by a majority vote of physically present members.²⁷ The Parliament may approve the measure, reject it, or amend it. The (possibly amended) proposal then moves to the Council, which acts by a qualified majority vote of its members²⁸ (unless the Commission disagrees with any amendments that may have been made by the Parliament, in which case unanimity applies). If the Council agrees with the EP’s position, the bill is adopted. Should the Council disagree with the EP position, it is called upon to state its own position and communicate it to the EP.

1.3.1.3 Second reading

The amended proposal is then subject to another vote of the EP. The EP may approve it by an affirmative vote of the majority of members physically present and voting. Or the EP may reject the measure, but only by achieving an absolute majority of all its members, whether or not they are present.²⁹ Thus, approval of a Commission proposal has an easier path in the EU Parliament than rejection. Once again, the EP may propose further amendments to the Council’s position, if such amendments are approved by a majority of the EP’s component

²⁴ Article 294 TFEU.

²⁵ The Council (Article 241), the EP (Article 225) or a European Citizens’ Initiative (Article 11 (4) TEU and Article 24 TFEU) can formally invite the Commission to adopt a proposal. Some exceptions to the exclusive right of initiative exist across the Treaty, such as that foreseen in Article 76 TFEU referring to legislative measures in the field of police and judicial cooperation. But for TTIP purposes, the “ordinary” legislative procedure is the one that matters most.

²⁶ Article 293(1) TFEU.

²⁷ Article 294(3) TFEU.

²⁸ What constitutes a qualified majority vote of Member States in the Council is defined according to a system of *weighted votes*. Member States possess a number of votes that correlate with the size of their population. The voting ratio between the biggest and smallest states is currently ten to one. A qualified majority is 255/345, but these affirmative votes must be cast by a majority of the Member States representing a majority of the Union population. From November 1, 2014, a new system of voting will apply in the Council: a qualified majority will be defined as at least 55% of the members of the Council, comprising at least 15 of the 28 Members and representing Member States comprising at least 65% of the population of the Union. See Article 16(4) and 238(2) of the TFEU.

²⁹ Article 294(7) (b) TFEU.

members.³⁰ The amended version is once again transmitted to the Council and the Commission (which is expected to deliver an opinion on the amendments). Once again, the Council may adopt the legislative act forthwith by approving the latest EP version of the legislative proposal in its entirety.³¹ If, however, the Council rejects or amends the bill on the second reading, the bill enters into the conciliation stage.

1.3.1.4 Conciliation stage

If the EP and the Council are not able to reach an agreement within two readings, the two competing versions of the bill are referred to a joint committee, called the Conciliation Committee, which is composed of members representing the Council and an equal number of members representing the EP (so as to reflect its political composition). The mandate of the Conciliation Committee is to find an agreement on a joint text “on the basis of the positions of the EP and Council at second reading.”³² If the Conciliation Committee cannot reach agreement on a common text, the bill fails. If it succeeds in reaching agreement on a joint text, the duly amended bill returns to the EP and the Council for a third reading.

1.3.1.5 Third reading

Once the joint text is received back from the Conciliation Committee, neither the EP nor the Council have the power to further amend it. They must vote on the bill in an up-down vote that will pass the EP by a majority of the votes cast, whereas the Council must adopt the text by a qualified majority. Should one of the Chambers fail to approve the joint text as received from the Conciliation Committee, the legislative proposal is rejected.

1.3.1.6 Signature and publication

If both Chambers approve the Commission proposal as amended, the adopted bill must be signed by both the President of the EP and the President of the Council and published in the Official Journal of the EU in order to acquire force of law.³³ Unlike the US system, where the President is empowered to either sign or veto legislative enactments arriving on his desk, the signature of enacted bills by the Presidents of the EP and Council, respectively, is a ceremonial and non-discretionary step. However, publication of any legislative act must be accompanied – under the ‘duty to state reasons’ – by a statement of the reasoning on which the Act is based.³⁴ Although this obligation represents ground for judicial challenge, it is not often raised in court.

1.3.2 Other legislative procedures

Apart from the ‘ordinary’ legislative procedure described above, the Treaties also recognise two special legislative procedures.

In the first variant, the EP acts as the lead institution with the participation of the Council in the form of consent.³⁵ This variant applies, for instance, to the setting up of temporary

³⁰ Article 294(7) (c) TFEU.

³¹ The Council will act by a qualified majority unless the Commission disagrees with any of the amendment suggested by the Council or the EP (see Article 294(9)). In the latter case, the adoption of the act will require unanimity in the Council (see Article 293(1)).

³² Article 294(10) TFEU.

³³ Article 297 TFEU.

³⁴ Article 296 TFEU.

³⁵ See, e.g., Article 223(2), 226 and 228 as well as 314 TFEU.

Committees of Inquiry to investigate alleged contraventions or maladministration in the implementation of Union law.

In the second variant, the Council acts as lead institution, with the EP either participating through its consent or in the form of consultation.³⁶ This variation applies, for instance, to the adoption of measures concerning social security. In both instances, the EP's role is limited to providing a mere opinion on the text.

1.3.3 Constitutional practice: informal trilogues

Given the lack of detail governing the ordinary procedure in the text of the Treaty, informal practices have not only developed but also found some expressed recognition by the EU institutions.³⁷ One such practice involves tripartite meetings generally called 'trilogues'. This informal institutional arrangement enables the Commission, EP and Council to create informal bridges during the formal legislative procedure that may help facilitate "agreements at first and second reading stages, as well as ... the preparation of the work of the Conciliation Committee."³⁸

Trilogues may be held at any stage of the legislative procedure. The current practice generally involves the Council President (i.e. the Permanent Representative of the Member State holding the rotating presidency of the Council), the Director General of the relevant DG of the Commission, and the chairs of the relevant committees and / or rapporteurs of the EP and – in case of conciliation - the co-chairs of the Conciliation Committee. To facilitate informal agreements between the different institutional actors, all informal agreements reached in a trilogue – regardless of the stage of the process in which such agreements are reached - are forwarded to EP or Council, respectively. This practice has proved particularly successful over the years. Partly as a result of informal facilitating arrangements such as trilogues, the EU has been quite successful in enacting needed legislation: 72% of legislative acts are adopted at first reading, 23% at second reading and only 5% require conciliation and a third reading.³⁹

1.3.4 Transparency of the EU legislative procedures

Although all EU institutions are subject to the principle of openness, public access to the deliberations of the EU institutions varies greatly in the EU. Currently enshrined in Article 1 TEU ("decisions are taken as openly as possible to the citizen") and Article 15 TFEU ([the] "EU's institutions shall conduct their work as openly as possible"), the openness principle expresses the precepts of good governance and, as such, is instrumental to the enjoyment of the newly Treaty-sanctioned right to participate in the democratic life of the Union.⁴⁰

Under the Treaty on the Functioning of the European Union (TFEU) Article 11 (3), the Commission is required to carry out broad consultations with parties concerned in order to ensure that the Union's actions are coherent and transparent. While it will be seen (below) that most of the Commission's legislative work prior to the transmittal of legislation to the Parliament involves exchanges with the public and is easily accessible,⁴¹ the Commission's

³⁶ See, e.g., Article 21(3) TFEU.

³⁷ See Joint Declaration on Practical Arrangements for the Codecision Procedure (2007) OJ C145/5.

³⁸ Ibid., para. 7.

³⁹ http://www.europarl.europa.eu/code/information/guide_en.pdf.

⁴⁰ See Article 10 TEU.

⁴¹ The Commission has recently decided to create a register listing in the first instance certain categories of documents, primarily legislative documents with COM, C and SEC numbers and other categories

rules of procedures provide that meetings of its College of Commissioners “shall not be public and discussions shall be confidential”.⁴² The rationale for this is to ensure the collegiality of an organ whose members should act independently from the Member State of origin.

In the EP, all debates of the Parliament and its committees are public, with two exceptions. Parliamentary committees holding meetings may decide “to divide the agenda for that meeting into items open to the public and items closed to the public”.⁴³ Secondly, the TFEU provides that “the consideration by the Committee on Legal Affairs of requests relating to procedures on immunity shall always take place in camera.”⁴⁴

The Council, after years of a policy of limited openness, is now required to meet in public when considering and voting on a draft legislative act.⁴⁵ As a result, the Council's Rules of Procedure sharply differentiate between legislative and non-legislative activities.⁴⁶ While the meetings discussing non-legislative proposals are – unlike those relating to legislative acts – in principle not public, the Council's rules of procedure provide that, should these proposals be “important and concern the adoption of rules legally binding in or for the Member States, the Council's first deliberation on important new proposals shall be open to the public”.⁴⁷ It is up to the national government holding the Council's rotating presidency to decide which proposals count as “important”, but the Council may overrule this. Moreover, besides the publicity of these specific decision-making issues, there are several other categories of debates by the Council that may be held in public when they focus “on important issues affecting the interests of the European Union and its citizens”.⁴⁸ In general, the Council's debates are made public through audiovisual means through the broadcasting of the major meetings.

Overview of the EU Regulatory Process

1.4 Non-legislative procedures (or rulemaking)

Recognising that legislation is not always sufficient, the EU treaties also provide for the delegation of regulatory power to the EU Commission. This delegation may confer ‘legislative power’ – i.e., the power to supplement or amend primary legislation in its non-essential parts – or ‘executive power’ – i.e., the power simply to implement primary legislation where uniform conditions of implementation are required. While the exercise of the former power takes the form of ‘delegated acts’, the exercise of the latter occurs via the adoption of “implementing acts”.

Given the frequent need to flesh out EU legislative acts with further details, a sizeable share of legislative acts includes a delegation of authority to the EU Commission to enact either delegated acts or implementing acts. Often, the same legislative act foresees the adoption of

such as the agendas and minutes of Commission meetings. This register contains references to documents produced since 1 January 2001 only. Coverage will gradually be extended to other categories of documents. See, e.g., A. Alemanno, “Unpacking the Principle of Openness under EU Law: Transparency, Participation and Democracy”, *European Law Review* 1, 2014.

⁴² Article 9 of the Commission Rules of Procedure, 2010 OJ L55/60.

⁴³ Rule 103(3) of the EP Rules of Procedure, 2011 OJ L116/1.

⁴⁴ Rules 103(4) of the EP Rules of Procedure, 2011 OJ L116/1.

⁴⁵ Article 15(2) TFEU.

⁴⁶ Article 8 of the Council Rules of Procedure.

⁴⁷ *Id.*

⁴⁸ Article 8(2) of the Council Rules of Procedure.

both delegated acts and implementing acts. In other words, delegation of authority is the rule, not the exception, in the EU as in the US. In the EU, however, such delegations to agencies may include power to amend the legislative acts themselves, whereas power to amend statutes can never be bestowed on the US President or any US agency.

The EU rulemaking process used to be referred to as “comitology,” since the exercise of the delegation authority entrusted to the EU Commission required the consultation of committees made of representatives of the Member States (in 2012 there were 270 committees of national representatives). After the entry into force of the Lisbon Treaty (on December 1, 2009), however, it is no longer correct to describe the EU rulemaking process, in general, as one involving comitology. This is true for two reasons. First, the EU rulemaking process has been reformed and, following the creation of two categories of output (delegated acts and implementing acts), it is now more accurate to speak of two distinct types of “non-legislative procedures” as opposed to a single “rulemaking process” involving comitology. Second, the adoption of the first category of output, delegated acts, by the EU Commission no longer legally requires the formal consultation of committees composed of Member State representatives. Because only implementing acts continue to require the consultation of such committees, the term ‘comitology’ now refers only to this subset of non-legislative enactments.

While both forms of delegated authority – delegated acts and implementing acts -- foresee the EU Commission as the recipient of authority, the two regimes differ significantly in the control mechanisms placed on the exercise of this authority and exercised by the EU co-legislators: the EP and the Council. The process for developing and promulgating delegated acts and implementing acts, respectively, is described more fully below.

1.4.1 *Delegated acts*

A legislative act, such as a regulation or a directive, may delegate to the Commission the power to adopt non-legislative “acts of general application to supplement or amend non-essential elements of the legislative act”.⁴⁹ This is, in essence, the power to supplement or amend primary legislation in its “non-essential elements”, i.e. provisions that are not intended to give concrete shape to the fundamental guidelines of Union policy,⁵⁰ for example, the choice of a mandatory labelling scheme (e.g. warning label design, green label, country-of-origin labelling in food products, etc.). The decision about whether an amendment is “non-essential” or “essential” – i.e., whether the Commission is empowered to amend primary legislation – is made in the first instance by the co-legislator when framing the empowerment, then by the EU Commission when using the empowerment and it may be reviewed by the EU Court of Justice upon the request of the Council, the Parliament or private parties.⁵¹

The objectives, content, scope and duration of the delegation are defined in the legislative act. In addition, the conditions on the use of the power of objection and revocation are included through standard clauses elaborated by the Common Understanding⁵² in order to allow the delegation of the legislative power to be subject to the political control of the two co-legislators.

⁴⁹ Article 290 TFEU.

⁵⁰ This category of acts largely corresponds to those that used to be subject to the Regulatory Procedure with Scrutiny (RPS).

⁵¹ See Judgment of 18 March 2014 related to the delineation of delegated and implementing acts, in Case C-427 / 12, European Commission v European Parliament, Council of the European Union, ECY, not yet published.

⁵² Common Understanding on Delegated Acts, Council 8753 / 11.

After the Treaty of Lisbon,⁵³ the EU Commission now prepares and adopts a draft delegated act without being obliged – as in the past – to consult committees made of national representatives. It remains however subject to Article 11 TFEU (requiring broad consultations with parties concerned) and it is committed to listen to experts' input from the European Parliament. In line with its political commitment the Commission gathers expertise, notably through consultation of experts from the Member States, and in many cases, stakeholders – before adopting delegated acts.

The adopted act is then presented to the EP and the Council for review for an examination period of two months, which may be extended upon request for an additional two months. In this review, the EP must act by a majority of its members. The Council, by contrast, acts by qualified majority. Both the EP and the Council must indicate on what grounds they oppose the act (e.g. *ultra vires*, breach of a procedural requirement, etc.). Should the co-legislators give their affirmative approval to a delegated act, the act will enter into force earlier than at the expiration of the examination period. Without affirmative approval by the EP and/or Council, the delegated act may enter into force only if the EP or the Council has expressed no objection within the period indicated above. Moreover, the EP and Council may also decide at any time to revoke the delegation all together. However, any revocation of a delegation is prospective only. It does not affect any previously adopted delegated act or any act that is under the examination of the EP and Council.

The power to issue delegated acts allows the Commission – unlike what US agencies may do – to alter legislation so long as what is amended is “non-essential”. While this notion has not yet been defined by the EU Courts, most observers suggest that the EU Commission may modify only those provisions that are not intended to give concrete shape to the fundamental guidelines of Union policy.⁵⁴

1.4.2 Implementing acts

The second category of non-legislative acts that can be delegated to the EU Commission consists of implementing measures. Unlike the adoption of delegated acts, their adoption requires the Commission to chair and consult committees made of Member States' representatives.⁵⁵ Thus, with reference to the adoption of these acts, the term “comitology” is still in use. The committee's members are a mix of national diplomats and officials coming from the relevant ministries who follow one or more policy areas. They ensure that the interest of their Member States is represented during the discussion leading to the adoption of an implementing act.⁵⁶

⁵³ The Lisbon Treaty amending the EU Treaties entered into force on 1st December 2009.

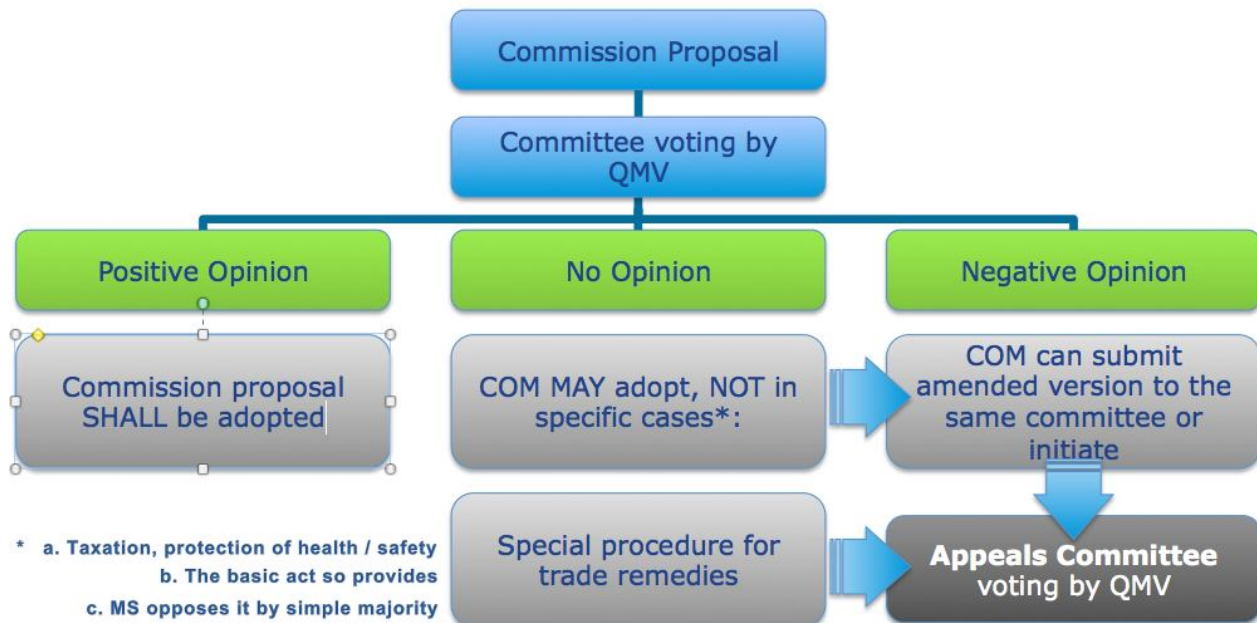
⁵⁴ In the “Schengen Border” case (C355/10) the Court clarified that provisions that require “political choices falling within the responsibilities of the EU legislature cannot be delegated, in particular where conflicting interests at issue must be weighed up on the basis of a number of assessments”.

⁵⁵ The adoption of these measures is governed by Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers.

⁵⁶ While the default procedure for implementing rules is the so-called examination procedure, there is another one – which applies only to non-controversial measures such as grant and funding proposals – known as the advisory procedure (Art. 4). This rarely used procedure provides for Committee review by simple majority vote (rather than QMV) and results in an opinion that the Commission is required to “take utmost account of”, but is not strictly obliged to follow.

The examination procedure applies to most significant or controversial implementing measures and is organised as illustrated in Figure 2 below.

Figure 2. The examination procedure

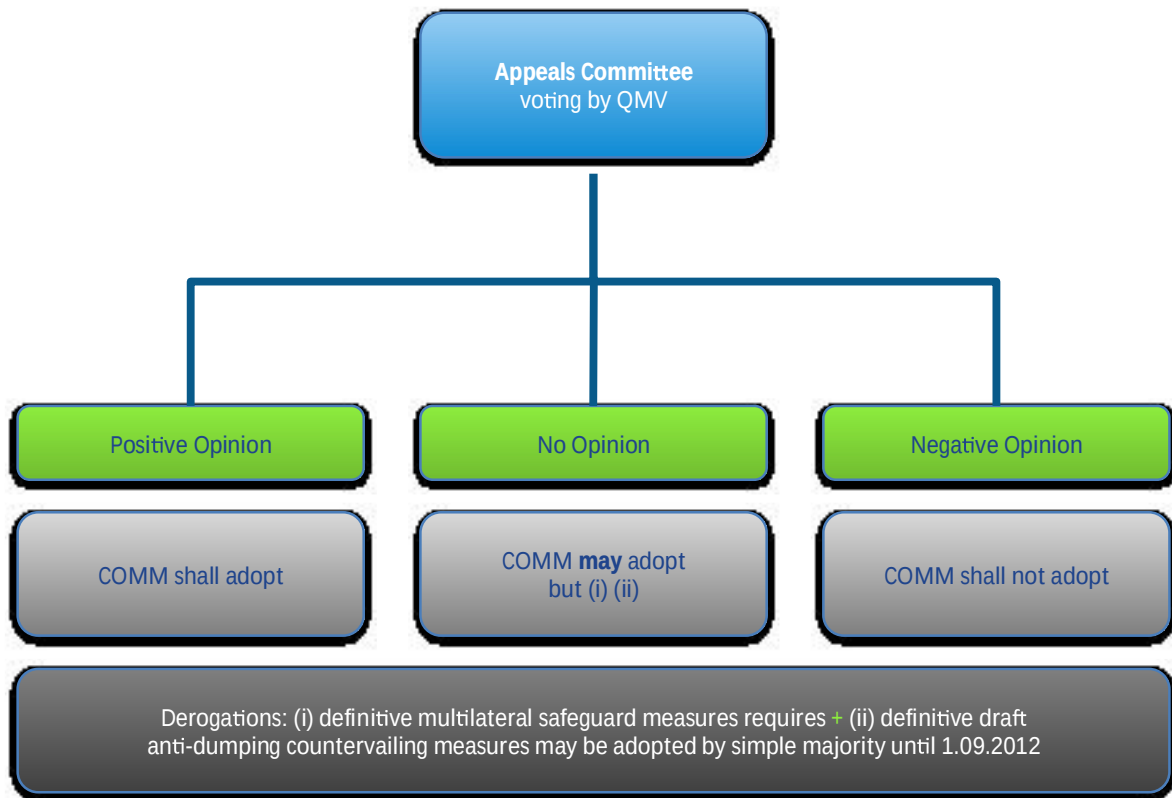


Under the examination procedure, the Committee must deliver its opinion by a qualified majority vote (QMV) – the same foreseen for the adoption of legislative proposals – within the relevant committee in order to take effect. Generally speaking, if the committee is unable to find a QMV (for or against), it issues a “no opinion” and the Commission is free to adopt or withdraw the implementing act in question. However, in the areas of taxation, financial services, health and safety, or (trade) safeguard measures, the Commission *cannot* adopt a proposed implementing act in the face of a “no-opinion” vote on that act in the Examination Committee. In any event, the Commission cannot adopt the implementing act if a simple majority within the committee opposes it.

As illustrated below, if the committee votes against the implementing act then the Commission may forward the decision to the Appeal Committee, which is another committee – also made of Member States’ representatives but at a higher level – chaired by the Commission. The Appeal Committee may change the text of the implementing act, adopt it or reject it.

Figure 3 depicts the role played by the Appeal Committee within the examination procedure.

Figure 3. The Appeal Committee in the examination procedure



Contrary to what is the case under the delegated acts there is no direct role for the EP and the Council to control the exercise of the delegation of executive powers, but, both the EP and the Council are entitled to inform the Commission if they conclude that the draft act exceeds the implementing powers provided for in the legislative act. The EP and the Council are fully informed about the Committees' activities. The Commission is not obliged to amend its proposed act accordingly. It is merely subject to a duty to review its text by "taking account the positions expressed", though the EP and Council could bring a challenge before the EU Courts to have it repealed on grounds of lack of competence.

In sum: the EP and Council have no say with regard to the wisdom or policy soundness of implementing acts. They can weigh in only if they believe the Commission has exceeded its competence.

1.4.3 Transparency of the EU regulatory process

Historically, the operation of hundreds of committees operating within the European Commission's walls has always been difficult to detect from the outside world. Being aware of this, the Commission has undertaken some reforms aimed at enhancing the overall level of transparency surrounding the adoption of non-legislative acts through the establishment of an improved search engine. This enables the public to retrieve policy documents subject to the EU rulemaking process and their committees.

For *implementing acts*, there is a "Comitology Register" that has been operational for several years. It contains a list of all comitology committees (including the appeal committee); agendas of committee meetings; summary records of the meetings and the lists of authorities representing the Member States; draft implementing acts submitted to committees; the results of voting; the final draft implementing acts following delivery of the opinion of the

committees; information concerning the adoption of the final draft implementing acts by the Commission and statistical data on the work of the committees.

For *delegated acts*, the Commission has established a Register of Expert Groups and Other Similar Entities to offer the public an overview of the consultative entities that aid the Commission in the preparation of delegated acts (among other things). For each group, the register provides standard information such as the Commission department running the group, as well as the group's mission, tasks and membership.

Transparency, Public Participation and Impact Assessment of Legislative and Regulatory Proposals

In the European Union, opportunities for public consultation are usually provided for all legislative measures and significant non-legislative measures. These opportunities are concentrated in the pre-proposal phase in which the Commission undertakes impact assessment of (most) legislative proposals.

Major legislation that goes from EU Commission to Parliament and Council is the product of an elaborate administrative process that generally will include “early” warnings in the form of public Commission Roadmaps; extensive stakeholder consultations; fully-fledged Impact Assessment (IA); Impact Assessment Board (IAB) review; Inter-Service Consultation (ISC), and final adoption by the EU College of Commissioners.

Delegated acts and implementing measures are subject to IA when they are expected to have significant economic, social or environmental impacts. However, as their number remains limited today, only a few IAs have been carried out thus far.

1.5 Ex ante analysis of EU policymaking: Impact Assessment

In Europe, regulatory review was not formally established until after 2000 but has since grown extensively. Unlike the US, where IA is only carried out for certain rules of economic significance that flesh out and implement statutes, the EU carries out IA on virtually all its legislative proposals, delegated acts and implementing acts that can be expected to have significant economic, social or environmental effects.

As will be illustrated, virtually all TTIP-relevant legislative measures, due to their trade impact, are likely to be considered ‘significant proposals’ and as such are subject to IA.

1.5.1 Introduction to the EU Impact Assessment System

The European Union launched its formal impact assessment (IA) system in 2002 as a regulatory review system within the European Commission to be applied to the preparation of its legislative proposals. To simplify greatly, IA requires the Commission services to identify – through “a set of logical steps”⁵⁷ – the advantages and disadvantages of possible policy options, including no action, by assessing their potential impacts. However, legislative action is not conditioned upon a favourable cost-benefit analysis, i.e. a report showing that the quantitative benefits of the regulation or directive outweigh its costs. The Commission IA is an aid – not a substitute – for political decision-making.⁵⁸

⁵⁷ Ibid.

⁵⁸ Unlike the situation in the US, it is not a mechanism for controlling delegation of powers – this is rather ensured by other mechanisms such as Regulation No 182 / 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission’s exercise of implementing powers and the Common Understanding on Delegated Acts.

Impact Assessments are carried out for the preparation of Commission's "most important initiatives" and those that have "the most far-reaching impacts"⁵⁹ regardless of whether they are of legislative or non-legislative nature. Their objective is to guarantee that "all policy-decisions... [are] based on sound analysis supported by the best data available."⁶⁰ Apart from quality control, the main purpose of the IA is to ensure policy coherence across different areas and gather the relevant expertise spread among different Commission departments. IA is performed according to Impact Assessment Guidelines that were revised several times and comprehensively updated in 2009.⁶¹ The results of the Commission's assessment are summarised and presented in the IA report.

Unlike the US system that requires IA of all "significant" rules, IA is not legally required, but merely foreseen as a commitment undertaken by the EU Commission in its IA Guidelines.⁶²

These guidelines, which are currently under review (a new set is set to be published by the end of 2014), represent the only textual authority, currently, underlying the Commission's reliance on impact assessment.⁶³ However, it should be noted that a growing number of legislative measures contain a delegation of authority that requires the preparation of an IA for either delegated acts or implementing acts.

Although the EU IA system developed "after examining established procedures in Member States and other OECD countries",⁶⁴ the EU assessment practice exhibits its own unique features in terms of scope of application, methodology, rationale and procedures.

1.5.2 Scope of Application

While most countries apply IAs exclusively to acts of either a legislative nature (e.g. France) or those of non-legislative nature (e.g., the US), the Commission's IA system boasts a broader coverage, including both legislative and non-legislative regulatory proposals, while extending to other initiatives such as communications, expenditure programmes and negotiating guidelines for international agreements.

The general principle is that each year the EU Commission Secretariat General, the Impact Assessment Board (IAB), and the departments concerned determine those Commission initiatives that need to be accompanied by an IA because they meet the Guidelines' criteria as being among the Commission's "most important initiatives" and those which have "the most

⁵⁹ IA Guidelines 2009, p. 6. Apart from suggesting these indicative criteria, these guidelines do not define which Commission initiatives need to be accompanied by an IA. This is determined each year the EU Commission Secretariat General, the Impact Assessment Board and the departments concerned and included in the Commission's Legislative Working Programme (CLWP).

⁶⁰ Ibid., p. 6.

⁶¹ European Commission, Impact Assessment Guidelines, SEC(2009) 92. The Commission issued Impact Assessment Guidelines in 2003, revised them in 2005, and updated them in 2006, before they were replaced by new ones in 2009.

⁶² As will be illustrated below, in the EU rulemaking process, significant delegated and implementing measures require the preparation of an IA.

⁶³ European Commission, Impact Assessment Guidelines, SEC(2009) 92. The new guidelines contain an important Part III: Annexes to Impact Assessment Guidelines, which –like the US Office of Management and Budget's Circular A-4 on Regulatory Analysis – provide more detailed guidance on how Commission services should prepare their Impact Assessments.

⁶⁴ Commission report on Impact Assessment: "Next steps - In support of competitiveness and sustainable development", SEC(2004) 1377.

far-reaching impacts”.⁶⁵ (Apart from offering these indicative criteria, the guidelines do not define which Commission initiatives need to be accompanied by an IA.)

As “it is not possible or necessary to write an IA report in all cases”, today a formal IA is only required for items on the Commission’s Legislative Work Programme (CLWP).⁶⁶ However, the Commission may, on a case-by-case basis, decide to carry out an impact assessment of a proposal that does not appear on the CLWP.⁶⁷ While this occurrence is not frequent, it may actually be decided that due to the salience of a particular policy initiative, it will be subject to an IA even though it did not previously appear on the CLWP.

Under the current practice, IAs are prepared for:

- legislative proposals that have significant economic, social and environmental impacts;
- certain non-legislative measures: implementing acts and delegated acts that are likely to have significant economic, social and environmental impacts;
- other initiatives (white papers, action plans, expenditure programmes, negotiating guidelines for international agreements) that define future policies.

Each such proposal or initiative is preceded by a roadmap. This is a document that provides the first description of a planned Commission initiative and either sets out the planned impact assessment work or explains why an IA is not needed.

In addition, the roadmap must identify clearly the problems to be addressed by the initiative and a proper justification of EU action on grounds of subsidiarity. And it should indicate which DGs will be invited to the Impact Assessment Steering Group (IASG); one of the IA’s quality control mechanisms.

The CLWP and subsequent roadmap will generally be the first official communication provided to the outside world about the launch of a new Commission initiative.

Any person or organisation wishing to be informed of new roadmaps published on this website may set up an RSS feed for that purpose.

1.5.3 Methodology

Whereas the US practice in regulatory impact assessment focuses heavily on a comparison of quantified costs and benefits, the Commission’s system favours a more holistic approach integrating the features of impact assessment, sustainable impact assessment and other types of *ex ante* policy evaluations, such as cost-benefit analysis (CBA), cost-effectiveness analysis (CEA), and multi-criteria analysis (MCA).⁶⁸ In particular, the European Commission has relied, since 2002, on an ambitious Integrated Impact Assessment model as a tool for

⁶⁵ IA Guidelines 2009, p. 6.

⁶⁶ Under the Commission’s rules of procedure (Art 2), the Commission defines annual priorities and adopts a work programme for each year. This programme sets out major political priorities and identifies legislative initiatives, executive and other acts that the Commission intends to adopt for the realisation of these priorities. The President presents the Commission work programme to the Parliament and the Council. See IA 2009, p. 7-8.

⁶⁷ IA 2009, p. 6.

⁶⁸ Jonathan Wiener and Alberto Alemanno (2011), “Comparing Regulatory Oversight Bodies across the Atlantic: US OMB/OIRA and the EU IAB”, in Susan Rose-Ackerman and Peter L. Lindseth (eds), *Comparative Administrative Law*, Edward Elgar.

improving the quality and coherence of its policy development process.⁶⁹ One of the few constant features is the Commission's insistence on the application of an integrated approach covering the economic, social and environmental dimensions comprehensively.⁷⁰

1.5.4 Rationale

In EU practice, as in the US, Impact Assessment is regarded as “an aid to decision-making, not a substitute for political judgment”⁷¹ and it is developed in parallel with development of the Commission proposal while contributing to that development. This means that the IA informs the decision of the College of Commissioners, but does not replace it. However, in the EU, IA is promoted not only as a tool aimed at gathering information upon which it can rely upon in order to improve regulatory rationality, but also as a way to get input from stakeholders, disseminate information, to enhance legitimacy and acceptance of measures and, ideally, to provide a tool for overseeing and controlling regulators in the conduct of their activities.⁷²

1.5.5 Procedure

Under the Commission guidelines (which are addressed to the Commission staff in charge of preparing policy proposals), IAs are initiated and carried out by the relevant Directorates-General (DG), which rely on dedicated “IA support units” to prepare the assessments under the supervision of an Impact Assessment Steering Group (IASG).⁷³

The various procedural steps accompanying the preparation of an IA are set forth in Figure 4 below.

During this period of preparation (the average duration of which is 52 weeks), the lead DG is expected to:

- hold a public consultation
- collect evidence, and
- draft an IA

The expected outcome of this phase is the preparation of both a draft IA report and the underlying Commission proposal.

⁶⁹ IA 2002. For an overall evaluation of the Better Regulation initiative from a US perspective, see Jonathan Wiener, ‘Better regulation in Europe’ [2006] 56 *Current Legal Problems* 447-518.

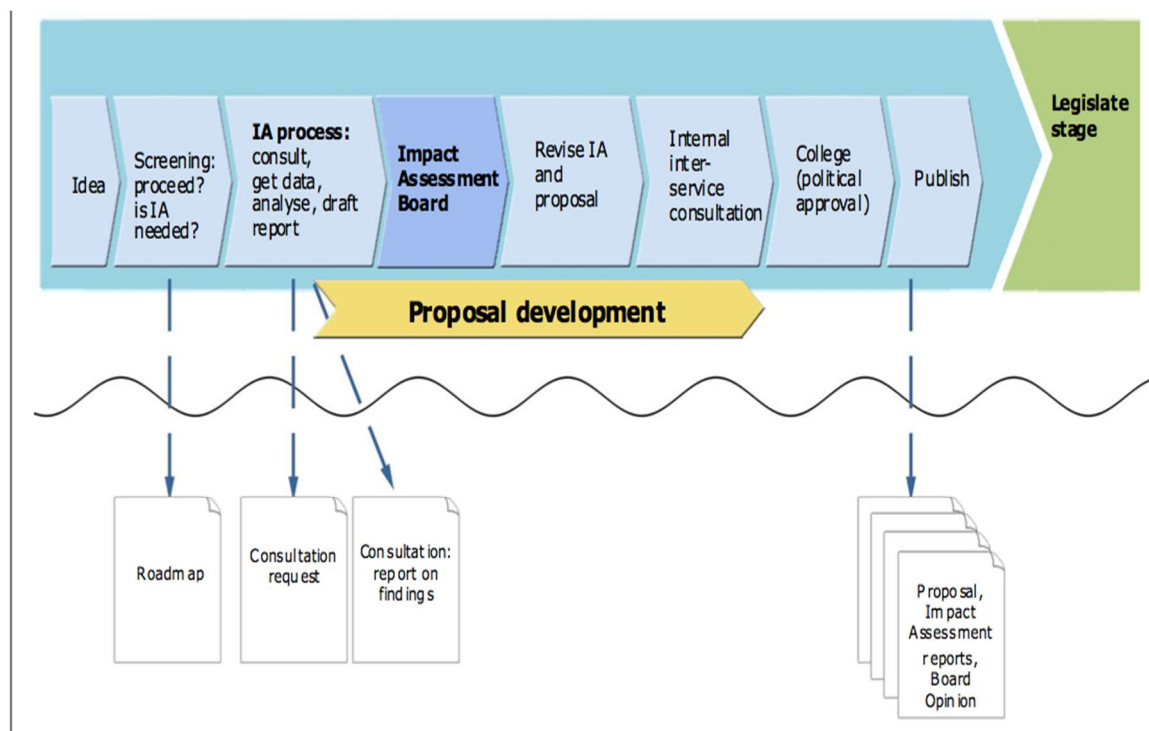
⁷⁰ This is the case since the issuance of IA 2002, p. 2.

⁷¹ Id. at 3. See also IA Guidelines 2009, p. 4.

⁷² For an analysis of the current EU IA system under the perspective of the principal-agent theory, see G. Crowe (2005), “Tools for the control of political and administrative agents: impact assessment and administrative governance in the European Union”, in H.C.H. Hoffman and A.H. Turk (eds), *EU Administrative Governance*, London: Edward Elgar Publishing.

⁷³ This group that is established ad hoc for each IA is made of representatives of those DGs whose policies are likely to be affected by or contribute to the objective of the initiative as well as the relevant policy coordination unit of the Secretariat General (SG) of the EU Commission. It excludes any input from outside of the Commission's services. Since the 2005 Guidelines, its establishment is compulsory for all proposals of a cross-cutting nature. See IA Guidelines 2009, p. 8.

Figure 4. The preparation of an IA



1.5.5.1 Public consultation

Under the Commission's Guidelines, consultation with interested parties is foreseen for every IA and must follow the Commission's guidance on minimum standards.⁷⁴ Consultation can be carried out on any or all of several distinct elements of the impact assessment: determining the nature of the regulatory problem, identifying policy objectives and policy options, and assessing costs and benefits of each option.⁷⁵ The lead DG may start the consultation process as soon as the roadmap for CLWP has been published.

Consultation is not a one-off event. It runs throughout the preparation phase of both the draft IA and the proposal. Thus, it requires the preparation of a consultation plan – by the lead DG and the IASG – that determines: the objective of the consultation, the elements for which this is necessary (nature of the problem; policy options; etc.), the target group (general public or a special category of stakeholders, etc.), the appropriate consultation tool (consultative committees, expert groups, ad hoc meetings, consultation via internet, etc.), and the appropriate time frame for consultation.

While there is no standardised model for public consultation, the Commission's Guidelines stipulate that minimum standards for consultation should be respected.⁷⁶ These standards call for clear, concise consultation documents that include all necessary information for stakeholders. The guidelines also call for consultation of all relevant target groups. They

⁷⁴Commission Communication, "General principles and minimum standards for consultation of interested parties by the Commission", COM(2002) 704 (hereinafter 'minimum standards').

⁷⁵ See IA Guidelines 2009, p. 19.

⁷⁶Ibid.

foresee that a minimum period for written public consultations of 12 weeks, and 20 working days' notice for meetings. While the Guidelines encourage the Commission to provide feedback and take into account the comments received, unlike the US system, the Guidelines do not require that comments, or Commission responses to comments, be incorporated as such in the Preamble or the text of the proposed regulation or directive, though they do need to be reflected in the IA report.

Built into each Impact Assessment is a public consultation process that identifies the problem along with various policy options for responding to the problem, and solicits public comment on those options. EU practice is not to disclose the text of the draft act itself, or the draft Impact Assessment supporting it, before the act is adopted by the College of Commissioners and sent along to the EP and Council for review. But the policy options are thoroughly aired, comments are sought relatively early so that they have a real chance to shape policy development, and all comments are made public on the Commission's website.

In practice, the lead DG publishes a report that sums up the main findings gathered via the consultation and circulates it among stakeholders before finalising its draft IA and accompanying proposal.

1.5.5.2 *Collection of expertise*

As they follow the process (reviewed above) for identifying the problem and alternative solutions, the Commission services also follow EU guidelines on the collection and use of expertise,⁷⁷ another guidance document that is non-binding but nonetheless shapes the Commission's activity.

Expert groups and scientific committees⁷⁸ existing within the Commission and EU agencies⁷⁹ offer the primary source of advice. However, IAs are often supported by external consultants who remain subject to both the IA Guidelines and the "minimum standards" for consultation. In this case, as the lead Directorate-General of the Commission remains responsible for the content and quality of the IA, the external study is generally not endorsed by the EU Commission but merely offers a basis for the Commission's work.

An IA that addresses a policy issue which confronts significant uncertainty about possibly serious negative consequences should rely first on a risk assessment, an analytical tool that aims at identifying a hazard, determining exposure to the hazard, and characterising overall public risk from that hazard. According to the 2009 Impact Assessment Guidelines, whenever the risks involved may involve "irreversible damage or fatalities on an unforeseeable scale", a separate formal risk assessment must be carried out.⁸⁰

⁷⁷ Communication from the Commission of 11 December 2002 on the collection and use of expertise by the Commission: principles and guidelines – "Improving the knowledge base for better policies", [COM\(2002\) 713 final](#).

⁷⁸ Examples include the Regulatory Committees, such as the Standing Committee on the Food Chain and Animal Health.

⁷⁹ It must be observed that decentralised "agencies" in the EU are not regulatory bodies like the US Environmental Protection Agency (EPA) or the Food and Drug Administration (FDA). Rather, they are advisory bodies who may study and recommend but not regulate. Examples include the European Food Safety Authority (EFSA), the European Medicines Agency (EMA), the European Chemical Agency (ECHA). Exceptions are the European Banking Authority (EBA) and the European Securities and Market Authority (ESMA).

⁸⁰ IA 2009, p. 24.

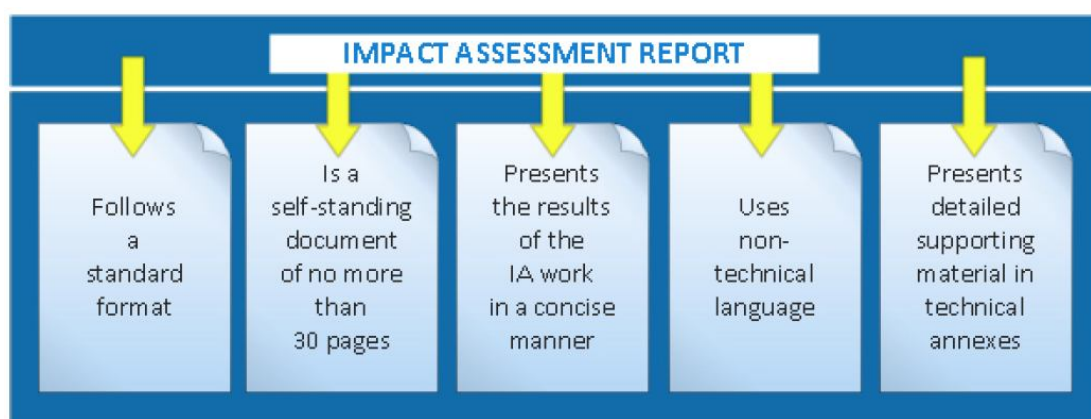
1.5.6 Draft of the IA report

It has been claimed that EU Impact Assessment is an exercise “whose complexity goes probably beyond that of any other impact assessment model implemented worldwide”.⁸¹ In any case, the EU IA model clearly involves a complex exercise, one aimed at predicting all possible consequences that may ensue from the enactment of a new legislative proposal.

Under the current guidelines, Impact Assessment is structured upon identification and clarification of the following six key elements: (1) the problem, (2) the objectives, (3) policy options, (4) likely economic, social and environmental impacts, (5) comparison of the different options in the light of their respective impacts, and (6) steps to be taken for future monitoring and evaluation.⁸² All these elements come together in the draft IA Report, which combines in-house analysis, consultants’ analysis and feedback from public consultation.

The report – which must specify which analytical method has been used to assess and compare the impacts (e.g. cost-benefit analysis, multi-criteria analysis, or another method) – is structured as depicted in Figure 5 below.

Figure 5. Structure of an IA report



1.5.7 Quality control mechanisms

The draft IA report must be transmitted to the Impact Assessment Board (IAB),⁸³ an internal quality control mechanism, at least eight weeks before the launch of the inter-service consultation (ISC) (described below) in order to have a discussion with the Board’s members,

⁸¹ A. Renda (2006), *Impact Assessment in the EU: The State of the Art and the Art of the State*, CEPS Paperbacks, Centre for European Policy Studies, Brussels, p. 55.

⁸² IA 2009, p. 4-5.

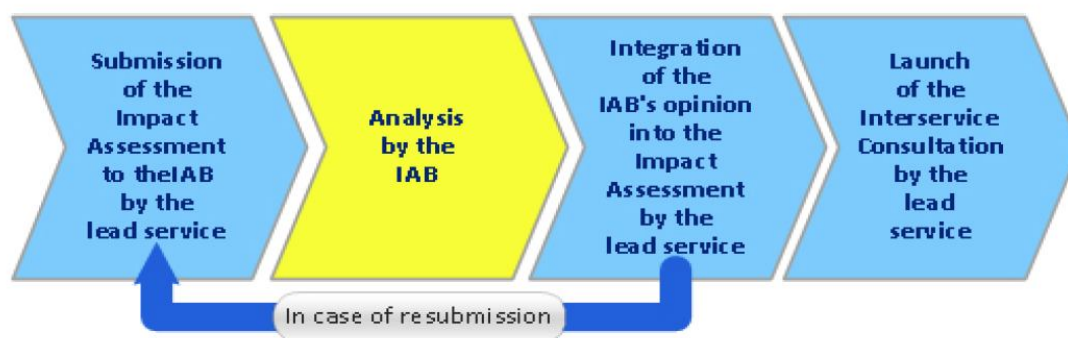
⁸³ The IAB is a nine-member board of representatives from DG Enterprise and Industry, DG Markt, DG Environment, DG Climate Action, DG Employment, Social Affairs and Inclusion, DG Economic and Financial Affairs, DG Home Affairs, DG Taxation and Customs Union, and chaired by the Deputy Secretary-General. Its members are appointed by the Secretary General subject to approval of the President on the basis of their professional expertise and act independently of the interests of their home departments. The IAB operates in a composition of five members where four members rotate and its chair presides. For an initial analysis of the IAB, see A. Alemanno, “*Quis Custodet Custodes* dans le cadre de l’initiative Mieux Légiférer? Une analyse des mécanismes de surveillance réglementaire au sein de la Commission et la création du Comité d’évaluation des études d’impact”, *Revue du droit de l’Union européenne* 1, (2008) pp. 43-86.

and take into account their opinion. The role of the IAB is to provide a central quality-control and support function for the IAs but its scope is limited to reviewing and commenting on the quality of the analysis. It does not review or take a position on the policy merits of legislative or regulatory proposals. The latter role is played instead by the Commission Secretariat General.

The opinions of the IAB are not binding, formally. However, the IAB opinion accompanies both the draft initiative and the impact assessment report throughout the Commission's political decision-making. Thus, in practice, a positive opinion from the IAB is needed before a proposal can be put forward for Commission (College) decision.⁸⁴

Figure 6 illustrates the main steps of the quality control mechanism within the EU Commission.

Figure 6. The quality control mechanisms of IA



If the responsible directorate-general of the Commission concludes from the IA that action is necessary and that the proposed response is the appropriate one,⁸⁵ a corresponding proposal will be finalised and put into inter-service consultation (ISC),⁸⁶ together with the IA report and the IAB opinion, before the entire package is finally transmitted to the College of Commissioners for adoption. The IA report is then sent, after the adoption of the proposal, to the other institutions along with that proposal and is eventually made available to the public through its publication on the Europa website.⁸⁷

This process illustrates that in the current EU system of Impact Assessment, the public is consulted in the preparation of the IA but is not allowed to see the actual draft IA until it is published together with the adopted EU Commission proposal. Moreover, in the EU, once the IA is published this document cannot be modified. That means that no opportunities exist – unlike what occurs in the US system – for the public to submit comments on the draft proposal or the draft IA for the purpose of altering either the assessment or the proposal, although the IA may be complemented at the legislative phase (see section 2.5.9).

⁸⁴ The Working Methods of the Commission 2010-2014, C(2010) 1100.

⁸⁵ An IA report should be produced even when the Commission decides not to proceed with a proposal.

⁸⁶ Similar to an inter-agency consultation, this process allows all other directorates-general to be informed and to have a say on the draft Commission proposal before its adoption by the College of Commissioners.

⁸⁷ While the public has no access to the draft IA, it is generally informed about the planned IA work by the original roadmap and may contribute through the public consultation to its preparation.

1.5.8 Timeline

In terms of duration, Figure 7, below, lists the recommended duration for each stage of the EU Impact Assessment system.

Figure 7. Typical countdown for preparing an impact assessment



1.5.9 Impact Assessment and use of the IA report by the Council and Parliament

Under the 2003 Inter-Institutional Agreement on Better Lawmaking,⁸⁸ the EU co-legislators – the European Parliament (EP) and the Council – are supposed to produce their own impact assessments of “substantive amendments” in order to guarantee a uniform implementation of IA along the whole regulatory life-cycle.⁸⁹ Figure 8 illustrates the use of the IA report by the EP and the Council:

Figure 8. IA by the EP and Council



In practice, EP Impact Assessment does not occur very often, even though the EP recently established a dedicated IA directorate aimed *inter alia* at discharging this duty.

⁸⁸ Inter-Institutional Agreement (IIA) on Better Law-making between the European Parliament, the Council and the Commission (2003) (OJEU 2003, C 321).

⁸⁹ On how to turn this commitment into practice, see the Inter-institutional Agreement on a Common Approach to Impact Assessment (November 2005). Yet the definition of what constitutes a “substantive amendment” is for each institution to determine.

See http://ec.europa.eu/governance/better_regulation/documents/ii_common_approach_to_ia_en.pdf (accessed on 10 May 2014).

1.5.10 IA of non-legislative acts

Only fairly recently the scope of the Commission's impact assessment system has gradually been extended so as to include also certain non-legislative acts.⁹⁰ Although the Commission is progressively expanding the use of Impact Assessment for non-legislative measures in its impact assessment practice, it has not yet clarified the essential parameters.

The implementation of Article 290 and Article 291 TFEU remains a matter of work in progress and – as a result – the production of non-criteria for determining when IA will be used outside the legislative domain.⁹¹

Carrying out an IA on a proposed non-legislative act inevitably implies engaging in a rather different type of analysis compared to that performed in the original IA for the underlying legislative act. This is true for at least three reasons.

First, the basic legislative act, having determined the principles and the policy choices of regulatory action, inevitably constrains the scope and nature of the analysis, regardless of whether it confers on the Commission a delegated authority to amend the act or simply implementing powers.

Second, the problem to be addressed may have evolved since passage of the basic act, and may require fresh scrutiny of policy options.

Third, non-legislative measures, regardless of whether they are implementing acts or delegated acts, typically add something to the basic act that may warrant further analysis. This is clearly the case for delegated acts insofar as they “amend or supplement non-essential elements of the legislative acts”.

Despite these clear differences, the IA Guidelines offer only limited guidance on how to perform ‘IA’ on delegated and implementing acts. This raises the question of the extent to which an IA for a non-legislative act can be subject to the same procedures, timeframes, and methods as an IA for a legislative proposal. What kind of relationship should exist between the IA performed on the basic act and the one carried out on the ensuing non-legislative act? And to what extent, and in which circumstances, does the basic act mandate and / or shape the kind of IA to be conducted? What role, if any, should the IAB play in the review of the draft IA of a non-legislative act?

Unfortunately, these questions – given the limited practice developed thus far on IA on non-legislative acts – have not yet found a clear answer.

It does appear necessary, however, that the level of analysis expected in each case is tailored to the situation and proportionate to the need. Measures that do not add much to the legislation they implement may receive less analysis than those involving important discretionary choices that were not previously assessed.⁹²

⁹⁰ Commission Legislative and Work Programme 2008, COM (2007) 640 final.

⁹¹ A. Alemanno and A. Meuwese (2013), “Impact Assessment of EU Non-Legislative Rulemaking: The Missing Link of ‘New’”, *European Law Journal*, Vol. 19, No. 1, January.

⁹² The implementation of Article 290 TFEU governing delegated acts remains a work in progress. So far, a bit more than 100 delegated acts have been adopted. The Commission adopts on average 1700 implementing acts per year. They are of very different nature, many of them single-case decisions. Only a few of these acts were subject to a formal IA. See, e.g., the Commission's IA website (http://ec.europa.eu/governance/impact/index_en.htm) which contain lists of all published impact assessments per year, along with contain references to the proposal title and clickable proposal numbers.

In some cases, in fact, the Commission engages in a more targeted consultation process through which the Commission services receive comments upon a draft implementing act and its expected impacts – rather than formally preparing an IA for that measure. In other cases, Commission services may choose to go through a fully-fledged IA with public consultation. In any event, where an IA will be conducted the minimum consultation requirements always apply, and if the DG wants to deviate from them they must explain the reasons in the roadmap.

Overview of the legislative and regulatory processes of the US

Regulatory policy in the United States is shaped by three main processes: legislation by Congress, rulemaking and enforcement of laws or rules by agencies, and judicial review by courts. This Part will consider each in turn.

Overview of the US Legislative Process

In a nutshell, a bill becomes law in the United States when it is passed in identical form by majority vote in both the House of Representatives and the Senate, and signed by the President. If the President vetoes a bill sent to him by the House and Senate, his veto may be overturned by a two-thirds majority of both the House and Senate.

Very few bills ever become laws.⁹³ As one analyst put it: “Congress ... is a procedural obstacle course that favours opponents of legislation and hinders proponents.”⁹⁴ This overview will first examine the sources and limits of Congress’s power to legislate (as that has direct implications for the TTIP talks) and then follow the passage of a hypothetical bill from conception to final enactment.

2.1 The source and limits of Congress’s legislative powers

The US Constitution clearly stipulates (with a few narrow exceptions not relevant here) that all agency power, including the regulatory power, derives from Congress. This means that no federal agency has authority to regulate *anything* unless it has been delegated power to do so in a statute passed by Congress. Courts are available to enforce this requirement at the request of regulated entities, and they regularly do so.

Article 1 of the Constitution enumerates the specific powers of Congress, while the Tenth Amendment states that any powers not expressly enumerated for the federal government are reserved to the States or to the people. Among the powers enumerated in Article I is the power to regulate inter-state and foreign commerce. This “Commerce Clause” power has been interpreted quite broadly, and it generally gives Congress the constitutional authority to legislate on most (if not all) issues of interest to TTIP negotiators. Moreover, the Supremacy Clause of the Constitution empowers Congress to pre-empt any inconsistent state law that might restrict foreign trade or investment, provided Congress is acting within the scope of the Commerce Clause or some other enumerated power.

Constitutional authority and political will are two different things, however. TTIP negotiators will recall that in the United States, state governments and/or licensing boards have traditionally wielded primary regulatory power in certain sectors such as insurance regulation; land use planning; regulation of alcohol, and the licensing of professions, including doctors and lawyers.

⁹³ Bills that are not passed die automatically at the end of each 2-year Congress. In the 112th Congress, there were 6,722 bills introduced in the House, and 3,715 in the Senate. Only 220 actually became a law, and most of these were of minor significance. See Library of Congress, Thomas, *List of Bills Introduced in the 112th Congress*, available online at <http://thomas.loc.gov/home/Browse.php?n=bills&c=112>; and Congressional Record, *A Summary of the Record of the 112th Congress* (2011- 2012) of the United States, available online at http://www.congress-summary.com/B-112th-Congress/Laws_Passed_112th_Congress_Seq.html.

⁹⁴ Davidson et al., *Congress and Its Members* (14th ed.), at 205.

As a practical matter, Congress and the Administration have been extremely reluctant to consider intrusions into these long-established reserves of traditional state power. For example, in the NAFTA and GATS Agreements there was no case in which the federal government pre-empted state law or professional codes regulating the professions, even for the clear purpose of achieving greater market access for US professionals abroad. The most the US would contemplate (and deliver) was a US commitment to national treatment and market access in certain listed sectors, supported domestically by a listing of voluntary commitments from state regulators or professional associations relevant to those sectors. Likewise, compliance with the substantive obligations of the Agreement on Technical Barriers to Trade (“TBT Agreement”) by the states is promised only on a sort of ‘best efforts’ basis.⁹⁵

2.2 The legislative process

2.2.1 Introducing the bill

The legislative process begins when a Member of Congress introduces a draft law, or “bill.” Note that the President and his Administration have no power to introduce a bill in Congress, nor can any citizen do so. Only Members of Congress can introduce a bill, though bills may be supplied to them by the Administration, lobbying groups, or other outside interests. The Member or Members who introduce the bill become its sponsor(s), and they often work hard to acquire co-sponsors, including bipartisan co-sponsors, to add to its appeal.

2.2.2 Referral to Committees and Sub-committees

The next step on the road to passage typically is referral to one or more committees which have subject-matter jurisdiction over the topic of the bill. There are 20 standing committees in the House and 17 in the Senate. Committees and sub-committees in both chambers are comprised of both Republican and Democratic Members in a ratio that is roughly proportional to each party’s representation in that chamber, and they are chaired by a Member (usually but not always the senior Member) from the party that controls a majority of seats in that chamber.

One or more of these committees will hold hearings on the bill and then (normally) “mark-up” the bill by receiving, debating, and voting on various amendments proposed by committee members. In cases where there is more than one committee with a plausible claim to the referral, the Speaker of the House and Senate Majority Leader must decide – in consultation with their Parliamentarians – which committee(s) in their respective chambers are given the referral. In the House, the Speaker commonly refers a single bill to two or more

⁹⁵ TBT Article 3 states that “With respect to their local government and non-government bodies within their territories: 3.1 Members shall take such reasonable measures as may be available to them to ensure compliance by such bodies with the provisions of Article 2 ... [and] 3.5 Members shall formulate and implement positive measures and mechanisms in support of the observance of the provisions of Article 2 by other than central government bodies.” See *Agreement on Technical Barriers to Trade*, Art. 3 (1994). Article 4 similarly states that central government standardizing bodies must comply with the Code of Good Practice for the Preparation, Adoption and Application of Standards, but it only requires them to “take such reasonable measures as may be available to them to ensure that local government and non-governmental standardizing bodies within their territories” do likewise. See *Agreement on Technical Barriers to Trade*, Art. 4 (1994). See also TBT Article 7 (conformity assessment procedures by local government bodies).

committees – a practice known as “multiple referrals.” In the Senate, however, multiple referrals require unanimous consent of the Senate and are much less common.⁹⁶

Because the orientation of each committee is often strongly shaped by the ideology, beliefs and interest group orientation of the Committee Chair and key staff, the seemingly arcane choice of which committee gets the referral can be highly strategic and may well shape the fate of the bill, or of key provisions in the bill. This matters to TTIP negotiators because bills dealing with regulatory matters that incidentally affect international trade are more likely to be referred to committees that specialise in the regulatory area in question, and less likely to be referred to the House Ways and Means Committee or Senate Finance Committee – bodies that deal with trade routinely and are more receptive to trade-related concerns.

Though committee referral is a typical and extremely important step, it is not an essential and universal prerequisite to passage. There are examples of bills that do not pass in stand-alone form, but get added on to some other bill during floor debate without a committee referral at all. Passage of a measure without a committee referral is not typical, it “raises eyebrows” and it almost invariably requires the assent of the Senate Majority Leader and/or House Speaker. But it does happen.

2.2.2.1 Committee Hearings

Once a bill has arrived at its assigned committee, it faces two possible fates: (a) it will get a hearing and, perhaps, a “mark-up” and a vote, or (b) it will just languish in committee.

The most frequent outcome, statistically, is that it will die in committee unexamined: most committees have had far too many bills referred to them to give full attention to every bill, and Committee chairmen have very broad discretion about whether to consider any given bill at all.⁹⁷

Committee and Subcommittee hearings are open to the public – and the proceedings transcribed and published – unless classified information is being presented. Witnesses are selected and called by the Chair of the Committee or Subcommittee in consultation with his or her staff, and sometimes in consultation with the Minority Party. Only a handful of witnesses are invited to testify and participation is by invitation only. Regulated entities or affected interest groups may attend the hearings but they have no right to testify at them. Their participation is completely at the discretion of the Chair and his/her staff, though they may be influenced by Party leadership and colleagues.

⁹⁶ A similar set of issues arise within individual committees, since each committee typically contains multiple sub-committees that may have competing claims of jurisdiction. Within a committee, the sub-committee referral is typically decided by the Committee Chair, which is always a member of the Majority Party.

⁹⁷ The House of Representatives has three committee “discharge” procedures – discharge petition, Calendar Wednesday Rule, and a Rules Committee-issued rule – but these procedures are seldom used and almost never succeed unless wielded by the House Speaker or Senate Majority Leader. However, circumventing a Committee block is somewhat easier in the Senate since, in the absence of a general germaneness (or relevancy) requirement, any Senator can force a vote on any measure – whether or not a Committee has considered it previously – by simply proposing it as an amendment to some other Bill on the floor of the Senate. This tactic will be thwarted if (as is sometimes the case) the target bill is protected by a “unanimous consent” agreement limiting non-germane amendments to the bill in question.

The Administration may, or may not, be invited to send a witness to the hearing. That, too, is at the discretion of the Chair and his/her staff, as is the topic of the hearing itself. There may be more than one hearing on any given bill.

Each hearing typically consists of an introductory statement by the chair, followed by the oral statements of the witnesses, followed by an exchange of questions and answers between various Committee members and witnesses. Other Committee members often take this opportunity to air their own views on the issues in the course of asking a question of the witness.

2.2.2.2 Committee mark-ups

If the Committee or Sub-committee Chair decides to move on to a mark-up of the bill, it will schedule a session that begins by the Chair circulating the “mark” (the draft bill that the chair wishes the committee to consider). During the mark-up session committee members will debate the bill overall and also propose and debate amendments to the bill.

Mark-up sessions are likewise open to public *attendance*, but there is no opportunity for public *participation*. Amendments presented to the Committee by other Committee members may take the form of proposed changes to the text of the mark, or they may be presented in “concept” form, with legislative counsel or staff asked to translate concepts into statutory language at a later time.

Amendments will be proposed, discussed, and voted on until such time as there are no more amendments offered, or the chair decides that the amendment process has run its course. At that point the sub-committee will vote on the amended bill. If it passes by majority vote of those present and voting it will be sent to the full committee, which may conduct hearings and mark-ups of its own. If the full committee then endorses the bill (perhaps with amendments) it will be sent to the House or Senate, accompanied by a Committee Report.

The Committee Report is a strategic document: one that both explains the bill (which may be very long and technical) and tries to ‘sell’ the bill on its merits. However, it is not comparable to a rigorous Impact Assessment of the bill and, in fact, is not constrained by any particular analytical requirements. As will be seen below, judicial review of legislation on its merits is so completely deferential that the Report is not needed to defend the bill on judicial review. Of course, the Congressional Research Service (CRS) *could* be asked to study and report on the trade or other impacts of a proposed measure, but that would require a specific request for such a study from one or more Members.

2.2.3 The road from committee to floor

If surviving referral to a committee is difficult, getting to a vote on the floor of House or Senate is even more difficult. Many bills are introduced, and each has sponsors vying for the attention of the House and Senate Members. A bill’s success or failure in getting to the floor will depend on a variety of political factors:

- the position, energy and persuasiveness of the Member sponsors,
- the priorities of the party leadership (complicated by the fact that different parties may control the House and Senate, as is currently the case),
- media coverage of the issues addressed in the bill; and,
- the political environment overall, including what else is happening at the time.

Most of all, the scheduling of floor debate and vote on any bill other than a ‘privileged’ bill – one involving budget, appropriations and certain other measures – will depend on discretion of the Speaker of the House and the Senate Majority Leader.

2.2.3.1 *From committee to floor in the House*

In the House, the Speaker (working through the Rules Committee) largely determines when a bill will be brought up for a floor vote, though he may consult with his or her party, other committee chairs, and the President.

Minor and relatively uncontroversial bills may be brought to a floor vote on special days dedicated to such measures in the House, through a process known as “suspension of rules”. Indeed, a recent study showed that since 2000, more than 75-80 percent of bills enacted into public law have come to the House Floor through this procedure.

Legislation presented through suspension of rules does not have to be reported from committee before being voted on by the House. It is subject to only 40 minutes of debate and no amendments are allowed, even though it is possible that the bill being voted on could have been amended after its introduction. However, use of the suspension procedure requires a two-thirds vote for passage, which is very difficult to obtain for any controversial measure in the nearly evenly divided House. Also, under Conference Rule 28, suspension bills must not be opposed by more than one-third of the committee members reporting the bill. They must be accompanied by an informal cost estimate (though impact assessment is not required). And they cannot be used to create new government programs unless they reduce or eliminate a government program of comparable size (a Republican favourite idea). Clearly, the suspension-of-rules procedure will not work for more complex regulatory bills.

Major bills may reach the floor by one of two expedited procedures known as “privilege” or “unanimous consent”, respectively. Privileged bills – which include budget, appropriations and certain other measures – may be called up for a floor vote at any time, at the discretion of the Speaker. Unanimous consent bills may likewise receive expedited consideration, but only if the Speaker is assured that the majority and minority floor leadership and the relevant committee chairs and ranking minority members of the relevant committees have no objection.

In all other circumstances, the bill must come up under a “rule” that is given by the Rules Committee. Normally, House rules require that bills be heard in the order presented, unless they meet the criteria for expedited treatment listed above, or unless they benefit from a “rule” awarded by the Rules Committee. This rule can move a bill to the front or towards the front of the queue of bills awaiting floor debate. The rule will also set time limits for debate and establish whether amendments will be allowed, how many amendments will be allowed, and what kind of amendments will be allowed.

Requests for a rule usually originate with the Committee Chair reporting the bill. The request is considered, and the rule fleshed out, in Rules Committee hearings much like the hearings on the substantive bill itself, except that only Members of Congress testify.

While the Rules Committee seems to wield enormous procedural or agenda-setting discretion, appearances can be misleading. In recent times, the Rules Committee has become an arm of the Speaker, and rules are used strategically by the Speaker and the Majority Party to promote the outcomes they favour. Restrictive rules are perennially unpopular with the Minority Party, because they often limit the ability of the minority to propose amendments and air their dissenting opinions.

2.2.3.2 *From committee to floor in the Senate*

The road from committee to floor in the Senate is even more obstacle-filled than the House. The Senate has no Rules Committee. The majority and minority parties actively consult about scheduling, but the Senate majority leader has the primary role in scheduling floor debate, aided by the fact that he himself is always the first to be recognised on the floor.

Whenever they can arrange it, sponsors of a bill (which may be bi-partisan in some cases) will work with their leadership to secure a “unanimous consent” agreement to benefit their bill. This agreement, analogous to the House “rule”, will move their bill ahead of other, less favoured bills, and may also limit debate on the bill or bar non-germane amendments. These unanimous consent agreements are often negotiated in private though they are voted on in public. Conversely, in the absence of such an agreement, any Senator may propose any amendment to the bill, relevant or otherwise, and may ‘filibuster’ the bill indefinitely, unless 60 votes can be found to limit debate – and even then debate will continue for up to 30 hours after the “cloture” vote.

For measures not so privileged it would appear, in the words of one analyst, that “The new normal today in the Senate is that [in the absence of a unanimous consent agreement] nearly everything requires sixty votes to pass.”⁹⁸

There is one exception to this rule, however. A former Senate Parliamentarian has observed that, in addition to unanimous consent agreements:

We have on the books probably a couple of hundred laws that set up specific legislative vehicles that cannot be filibustered or only amended in a very restrictive way... [including] the War Powers Act, the Budget Act of 1974, the Trade Act of 1974 (and subsequent ‘fast track’ votes on trade), arms export controls, Federal Election Commission regulations, the Alaska Natural Gas Transportation Act of 1976, the Nuclear Waste Policy Act of 1982 (including the choice of Yucca Mountain as a national waste-disposal site), the 1991 act governing military-base closings, US participation in the World Trade Organisation, and the Andean Counterdrug Initiative.⁹⁹

Thus, it is possible (and not entirely implausible) to envision Congress passing a law that would privilege future bills that are needed to achieve some important regulatory cooperation objective – though it must be said at the same time that Congress institutionally is highly reluctant (now, it seems, more than in the past) to bind its own hands in that way.

2.2.4 Floor debate and lobbying

Floor debate in the House and Senate proceeds in accordance with the guidelines for debate (regarding time limit and number and kind of amendments permitted) as set forth in any applicable rule or unanimous consent agreement. However, as is the case with committee debate, congressional floor debate is largely theatre in most cases. With rare exceptions, Speakers read previously prepared statements while the important action takes place off the floor, in lobbies and antechambers. There, lobbyists and Administration leaders meet with legislators and their staff to push their amendments or negotiate compromises that are then presented for a vote in floor debate.

When all allowable amendments have been introduced, debated and voted on and the allowable time for debate has expired, a motion may be made and seconded to hold an on-the-record (“roll-call”) vote and such a vote will be held, resulting in either passage or failure.

⁹⁸ Davidson et al, *Congress and Its Members* (14th ed.) at 237 (adding that the January 2013 bipartisan changes to filibuster rules offered only very limited improvement).

⁹⁹ Gail Russell Chaddock, “Limits on Filibusters Are Already Pervasive”, *Christian Science Monitor*, 24 May 2005, p. 2 (<http://www.csmonitor.com/2005/0524/p02s01-uspo.html>).

If the House and Senate both enact an identical bill, that bill will be “enrolled” and sent to the President for signature. If, however, they pass bills that differ in any respect then the two chambers must find a way to resolve their differences and come to agreement on a single bill.

One key difference between the House and the Senate is important for our present purposes. In the House, non-germane (i.e. topically irrelevant) amendments are subject to a “point of order” (i.e., a procedural objection). In the Senate there is no such rule and non-germane amendments can be tacked on to any bill and presented for a vote – unless there is a unanimous consent agreement prohibiting such amendments – even without the benefit of a committee hearing on the topic of the amendment. This means that certain measures (including trade-restrictive measures) may pass the Senate with very little advance notice – riding on the back of some other bill – though of course such measures cannot be enacted into law without also being approved by the House of Representatives and the President.

A classic example illustrating the risk of trade-restrictive “midnight amendments” can be found in the Continued Dumping and Subsidy Offset Act of 2000 (“Byrd Amendment”), enacted in the final days of the 106th Congress. This amendment was tacked on, with little notice and minimal debate, to the Agriculture, Rural Development, Food and Drug Administration and Related Agencies Appropriations Act of 2001 by Senator Byrd, whereupon it passed both the Senate and the House.¹⁰⁰ As the title of bill suggests, the Byrd Amendment came to President Clinton attached to an essential appropriations bill, and could not be removed without vetoing the entire bill. So President Clinton signed the bill into law, with the Byrd Amendment included, thereby funding the Food and Drug Administration and the Department of Agriculture – but also subsidising US complainants in countervailing duties and anti-dumping cases by giving them the proceeds of the duties collected from the cases they had filed.

The Byrd Amendment was, of course, a violation of WTO rules and was adjudicated as such by a WTO dispute panel (and the Appellate Body) in a case brought by European Union and ten other complaining parties. Still, the US Congress could not readily find the votes to correct the mistake.¹⁰¹ On May 1, 2005, with the permission of the WTO, Canada and the EU began imposing retaliatory sanctions in the form of a 15 percent levy on a range of US goods, with Mexico and Japan following suit a few months later. Finally, after years of delay, in the face of external sanctions and after repeated Bush Administration calls for repeal of the Amendment, Congress did repeal the Byrd Amendment in December 2005. However, the Act’s provisions remained in place until Oct. 1, 2007 and companies continued to receive WTO-illegal subsidies during that period.

Such cases are not frequent, fortunately, but the example above makes clear that the threat of “midnight” trade restrictions imposed by Congress is a real one.

2.2.5 Resolving House-Senate differences

There are two ways to resolve differences between House and Senate bills. One way is to send amendments back and forth between chambers until each chamber is satisfied with the results. This has been called the “ping-pong” method. Due to the political difficulties party leaders have encountered in convening conference committees, the ping-pong method is now the most commonly used method of resolving House-Senate differences.

¹⁰⁰ Pub. Law No. 106-387, 114 Stat. 1549, § 1754 (19 U.S.C.A § 1675c).

¹⁰¹ WTO, Report of the Appellate Body, UNITED STATES – CONTINUED DUMPING AND SUBSIDY OFFSET ACT OF 2000, AB-2002-7, 16 January 2003.

Another, more traditional approach is to convene a conference committee of House and Senate leaders and Committee/Subcommittee chairs (and others) to meet to try to work out differences. These conference committees are not formally limited in size, and recent years have seen a trend towards extremely large committees. This complicates the task but the goal remains the same: to craft a compromise bill that will win a majority vote in both House and Senate and be signed by the President so as to become a new law (or “statute”).

2.3 Judicial review of legislation

Courts in the United States are empowered to hear challenges to statutes enacted by Congress as well as regulations promulgated by agencies. But the standard of review that courts apply to statutes is very different, and much more deferential, than the judicial review accorded to rules passed by agencies.

Judicial review of legislation asks only whether the legislation is within the enumerated power of Congress and does not violate some individual Constitutional right. Courts never examine the basic rationality of a statute passed by Congress. Nor do courts question whether there has been a “clear error of judgment” as courts routinely do in reviewing agency rules. This means that there is no legal requirement (only a political benefit) for Congress to explain its laws clearly, defend them cogently, or ensure that its statutes are even rational, much less optimal. And there is no requirement whatsoever for Congress to listen to objections on the merits to its bills, or supply reasons for rejecting or ignoring such objections. Rulemaking, it will be seen, is quite different in this respect.

2.4 Observations on the legislative process

Since numerous concerns have been expressed in the TTIP context about the transparency of the legislative and administrative processes on either side of the Atlantic, and in particular the use of formal Impact Assessment as a transparent tableau for organising the analysis of regulatory measures, it may be useful to address these two issues specifically.

2.4.1 Transparency of the legislative process

All bills introduced in either house are promptly published online, and the Library of Congress maintains a website, www.Congress.gov (scheduled to replace www.Thomas.loc.gov by the end of 2014), that compiles these bills in full text form along with much additional information. In addition, both the House and the Senate require that all mark-ups must be done in public session, except on national security matters. The House Republican leadership recently adopted a further rule that requires committees and sub-committees to make their mark-up vehicle available online to the public at least 24-hours prior to mark-up meetings. Adopted amendments must be published online within 24 hours, and record votes on mark-ups must be published within 48 hours. That said, deals are often hard to work out in public session, so many deals on amendments and on votes for bills themselves are actually struck behind closed doors, and then formalised and ratified in public session. Needless to say, unlike draft rules introduced by Federal agencies, Congress’s bills are not subject to notice and comment. Neither are they notified to the WTO under the TBT or SPS Agreements.

2.4.2 Impact assessment in the US legislative process

Individual committees frequently consider – and may invite witnesses to testify about – the economic, health, safety, environmental or trade impacts of measures contained in bills they are considering. In addition, individual committees, subcommittees or even individual members of Congress may request the Congressional Research Service (CRS) to investigate

and report on such impacts. And Members of Congress or Committees may ask the Administration to comment on the likely impacts, including trade impacts, of particular measures.

However, these are all informal, discretionary options. There is no formal requirement for any trade impact assessment of bills prior to their introduction, or thereafter. The Congressional Budget Office (CBO) regularly conducts budget impact assessments of proposed legislative measures that are likely to have significant budgetary impacts if enacted into law, but even these assessments are not mandatory. In fact, we are not aware of any precedent for asking Congress to commit, in the future, to commission studies of regulatory or trade impacts of particular legislation under consideration as a prerequisite for considering or passing legislation that might affect trade.

Overview of the US Regulatory Process

Federal regulatory actions are completely governed by “authorising” statutes (laws that provide an agency with authority to act on a specified subject), and may not contradict them (or, of course, the Constitution) in any way. In fact, agency rules and orders are routinely invalidated when a court determines that a regulation or enforcement decision taken by an agency conflicts with the governing statute.

Congress is empowered to legislate quite specific requirements that leave little room for agency discretion in implementing the law. But the most common practice is for Congress to state the overall purposes and core requirements of the law at a moderate-to-high level of generality, then set forth certain criteria to guide the agency’s implementation, and perhaps sprinkle in certain specific mandates or exclusions aimed at achieving a particular policy purpose, accommodating a special interest, or reflecting a specific concern of one or more members of Congress. Congress then delegates to agencies the responsibility to flesh out the details of the statute and thereby implement it by rulemaking or “adjudication.”¹⁰²

Most regulatory agencies have broad rulemaking authority (the Equal Employment Opportunity Commission being one rare exception) and enjoy discretion under prevailing case law to decide whether rulemaking or adjudication is the best approach to implementing the statute, according to the particular issue being addressed. But Congress often *requires* rulemaking in the enabling statute, thus pre-empting that choice.

Because rulemaking is so often required by law and in any event is the preferred approach to developing law and policy at the agency level – particularly for issues of interest to TTIP negotiators -- the remainder of this section will focus on fleshing out the rulemaking process.

2.5 Legal determinants of the rulemaking process

The rulemaking process at the federal agency level is shaped by three main sources of law: (1) The Administrative Procedure Act (APA); (2) the authorising statute that the agency is implementing (which may prescribe special procedures for making particular types of decisions); and (3) the agency’s own published procedural rules (which are binding on the agency until changed by other rules). Importantly, as will be discussed below, these norms are

¹⁰² “Adjudication” in the administrative context is a generic term that encompasses any binding agency action that is not a rule, and includes the issuance of orders by the agency after an opportunity for a hearing before an administrative judge to resolve a dispute at the agency level. See Administrative Procedure Act, 5 U.S.C. § 551 (6), (7) and §§ 554, 556, and 557.

enforced by federal courts during any judicial review that may be sought by challengers to the agency rule.

In addition, agencies – and even offices within agencies – have their own cultures, traditions and governing styles shaped by their past history and current leaders, all of which may lead to considerable variation in agency custom and practice within the overall framework established by law.

As a result, the description that follows is necessarily somewhat stylised and general. Precise answers to precise questions about agency process will often depend on the agency and even office in question, its authorising statute, its culture, and its traditions.

2.5.1 The Administrative Procedure Act (APA)

Virtually all federal agency rulemaking is governed first and foremost by APA §553, which envisages a very simple three-step rulemaking process:

1. The agency publishes in the Federal Register a Notice of Proposed Rulemaking (NPRM) that contains a proposed draft of the rule, supported by a brief explanation and a request for comments;
2. The agency receives comments and modifies the draft rule as appropriate;
3. The agency issues a final rule accompanied by a preamble in which it explains the rule and responds to comments. (In APA parlance, all final rules must be supported by a “concise general statement of their basis and purpose.”)

Most rules are subject to challenge in federal court by an adversely affected party, either immediately after issuance, or at the time they are enforced, depending on the circumstances. The reviewing court has the power to review agency interpretations of law, the rationality of agency findings of fact and analysis, and the agency’s conformity with required procedures in promulgating the rules.

2.5.2 The impact of judicial review

Given the contentious and litigious regulatory environment of the United States, agency rules are quite often challenged in court -- sometimes by industry, other times by public interest advocates and, not infrequently, by both sides.

Judicial review shapes the rulemaking process chiefly because the Supreme Court has held that the legality and rationality of agency rules must be reviewed in court on the basis of the public record created by the agency *during the rulemaking process itself*.¹⁰³ In other words, the agency cannot defend its rule in court on the strength of either non-record evidence or *post hoc* rationalisations offered by agency counsel for the first time in court.

As a result, agencies often find it prudent to offer much more process (such as oral public hearings, additional comment periods, and detailed, written explanation and response to comments) than the text of the APA requires – all in order to compile a record that will enable the agency to defend its rule against (often) multi-pronged challenges to the rule in court.

¹⁰³ See, e.g. *Camp v. Pitts*, 411 U.S. 138, 142 (1973). Although this case involved an adjudication, courts have since applied this doctrine to notice-and-comment rulemaking as well, see, e.g., *Ass’n of Private Sector Colleges and Universities v. Duncan*, 681 F.3d 427, 441 (D.C. Cir. 2012).

2.5.3 *The impact of OIRA review*

Public and presidential sensitivity to the economic burden of federal regulations has produced two important additions to the APA's rulemaking process: Regulatory Impact Analysis (RIA) and pre-publication review by the Office of Information and Regulatory Affairs (OIRA), an office in the White House Office of Management and Budget (OMB).

These additional analyses and reviews were introduced out of a concern that federal agencies may be tunnel-visioned in their focus on regulatory objectives and/or bureaucratically tempted to expand their power, and that they therefore may enact unduly numerous and burdensome regulations whose economic costs exceed their social and environmental benefits. This concern has led at least five successive Administrations, from the Administration of Ronald Reagan to the present Administration, to issue executive orders requiring executive agencies¹⁰⁴ to submit to OIRA for prior review all proposals for "significant" new regulations.¹⁰⁵

Executive Order 12,866, issued by President Clinton and still in effect today,¹⁰⁶ requires that the agency, before it may publish any proposed rule that is expected to be "significant", must submit the draft proposal to OIRA for review. The submission must be accompanied by an explanation of why the rule is necessary, along with a quantitative and, if appropriate, qualitative assessment of the costs and benefits of the regulation compared to various alternatives, including the alternative of no regulation. The agency also must explain why, given the anticipated costs and benefits, the rule is economically justified. Finally, other federal statutes or executive orders require the agency to assess the likely impacts of the proposed rule on small businesses; on competition; the environment; the energy supply and on state, local, and tribal governments.¹⁰⁷ These various assessments and findings together comprise

¹⁰⁴ These (and most other executive orders) do not apply to "independent agencies," the heads of which may not be removed by President except "for cause" (in other words, malfeasance). Such agencies are generally easy to recognise because most of them are headed by multi-member boards or commissions and hence have the word "board" or "commission" in their title: for example, the Securities and Exchange Commission, the Federal Communications Commission, the Federal Reserve Board. Independent agencies are bound by the rulemaking provisions of the APA and they follow a procedure for enacting rules that is very much like the process described above. Although President Obama has recently issued an Executive Order encouraging such agencies to prepare such analyses and to consult OIRA as they deem appropriate, so far the White House has not chosen to try to subject them to mandatory OIRA supervision. See Exec. Order No. 13,579, July 11, 2011. Hence, independent agencies do not submit their significant rules to OIRA for review, and they are only required to prepare cost-benefit analyses for their rules if their statute so requires.

¹⁰⁵ Under Presidents Reagan and Bush I, all rules went to OIRA regardless of "significance." The distinction that only "significant" rules are submitted was added by President Clinton. "Significant regulations" are regulations anticipated to impose more than \$100 million in compliance costs, conflict with an action taken or planned by another agency, or raise novel and significant questions of law or policy. See Exec. Order No. 12,866 § 3(f).

¹⁰⁶ President Bush II modified Executive Order 12,866 in certain significant respects, but President Obama eliminated those modifications and issued his own order in 2011, Exec. Order No. 13,563, which reconfirmed Exec. Order No. 12,866 with a few slight modifications.

¹⁰⁷ The Regulatory Flexibility Act (RFA) requires the regulator to determine whether a rule has a "significant economic impact on a substantial number of small entities," and, if so, prepare a Regulatory Flexibility Analysis that examines the likely effect of the rule on small businesses, responds to comments from small businesses, and explains why significant alternatives (including exemptions) that might limit the impact on small business were not accepted. This analysis must be submitted for review by the Chief Council for Advocacy of the Small Business Administration (SBA). The latter, however, is not in

the “Regulatory Impact Assessment” (RIA) of each proposed and final significant rule. This RIA must be submitted for review on two separate occasions: once before the proposed rule is issued, and again (in possibly modified form) before the final rule is issued.

OIRA will review the submission and may circulate it to other agencies for their review and comment. Ultimately, OIRA staff may (1) approve the draft or final rule, (2) request modifications in either the rule or the supporting analysis, or (3) return the rule to the agency for reconsideration. Returns, in practice, are rare, but they do occur and the prospect of an embarrassing return creates a sufficient *in terrorem* effect that agency staff tend to listen closely to OIRA staff if the latter object during the review process.

Because OIRA was created for the purpose of reining in agency regulation, and because it is staffed almost exclusively with economists who are principally concerned with reducing the cost and burden of regulation, it will come as no surprise that most (though not all) OIRA interventions are aimed at easing regulations, not making them more stringent or protective.¹⁰⁸ OIRA’s reviews also, in recent years, have tended to delay the completion of rules. According to Curtis Copeland, a former analyst for the Congressional Research Service, “From 1994 through 2011, the average time it took to complete a review was 51 days, and the highest average review time in any year was 62 days. However, in 2012, the average time for OIRA to complete reviews increased to 79 days, and in the first half of 2013 the average review time was 140 days – nearly three times the average for the period from 1994 through 2011.”¹⁰⁹ Such facts have made OIRA review something of a lightning rod, politically, for those who worry that regulations needed to protect public health, safety, the environment or economic welfare are being delayed or weakened by the spectre of OIRA review.

In sum: the twin prospects of judicial review and OIRA review have combined to yield a rulemaking process (and decision record) that is considerably more lengthy and complex than one might imagine by reading the simple requirements of APA § 553.

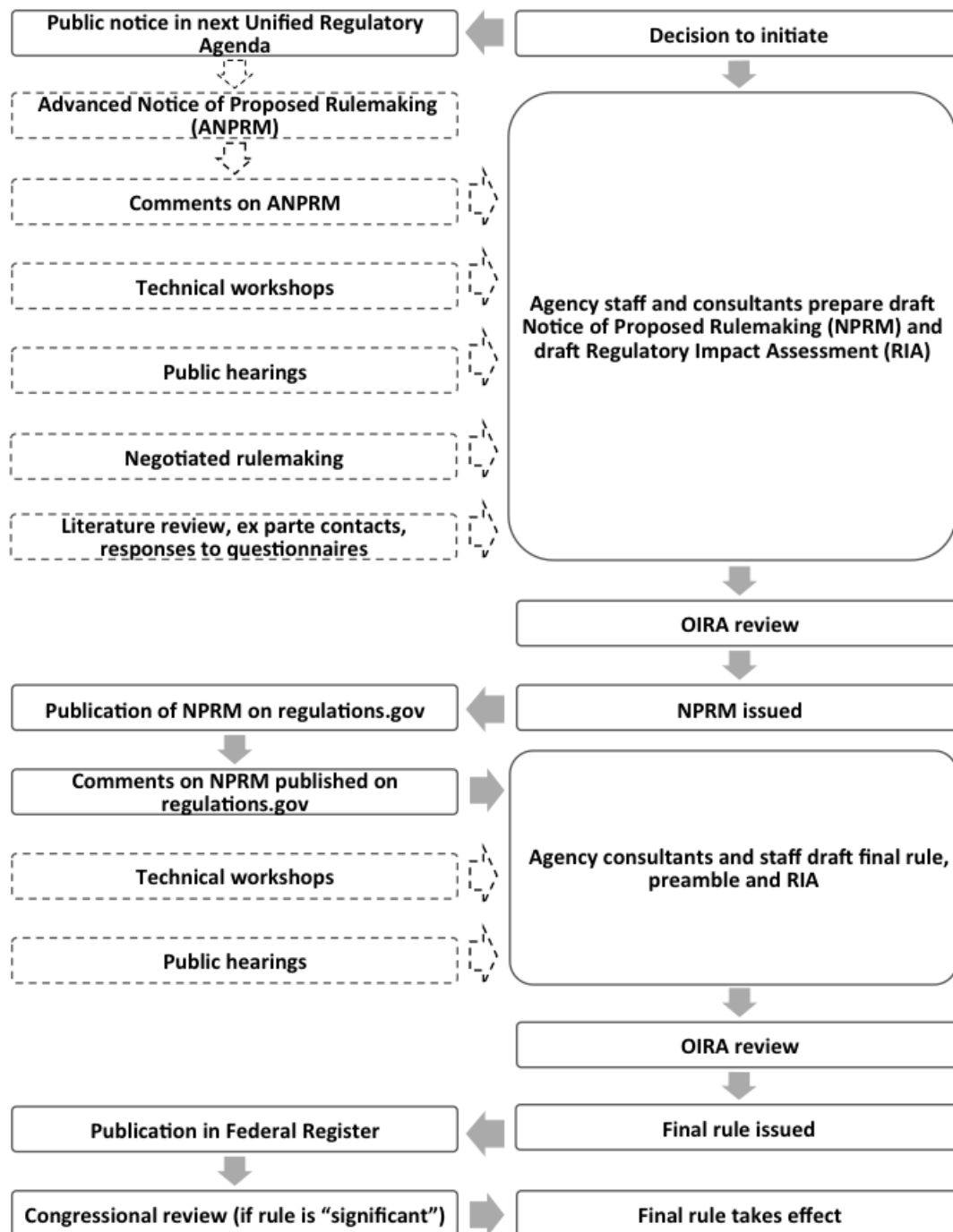
In fact, the process actually followed by agencies is illustrated in the diagram set forth in Figure 9 (see next page) and described in detail, below.

a position to prevent publication of the rule, and the RFA process followed by SBA review has not, traditionally, proved a major hurdle to effective rulemaking. See Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act, 5. U.S.C.A. §§ 601-612.

¹⁰⁸ Sensitive to the critique that OIRA review acts as a downward-ratchet on regulation, John Graham, Administrator of OIRA under President George W. Bush, initiated the practice of “prompt letters” that called agencies’ attention to overlooked opportunities for cost-effective new regulations on matters ranging from labelling of trans-fat content on packaged food to placement of defibrillators in airports. However, use of the “prompt letter” is rare (only 12 have been issued to date, and none since 2006). See <http://www.reginfo.gov/public/jsp/EO/promptLetters.jsp>.

¹⁰⁹ Curtis W. Copeland, *Length of Rule Reviews by the Office of Information and Regulatory Affairs*, Draft Report prepared for the consideration of the Administrative Conference of the United States, p. 4 (7 October 2013). In fairness to OIRA, it should be noted that there are anecdotal reports that a number of these delays may have responded to pressures from White House staff to avoid potentially controversial rulemakings, particularly during the 2012 electoral campaign.

Figure 9. The notice & comment rulemaking process (optional elements in dashed lines)



2.6 The US rulemaking process (for significant rules)

2.6.1 Phase 1: From initiation to NPRM

The process begins with an internal decision to initiate a rulemaking, a decision made by the agency head either at his or her own discretion or (quite frequently) in response to a statutory command to promulgate a regulation on a particular matter. The decision is notified to the public in the next issue of the *Unified Agenda of Federal Regulatory and Deregulatory Actions* (established by E.O. 12,866), which is published biannually in the *Federal Register* and on the

website www.reginfo.gov (though trade blogs and magazines usually leak the decision much earlier than that).

The period between the decision to initiate and the publication of the NPRM is a crucial one – perhaps the most important stage in the process. During this period agency staff (often assisted in major rules by outside consultants) review and analyse the public literature relevant to the rule. They may publish a general request for information. They also may issue questionnaires to affected industries or experts to gather information relative to the risk being addressed or possible solutions to it (although such questionnaires must be independently approved by OIRA under the Paperwork Reduction Act of 1980). They may hold technical workshops of experts and/or stakeholders – usually by invitation only. They may hold ‘town-hall-type’ public hearings to elicit public concerns.

Agency staff may, in some cases, go so far as to issue an “Advance Notice of Proposed Rulemaking” (ANPRM) in which they identify particular issues they are grappling with and request preliminary comment on those issues.

Agency staff almost certainly will consult widely (generally *ex parte* at this stage) with industry representatives, public interest groups, other agencies, other stakeholders, internal science advisory boards and outside experts to gather the information that rule-writers need to craft a sensible rule.

In some, relatively infrequent, cases, agencies may even convene a multi-stakeholder group to examine the issues and attempt to negotiate the text (or at least the essential terms) of a consensus proposed rule that the agency will then propose to the public at large in the Federal Register. This special process is called “negotiated rulemaking” and will be discussed more fully below.

The operative word in all of the above is “may.” None of the actions just enumerated are required (hence the dashed lines in the flow chart diagram in Table 1 above), unless the enabling statute requires such measures (which it seldom does). Agencies take these steps only insofar as they judge it necessary or prudent to do so, in their sole discretion, in order to (a) gather the information they need to craft a good rule and defend it in OIRA or on judicial review; and/or (b) build public support for the rule they are developing.

These measures all culminate in the drafting of the Notice of Proposed Rulemaking (“NPRM”). This notice is accompanied by any supporting studies relied on by the agency, and the agency’s draft Regulatory Impact Assessment.

2.6.1.1 Initial OIRA Review

Once the agency has drafted its proposed rule and supporting RIA it will send both of them to OIRA for review, and for circulation to any other relevant agencies. (Additionally, any initial Regulatory Flexibility Analysis focused on small-business impacts will be circulated to Chief Counsel for Advocacy of the Small Business Administration.) OIRA will moderate any inter-agency discussions and help resolve any inter-agency disputes, while conducting its own review to ensure that the rule’s supporting analysis is methodologically sound and that the substance of the rule conforms to the President’s agenda to the extent consistent with law. When OIRA is satisfied that the proposed rule and its supporting analysis are acceptable, it will conclude its review, leaving the agency free to publish the NPRM in the Federal Register and the government-wide regulatory portal, www.regulations.gov.

The alert reader will note that by the time the first mandatory notice of the “proposed rulemaking” is issued, the agency in most cases will have drafted the actual text of a proposed rule. It will have funded and helped write what is normally a very substantial and expensive

cost-benefit analysis supporting one particular approach as superior to the alternatives. And it will have bargained for its rule with OIRA and other agencies, defending the rule where it can and modifying it where it must.

Clearly, by the time the NPRM is issued, the agency has made a very substantial commitment to the draft rule it is proposing, and will be understandably reluctant to modify it very substantially afterwards.

2.6.2 Phase 2: From NPRM to Draft Final Rule

In most rulemakings, the NPRM normally offers the first official glimpse that the public at large gets of the agency's approach to the rule.¹¹⁰ The NPRM is then immediately followed by a public comment period of a length that is set by the agency in the NPRM itself. The APA does not prescribe a minimum or maximum comment period but, except in unusual circumstances requiring haste, agencies normally allow at least 60 days for comments and often longer.

Comments are posted in rough chronological order on www.regulations.gov – along with the agency's proposal and supporting analysis -- and are read by agency staff and /or consultants. As usually happens with deadlines, most comments come in shortly before the end of the comment period. As a result, commenters typically are unable, in practice, to reply to each other's comments. For this reason, some agencies readily allow extensions of comment periods, or, as the Federal Communications Commission has done, voluntarily adopt the practice of offering "Reply Comment" periods.

Once the final comment period has closed, agency staff and consultants finish their review of the comments and draft (often) detailed replies to comments, which will be published in the "Preamble" to the final rule. The goal of this exercise is to explain the agency's thinking, win support for the rule, diminish opposition, and, most of all, provide a basis for defending the rule from a later challenge in court.

As they prepare the final rule and explanation, agency staff will also consider whether any comments require a modification of the rule and/or RIA. If so, they will recommend those modifications and, if senior management approves, apply them to the rule. If the required modifications are major ones, the agency may even issue a supplemental NPRM and offer a second round of comment on the revised proposal.¹¹¹ In rare cases, the agency might withdraw

¹¹⁰ Earlier glimpses of the agency's intentions may be obtained from the Unified Agenda of Federal Regulatory and De-Regulatory Actions, a comprehensive listing of planned and pending regulatory actions published semi-annually in the Federal Register and posted on www.regulations.gov; by drawing inferences from any ANPRM issued by the agency; by examining any queries or questionnaires that such individuals or entities may receive from the agency; by meeting with agency staff; or by following industry news reports.

¹¹¹ Modifying a rule after the close of comment by inserting a novel provision risks introducing new issues and objections that were neither anticipated in the NPRM nor encompassed within the prior round of comments on the NPRM. Post-comment changes thus may prompt aggrieved stakeholders to complain, in court, that they were denied a meaningful right of comment on those changes. Courts do recognise that requiring a new round of comment every time an agency changes a rule in response to a comment would either bog agencies down in endless comment or discourage agencies from changing rules in response to comments. See *National Mining Ass'n v. Mine Safety and Health Administration*, 512 F.3d 696 (D.C. Cir. 2008). So courts have articulated the "logical outgrowth" doctrine, which holds that agencies need not re-open a comment period so long as the revised rule is a "logical outgrowth" of the NPRM, in the sense that the NPRM fairly apprised stakeholders that the issue raised by the final rule was on the table for discussion. This doctrine offers some comfort to agencies, but not a lot of comfort,

the rule in response to the comments. But it should be noted that the comment process is not a referendum. Agencies can and often do go forward with a rule that, when proposed, attracted a high volume of negative comments.

Once the rule and RIA have been appropriately amended, the draft final rule will go to senior agency management for clearance, and from there to OIRA for final review.

2.6.3 Phase 3: OIRA review

Under Executive Order 12866, OIRA has 90 calendar days to review a draft final rule. This period may be extended by another 30 days upon approval of the Administrator of OIRA and the agency head.¹¹² On the other hand, Executive Order 12866 calls on OIRA to take only 45 days to review a final rule if they have already reviewed the proposed rule and there is no material change in facts and circumstances. The Executive Order obviously cannot trump statutory deadlines, so it instructs agencies faced with such deadlines, or emergency situations, to strive “to the extent practicable [to] schedule rule-making proceedings so as to permit sufficient time for OIRA to conduct its review.” Nonetheless, for various reasons OMB has not always met these deadlines and some rules have remained bottled up in OIRA for months, even at the cost of occasionally forcing the agency to miss statutory and/or court-ordered deadlines.

During their review, OIRA staff will discuss the draft rule internally and with other agencies and stakeholders and try to resolve any staff-level differences separating OIRA, other agencies and the lead agency. If these differences cannot be resolved at the staff level, OIRA may “return” the rule or any part of it to the agency with a written explanation of the reasons for the return.¹¹³ Once all differences are resolved, OIRA will conclude its review and the agency will issue the rule.

2.6.4 Phase 4: Congressional review

The APA stipulates that, unless the agency reasonably asserts “good cause” for waiving the requirement, no substantive rule can take effect until 30 days after it is published in the Federal Register.¹¹⁴ The Congressional Review Act of 1996 takes this one step further by requiring that “major” (essentially equivalent to economically significant) rules may not take effect until they have first been submitted to Congress for review, and Congress has not, within 60 days,

since courts vary widely in their application of the “logical outgrowth” doctrine, leaving results unpredictable. Moreover, the logical outgrowth doctrine helps only with the risk of a procedural challenge. It does not address the risk of a substantive challenge (the risk that the agency will have no good answer on the record to an unforeseen substantive objection raised by a post-comment-period change in the rule). For this reason, agencies often find it necessary, as a precautionary matter, to offer a second round of comment if they make any post-comment-period changes that are significant and likely to arouse controversy. This prospect of having to hold a second round of comment may tend to further discourage agencies from altering rules significantly after the NPRM, e.g., in response to trade-related concerns. It offers another reason why it is prudent to ensure that EU-US regulatory cooperation occurs as early as possible in the process. For a detailed discussion of the logical outgrowth doctrine, see Lubbers, *supra* note 18, at 258-268.

¹¹² Exec. Order 12,866, § 6(b).

¹¹³ *Ibid.* § 6(b)(1), (2). Disputes between the agency and OIRA that cannot be resolved between them, may, in principle, be elevated to the Vice President or the President. *Ibid.*, § 7.

¹¹⁴ Administrative Procedure Act, § 553(d).

disapproved of them by joint resolution. However, only one rule has ever been rejected as a rule of Congressional review.¹¹⁵

2.6.5 Transparency in the rulemaking process

In general, the APA as applied yields a rulemaking process that is transparent and accessible. Still, the actual level of openness offered by US administrative process varies significantly depending on the stage of the rulemaking at issue.

Prior to the publication of the Notice of Proposed Rulemaking, agency staff and consultants draft the rule and prepare the supporting Regulatory Impact Assessment largely out of sight in most cases. Except in the fairly rare case where an agency elects to issue an Advance Notice of Proposed Rulemaking (ANPRM), or in the special case of negotiated rulemaking, agencies seldom if ever disclose their thinking to the public at this stage. In the words of one senior agency official, who prefers not to be quoted by name: “When it comes to communications with the public about a rule they are preparing, I tell my staff one thing: ‘Remember, you’re a sponge [of information], not a spigot.’”

While agency staff do not publicise their views, they do hear from many outside stakeholders and experts during this phase. Agencies may, and often do, hold informal hearings, public meetings and expert workshops. They circulate questionnaires to key stakeholders for the purpose of gathering information. Many private meetings, email exchanges and phone calls may occur as well. But all this is at the discretion of the agency, and is only disclosed to the public insofar as the agency chooses to do so. There is no legal barrier to *ex parte* contacts, but neither is there a reliable mechanism for learning the thoughts and predilections of agency staff, or for hearing about the contacts of the agency with other interested parties. Thus, for better or worse, the crucial pre-NPRM process remains open, accessible but largely opaque to the public and foreign governments, except in the special case of negotiated rulemaking as discussed below.¹¹⁶

¹¹⁵ See Congressional Review Act of 1996, 5 U.S.C.A. §§ 801-812. The “joint resolution” process requires that both chambers pass the identical resolution and that the President then sign that resolution. Since the President is quite unlikely to sign a resolution disapproving a rule that one of his agencies has just enacted and that OIRA has approved, congressional review very seldom results in the reversal of a rule. The one and only rule ever rejected via Congressional review was the ergonomics rule promulgated by the Occupational Health and Safety Administration (OSHA) at the end of the Clinton Administration: the next Congress rejected the rule, sending the joint resolution of disapproval to incoming-President George W. Bush, who signed it. This exceptional case underscores the general proposition that congressional review, though applied in principle to every significant rule, almost never results in a rule being overturned.

¹¹⁶ This statement of fact is not necessarily grounds for criticism. A good argument can be made that agencies need, and are entitled to, a reasonable period of privacy in their deliberative process as they develop their initial proposal. Moreover, agencies do change their rules, often in small respects and sometimes fundamentally, when they receive comments that raise serious questions about the wisdom of their proposed new policy. It is also true, however, that the extraordinary work and expenditure of funds involved in bringing a rule from conception to NPRM make it difficult, psychologically and institutionally, for the agency to contemplate fundamental changes to the rule after publication of the NPRM. The latter circumstance arguably renders it particularly important for the agency to take the time, and engage in the consultation, needed to get the proposed rule basically right *before* proposing it, so that comments can focus on correcting minor peccadilloes rather than major misconceptions in the proposal.

Once the Notice of Proposed Rulemaking is issued, however, the process opens up. The Notice itself is posted on the federal website, www.regulations.gov, as are key supporting analyses and comments that come in from the public about the proposed rule.

Although the APA itself states no prohibition on *ex parte* contacts during the post-NPRM rulemaking process, many agencies are required by their enabling statute to adopt, or have voluntarily adopted in practice, their own requirements limiting (or requiring public disclosure of) *ex parte* contacts during the post-NPRM rulemaking process. The most common practice is to make the prohibition on *ex parte* contacts effective after the close of the comment period, during which time the agency is responding to the comments and preparing its final rule. But some agencies ban or restrict *ex parte* contacts as soon as the NPRM is issued, while others (such as the Federal Communications Commission) appear to allow such contacts even after the close of the formal comment period, until virtually the eve of the final rule.¹¹⁷

The Freedom of Information Act (FOIA) offers all members of the public an additional window into communications of federal agencies with outside parties. FOIA provides that any person has a right to obtain access to federal agency records, except to the extent that such records are protected from public disclosure by one of nine exemptions.¹¹⁸ Agencies are required to disclose portions of documents that do not qualify for such exemptions, even if other portions of such documents are exempt. And President Obama, upon taking office, instructed agencies in the Executive Branch to apply a “clear presumption” in favour of openness and disclosure when responding to FOIA requests.¹¹⁹

However, FOIA does not require the memorialisation of phone calls and in-person meetings, and several of its exemptions bear directly on the process of regulation and regulatory cooperation. For example, confidential business information and trade secrets are protected from disclosure.¹²⁰ Confidential intra-agency staff discussions are likewise protected from disclosure by FOIA’s “deliberative process” exemption.¹²¹

Foreign governments who request (and receive a promise of) confidentiality in negotiations with USTR can expect to have this promise respected.¹²² This issue was recently litigated in the case of *Center for International Environmental Law v. Office of the United States Trade Representative*.¹²³ In that case, the D.C. Circuit reversed a district court decision ordering USTR

¹¹⁷ Jeffrey S. Lubbers, *A Guide to Federal Agency Rulemaking*, pp. 303-318 (5th ed.) (2012).

¹¹⁸ Freedom of Information Act, 5 U.S.C.A. § 552, et. seq. (2013). FOIA exceptions apply to documents that: (1) are properly classified as secret in the interest of national defence or foreign policy; (2) relate solely to internal personnel rules and practices; (3) are specifically exempted by other statutes; (4) involve a trade secret or privileged or confidential commercial or financial information; (5) are privileged inter-agency or intra-agency memoranda or letters (the so-called “deliberative process” exemption); (6) are personnel, medical, or similar files, the release of which would constitute a clearly unwarranted invasion of personal privacy; (7) were compiled for law enforcement purposes, such that release could reasonably be expected to interfere with law enforcement proceedings, or undermine a person’s right to a fair trial; (8) are prepared by or on behalf of any agency responsible for the regulation of financial institutions; and (9) involve geological or geophysical information, including maps, concerning wells. See 5 U.S.C.A §552(b).

¹¹⁹ President Barack Obama, MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES on Freedom of Information Act, available online at <http://www.whitehouse.gov/the-press-office/freedom-information-act>, accessed 24 April 2014.

¹²⁰ Freedom of Information Act, 5 U.S.C.A. § 552(b)(4)(2013).

¹²¹ Ibid, 5 U.S.C.A. § 552(b)(5).

¹²² Ibid, 5 U.S.C.A. § 552(b)(1).

¹²³ *Ctr. for Int’l Envtl. Law v. Office of the United States Trade Representative*, 718 F.3d 899 (D.C. Cir. 2013).

to release a document containing the USTR's interpretation of the phrase "in like circumstances" as communicated to foreign trading partners in discussions that all such partners had mutually agreed to keep confidential. Even the district court in that case did not dispute that it would be improper to compel revelation of the negotiating positions of *foreign* governments in those talks.¹²⁴ But CIEL persuaded the district court that this same restraint should not protect the USTR's articulation of its own position in those talks, since it had not been shown that forcing USTR to reveal its own position would cause enough harm to US foreign policy to outweigh the benefit of full disclosure.

The D.C. Circuit rejected that argument, however, and reversed the district court holding. First, the court noted that FOIA does not call for, or allow, a "balancing" of harm to foreign policy against the virtues of disclosure. The test under FOIA is simply whether the withholding agency reasonably could conclude that discernible harm to foreign policy might follow from mandatory disclosure of a confidential communication. In this case, the Circuit court was persuaded that forced disclosure of USTR's own position in a prior negotiation might harm US foreign policy by impairing USTR's flexibility in future negotiations with other trading partners that had not been party to those confidential talks.

CIEL v USTR thus clearly establishes that conversations between DG Trade and USTR on regulatory matters will be protected from disclosure if they are covered by a prior inter-governmental confidentiality agreement. The question is whether similar conversations between US and EU regulators pursuant to TTIP would be similarly privileged. In both cases, progress sometimes requires the opportunity for government officials of different countries to engage in candid, exploratory discussions with each other that only assurances of confidentiality can provide. For these reasons, it would appear that while the issue is not entirely settled, a strong argument can be made that inter-sovereign discussions of regulatory policy within the TTIP framework of regulatory cooperation should be allowed some opportunity for a "zone of privacy" to enable confidential conversations among decision-makers where necessary (and previously agreed) – within a general framework that is marked by transparency and openness to public participation.

Finally, it should be noted that special rules – unrelated to FOIA -- apply to communications with OIRA. Throughout the OIRA regulatory review process, the "sunshine" provisions of Executive Order 12,866 require that OIRA must designate a single contact point for all oral communications initiated by persons not employed by the executive branch of the Federal Government regarding a regulation under review. OIRA must invite relevant agency staff to any meetings with non-governmental stakeholders. Also, OIRA must, within 10 working days of receipt, forward to the issuing agency all written communications between OIRA personnel and any person outside the Executive Branch on such a matter. OIRA must publish a log of all phone calls (including dates, names, and "the subject matter discussed") between the OIRA contact point and outsiders on the matter. After the final rule has been issued (or a decision has been taken not to issue a final rule), "OIRA must make available to the public all documents exchanged between OIRA and the agency during the review by OIRA ...".

Thus, unless some privilege is asserted, Executive Order 12,866 will require publication of any documents received by OIRA from the EU Commission (and passed along to the regulatory agency) during the review process, along with any memoranda sent to the agency summarising an oral communication with the foreign government. The Executive Order does not address the issue of whether communications with foreign officials would benefit from a

¹²⁴*Ctr. for Int'l Envtl. Law v. Office of the United States Trade Representative*, 237 F. Supp. 2d 17 (D.C. D. Ct. 2002).

privilege that would enable confidential conversations – so that issue, to the extent that it matters to policymakers, would need to be addressed and resolved within the TTIP discussions.

Executive Order 12,866 also requires that the agency publish its RIA on or after the date of publication of the final rule, and that the agency identify in writing – albeit after the fact -- precisely what changes in the rule were made at the suggestion of OIRA. (Agencies also customarily identify changes in the rule that were made in response to public comments.)

In sum, OIRA interactions with agency staff on the merits of a rule are unusually transparent – particularly once the rule is issued.

2.7 Enforcement and implications for TTIP

Once a rule is in effect, agencies are fully empowered to enforce the rule against persons or entities that appear to be violating it. Agencies generally do this either through administrative enforcement actions heard by agency adjudicators such as an Administrative Law Judge, or, in more serious cases, by asking the Department of Justice to file a civil or criminal enforcement action in federal district court. Some laws, particularly environmental laws, provide for state government enforcement of federal laws, subject to federal agency oversight (an arrangement known as “cooperative federalism”). They may even authorise citizen suits to enforce the law.

Enforcement is one of the few areas of administrative law where US courts are quite prone to find that Congress has committed a type of decision to agency discretion by law, making agency enforcement (or non-enforcement) decisions typically non-reviewable in court.¹²⁵

This judicial latitude might be viewed as offering an opening for US agencies to recognise, quietly, EU requirements as “equivalent” to their US counterparts by simply promising not to enforce the statute or rule against imported products or services that meet EU regulatory standards, provided those requirements are reasonably found to be truly equivalent to US requirements, *de jure* and *de facto*. However, caution would need to be exercised in relying on this line of argument, because courts have held that in cases where an agency officially declares a new policy on enforcement as an official policy that ties the agency’s hands, that public statement of binding policy carries the force of a rule and must be reached through a normal rulemaking process.¹²⁶

This means that any official and public recognition by an agency of an EU requirement under a Mutual Recognition Agreement (MRA) must conform to the requirements of the government statute. Also, it must either be reached through a rulemaking process or it must at least be consistent with prior regulations issued by that agency. Otherwise, it will face a substantial risk of successful legal challenge.

¹²⁵ See *Heckler v. Chaney*, 470 U.S. 821, 833 n. 4 (1985) (finding non-enforcement action by Food and Drug Administration to be committed to agency discretion and therefore unreviewable, but cautioning that despite the general presumption against judicial review of agency enforcement or non-enforcement decisions, courts *may* review agency non-enforcement decisions in cases “where it could justifiably be found that the agency has consciously and expressly adopted a general policy that is so extreme as to amount to an abdication of its statutory responsibilities”).

¹²⁶ See *Community Nutrition Institute v Young*, 818 F.2d 943 (D.C. Cir. 1987) (holding that a publicly announced agency commitment to withhold enforcement under clearly specified conditions amounted to *de facto* rulemaking without proper process).

2.8 Exceptions and variations on the rulemaking theme

We have followed the development of an agency regulation from the initial decision to regulate a public risk, through OIRA review to the NPRM, OIRA review (again), the final rule, judicial review and eventual enforcement at the agency level or in court. What remains is to examine several important exceptions and variations on the rulemaking theme.

This section will examine three important exceptions and variations to the rulemaking process described above: 1) policy statements, interpretive rules and procedural rules, 2) emergency rules issued under the “good cause” exception, 3) foreign affairs matters, and 4) negotiated rulemaking.

2.8.1 Exception for policy statements, interpretive rules and procedural rules

Policy statements offer guidance as to how the agency plans to exercise its permitting or enforcement authority within the framework of pre-existing law and regulations. *Interpretive rules* clarify how an agency interprets a possibly ambiguous statute or regulation that the agency is charged with implementing. These two categories of rules are often called “guidance documents.” *Procedural rules* explain what procedures the agency plans to follow in doing its work.

These regulatory instruments all have two main things in common:

- 1) they do not need to go through notice-and-comment rulemaking; and
- 2) they do not have the force and effect of law and are not able to change regulated entities’ legal obligations.

In other words, these flexible and informal procedures may be used to clarify the law (or the agency’s interpretation of the law), but they may not change it. Thus, in the TTIP setting, policy statements can be used to signal recognition of a foreign regulatory or certification scheme, but only if granting that recognition can be justified through a plausible interpretation of prior rules and laws.

2.8.2 The “good cause” exception

APA § 553 authorises agencies to dispense with notice-and-comment rulemaking “for good cause” if special circumstances render a normal process “impracticable, unnecessary, or contrary to the public interest.” Agencies must give reasons for invoking this exception and those reasons are subject to judicial review on the same standards that apply to other agency decisions. In practice, courts appear to have construed the exemption narrowly to prevent it from swallowing the rule that notice-and-comment rulemaking is normally required.¹²⁷ Nevertheless, the courts have allowed agencies to dispense with notice and comment and issue rules immediately where the agency has shown an overriding need to take immediate action.¹²⁸

Congressional deadlines are also sometimes used to try to justify waiver of rulemaking procedure, but courts have shown a propensity to reject the invocation of such deadlines if

¹²⁷ Lubbers, *supra* note 18 at 93-101; *New Jersey v. EPA*, 626 F.2d. 1038, 1045 (D.C. Cir. 1980) (“Exceptions to the notice and comment provisions of section 553 must be narrowly construed and only reluctantly countenanced.”) See also *Administrative Procedure Act: Legislative History*, S. Doc. No. 248 (1946) (“The exemption of situations of emergency or necessity is not an ‘escape clause’ ... A true and supportable finding of necessity or emergency must be made and published.”)

¹²⁸ See, e.g., *Hawaii Helicopter Operators, v. FAA*, 51 F.3d 212 (9th Cir. 1995) (upholding invocations of good cause exemption for safety rule designed to address spate of helicopter accidents).

there is any feasible means by which the agency might have met the deadline without suspending notice-and-comment.

In general, it seems unlikely that agencies will be able to invoke the good-cause exception freely to avoid providing notice and allowing public comment on new measures arising from TTIP mechanisms. Use of this exception is too frequently litigated and actively supervised by courts.

2.8.3 *The foreign affairs exception*

The APA also contains an exemption from all previously described rulemaking procedures for matters involving “a military or foreign affairs function of the United States.”¹²⁹ Although the case law for this exemption is rather sparse it is possible that this exemption might have some application to TTIP in some especially sensitive circumstances. According to one guide:

Several circuits have concluded that “[f]or the [foreign affairs part of the] exemption to apply, the public rulemaking provisions should provoke definitely undesirable international consequences.” In a recent example, the Second Circuit applied this test in holding that an Attorney General notice designating the countries whose nationals were subject to a special registration process (that itself had been subject to notice and comment after 9/11) was within the foreign affairs exemption. The exemptions are not limited to activities of the State and Defense Departments, but, like the proprietary exemptions, they are “not to be loosely interpreted.”¹³⁰

2.8.4 *Negotiated rulemaking (“reg-neg”)*

Negotiated rulemaking is an innovative procedure which was inspired by the European tradition of regulatory covenants and introduced in the United States in the Nineties as a way of increasing stakeholder involvement in the rulemaking process. The Negotiated Rulemaking Act of 1990 expressly authorised negotiated rulemaking on a trial basis, and it became a permanent option for agencies in the Negotiated Rulemaking Act of 1996.¹³¹

Negotiated rulemaking works by creating a neutral forum for direct dialogue between representative stakeholders and government rule writers in an effort to develop consensus on the terms or text of a proposed rule.

In this process, an outside facilitator is brought in to convene and preside over the discussions of a balanced group of representative stakeholders – public interest groups, industry interests and government regulators – as they analyse the data, examine the issues, and try to form a common view on the text, or the main terms, of a proposed rule.

This group is limited to no more than 25 individuals acting in a representative capacity. It is typically proactively balanced so that no one interest group can dominate.¹³² Its goal is to reach consensus on a proposed rule or its main elements. Its plenary meetings are open to the public, with either transcripts or detailed minutes posted online shortly after each meeting.

If the committee does reach consensus, the agency agrees to propose that consensus as the NPRM. The agency then takes comments on that consensus proposal as it would in a normal

¹²⁹ 5 U.S.C § 553(a)(1).

¹³⁰ Lubbers, *supra* note 18 at 57 (footnotes omitted).

¹³¹ See *The Negotiated Rulemaking Act of 1990*, Pub. Law No. 101-648 and *The Negotiated Rulemaking Act of 1996*, Pub. Law. No. 104-320 (codified at 5 U.S.C. §§ 561-590).

¹³² The agency participates as just another member of the group, formally, though everyone at the table is aware that the agency has the final say at the end of the day.

rulemaking process, and the agency has plenary authority to modify the proposal as appropriate, if it determines that new data, further analysis or subsequent comments warrant a modification to the proposal. Moreover, the final rule, on judicial review, gets no more deference from courts than an ordinary notice-and-comment rule would receive. In practice, however, negotiated rulemakings that achieve consensus seldom attract major opposition during the comment period, and rarely if ever attract a lawsuit.

Despite its advantages, negotiated rulemaking is not yet the norm in agency rulemaking practice, for four main reasons. First, the requirement that negotiated rulemaking committees comply with the Federal Advisory Committee Act (FACA) has made it slow and difficult for some agencies to convene new advisory committees.¹³³

Second, the tendency until recently for agencies and academic observers to regard consensus as a litmus test of ‘success’ – and anything else as failure -- may have deterred some agency staff from making use of the process when they might otherwise simply write the rule without seeking the consent of regulated entities or public interest representatives. Only recently are agencies and participants coming to recognise that a collaborative procedure yields great benefits – better rules and more stakeholder buy-in for rules – even when the process does not yield total consensus in the end.¹³⁴

Third, agencies tend to have a short-term budget horizon, and while the savings of a collaborative rule drafting process are substantial, they occur mostly in the latter part of the process (and may accrue to other offices and agencies), whereas the incremental costs of getting the rule right to begin with are incurred up-front.¹³⁵

Fourth, some observers have expressed concerns that the collaborative process intrinsically favours those interests represented at the table over those not selected to serve on the collaborative committee. This concern is easily answered if the collaborative process is done properly. A properly-managed collaborative process will ensure that stakeholder representatives (a) are nominated through a public process with the aid of a neutral convenor and (b) are chosen so as to be truly representative of a broad range of stakeholder interests. Moreover, even interests not directly represented around the table are free to attend meetings, either physically or by webcast, and free to participate in the proceedings, all of which are open to the public. Thus, collaborative procedures in the “negotiated rulemaking” model give every stakeholder (not just committee members) far more insight, and input, into agency thinking and analysis than they ever would receive from a traditional notice-and-comment process. Viewed in this light, transparency, public participation and representativeness are

¹³³ Some agencies have solved or minimised this problem by creating one “permanent” parent FACA committee and creating all future negotiating committees as sub-committees of this parent. Subcommittees are currently exempt from the chartering paperwork requirements that have hindered the creation of full committees.

¹³⁴ As John Caskey, Assistant Vice-President for Operations of the National Electrical Manufacturers Association (NEMA) observed after participating in a recent, Department of Energy-sponsored negotiated rulemaking on energy efficiency standards for distribution transformers: “Even without a negotiated settlement, the negotiated rulemaking process can be extremely valuable because it helps all the participants improve their knowledge of the industry and while also helping DOE and its consultants improve the accuracy of their computer models and input assumptions. The DOE [Department of Energy] negotiated rulemaking process really can be a win-win for all participants.” Caskey, John, *Friend or Foe—Negotiated Rulemaking Offers Valuable Option*, *Electro-industry* at 7 (Nov. 2013).

¹³⁵ See Jeffrey S. Lubbers (2008), “Achieving Policymaking Consensus: The (Unfortunate) Waning of Negotiated Rulemaking”, *South Texas Law Review* 49, p. 987.

properly seen as paramount *strengths*, not weaknesses, of the collaborative process when compared to traditional alternatives.

Assuming resources can be found and the convening burden can be eased (and there are proposals for doing both) one might easily imagine a variation on the theme of negotiated rulemaking – “consultative rulemaking” – which adopts the basic approach of negotiated rulemaking while simply dropping the difficult requirement of consensus at the end. This variation on the theme would preserve the opportunity for sustained interaction between agency staff and stakeholders on the facts and the fairness of the rule, while eliminating the fear of staff that they may be seen as having ‘failed’ if they don’t manage to achieve full consensus of all stakeholders on all major provisions of the proposal.

US experience to date suggests that consultative rulemaking offers considerable promise as a way of bolstering transparency and participation in rulemaking, while greatly improving the quality of agency analysis. Moreover, consultative approaches need not be confined to development of rules and acts. Collaborative techniques are readily adaptable to virtually any kind of regulatory cooperation dialogue: they simply entail convening balanced groups of representative stakeholders to exchange information, meet periodically, and search together for solutions to regulatory cooperation problems, be they issues of mutual recognition or development of new standards. In whatever setting such techniques are used, they bring the advantage of much more rapid, efficient, transparent and robust exchange of information than is possible using conventional decision processes.

2.9 Judicial review and implications for TTIP

Judicial review of agency rulemaking is authorised in all but a small category of situations in which courts judge that Congress has expressly precluded judicial review in a particular case, or committed a particular decision to agency discretion by law.¹³⁶ Congress seldom precludes judicial review of agency rules, meaning that the vast majority of agency rules are subject to full judicial review.

Under APA §706, judicial review is available to set aside agency action that is “(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 ... (D) without observance of procedure required by law ...”.¹³⁷

American judicial review, in practice, is a very complex and intricate process, which many books and articles have attempted to dissect. We cannot hope to do justice to this difficult topic here.¹³⁸ Suffice it to say that judicial review of agency rules tends to range from highly deferential, at one extreme, to quite searching at the other, depending on a host of factors including the agency, the reputation of the agency, the facts of the case and, not least, the ideological propensities of the reviewing judges.

The official doctrine on judicial review is that courts owe agencies a certain amount of deference in their review of agency interpretations of law, findings of fact and applications of law to fact. Courts are generally admonished to defer to agency interpretations of law so long as: (a) the agency is empowered to make binding policy on the topic in question, (b) the agency is actually exercising that power, and (c) the law is ambiguous and the agency interpretation

¹³⁶ See APA §701.

¹³⁷ See APA § 706.

¹³⁸ For a thorough discussion of judicial review see Lubbers, *supra* note 18 at 423-476.

of the law is reasonable.¹³⁹ On questions of fact, the issues for reviewing courts are whether the agency has applied the statutorily-prescribed decision factors (and only those factors), and/or whether the undisputed facts clearly require a result contrary to the one reached by the agency, indicating that the agency made a “clear error of judgment.”¹⁴⁰

In practice, it rather often seems that what is ‘clear’ to one judge may be not so clear to another, and what is ‘reasonable’ to one judge may appear unreasonable to another, leading to the spectrum of levels of actual deference and the indeterminacy of outcomes mentioned above.

Despite the unpredictability of judicial review in many individual cases, the prospect of such review has two clear implications of relevance to the TTIP talks:

1. Judicial review, by order of the US Supreme Court, looks only to the administrative record compiled by the agency during its rulemaking.¹⁴¹ This unequivocal doctrine has driven the expansion and complication of rulemaking processes described above – as agencies expand their process and bolster their analysis and explanations in an effort to marshal a record that can be used to defend the rule in court.
2. A fuller and more transparent rulemaking process will often yield a more abundant and robust record in support of the rule. Ironically, however, that very transparency also will highlight any occasions in which the agency may have altered its rule to take account of

¹³⁹ The leading cases on judicial review of agency interpretations of law include *Chevron U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837 (1984)(announcing the “Chevron test” articulated above); *Christensen v. Harris County*, 529 U.S. 576 (2000); *United States v. Mead Corp.*, 533 U.S. 218 (2000)(holding that Chevron deference only applies to agency interpretations of law when Congress has delegated power to make binding policy in that area to the agency rendering the interpretation, and the agency is exercising that power); and *Gonzalez v. Oregon*, 546 U.S. 243 (2006).

¹⁴⁰ For a sampling of leading cases applying the “arbitrary and capricious” test to judicial review of agency fact-finding, and application of law to fact, see *Motor Vehicle Mfrs. Ass’n of US Inc. v. State Farm Mutual Auto. Insur. Co.*, 463 U.S. 29 (1983)(the “State Farm” case); *Sierra Club v. Costle*, 657 F.2d. 298 (D.C. Cir. 1981); *Baltimore Gas & Electric v. NRDC*, 462 U.S. 87 (1983) and *Ethyl Corp. v. EPA*, 541 F.2d. 1 (D.C. Cir. 1976).

¹⁴¹ See *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402 (1971); *Camp v. Pitts*, 411 U.S. 138 (1973); *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council*, 435 U.S. 519, 549 (1978). The administrative record for judicial review is the collection of documents compiled by the agency and certified under oath to the court as representing the set of documents that the agency “considered” in deliberating on the rule (whether or not the documents were previously published), minus any documents for which privilege is asserted. Privilege may be asserted in this context on the same grounds as are available to support withholding of documents from disclosure under the Freedom of Information Act: e.g., national security / foreign policy, trade secrets, internal deliberative process, law enforcement, etc. Of particular relevance for our purposes are: (a) the foreign policy exemption, which might justify withholding the substance of confidential communications between US agency staff and foreign government officials; and (b) the deliberative process exemption, which will shield from disclosure (to the public and to courts) the internal notes and memoranda of agency staff about such meetings. Agency practice varies as to whether an index is prepared to catalogue documents being excluded from the administrative record for judicial review, but it appears that such an index (the so-called “Vaughn index”) must be prepared in any case if a lawsuit requesting such documents is filed under FOIA. The FOIA challenger is also free, in principle, to litigate the claim of privilege for each and every document thus withheld. The time period covered by this disclosure requirement is comprehensive – it begins as soon as the agency decides to commence a rulemaking proceeding and does not end until the rule is published. For a detailed discussion of these and related issues see Leland E.Beck, *Agency Practices and Judicial Review of Administrative Records in Informal Rulemaking: Report Prepared for the Consideration of the Administrative Conference of the United States*, 14May 2013, pp. 28-40 and pp. 57-60.

certain factors (such as, perhaps, trade impacts) that are not clearly set forth as permissible bases for decision in the statute that the agency is implementing. Thus, TTIP negotiators must recognise that US agencies -- faced with the prospect of judicial review -- may encounter significant constraints in their ability to take account of trade concerns if the latter find no expression in the statute(s) those agencies are implementing.¹⁴²

In virtually all cases other than challenges to agency jurisdiction (or “competence” in EU parlance), the remedy that courts apply in successful legal challenges is *not* for the court to impose its own vision of the correct rule. Instead, the court normally will “remand” the rule to the agency for re-consideration, leaving the agency the option of either withdrawing the rule or re-issuing it (possibly in amended form) after curing whatever defect led to the initial remand.

US framework for assessing trade impacts of regulations

Recognising the importance of enhanced international regulatory cooperation, the Obama Administration has issued Executive Order 13,609, which lays a foundation for TTIP regulatory cooperation efforts on the US side in several important respects:

First, the Executive Order empowers the OIRA-chaired Regulatory Working Group established by Executive Order 12,866 to serve as the main forum for discussing and coordinating US agency initiatives in the regulatory cooperation field, albeit with instructions to avoid duplicating “the efforts of existing interagency bodies and coordinating mechanisms.”¹⁴³

Second, the Order instructs federal regulatory agencies (other than independent commissions) to include in their regulatory plans a description of any international regulatory cooperation activities that are expected to lead to significant regulations.

Third, the Order asks federal agencies to identify – in the *Unified Agenda of Federal Regulatory and Deregulatory Actions* and in the central regulatory online portals, www.reginfo.gov and www.regulations.gov – any significant regulations that the agency determines are likely to have “significant international impacts.”¹⁴⁴

Fourth, the Order directs federal agencies to consider, while implementing their retrospective review agendas under Executive Order No. 13,563, “reforms to existing significant regulations that address unnecessary differences in regulatory requirements between the United States and its major trading partners ... when stakeholders provide adequate information to the agency establishing that the differences are unnecessary.”

¹⁴² However, the Trade Agreements Act of 1979, 19 U.S.C. §§ 2531-33, prohibits agencies from setting standards that create “unnecessary obstacles to the foreign commerce” of the United States—though it also makes clear that legitimate domestic objectives are not considered unnecessary obstacles. See § 2532. It also stipulates that international standards should be considered and used as the basis for U.S. standards “where appropriate.” *Ibid.* Thus, although further research beyond the scope of this study would be needed to assess the argument, it may be possible to argue that the Trade Agreements Act of 1979 already provides a statutory mandate for agencies to consider trade impacts of their regulations alongside the various decision factors articulated in the enabling statutes these agencies are implementing.

¹⁴³ *Ibid.* §2(c).

¹⁴⁴ Executive Order No. 13,609, 77 Fed. Reg. 26,413, § 3 (May 1, 2012).

Fifth, the Order asks 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.”¹⁴⁵

This seems a promising beginning which clearly foresees: (a) the creation of regulatory cooperation council empowered to create a work plan for identifying high-priority regulatory cooperation initiatives and bringing them to fruition on some sort of agreed time schedule, (b) a process whereby stakeholders can attempt to establish, to the satisfaction of regulators, that existing regulatory disparities are truly ‘unnecessary’; (c) an allocation of the ‘burden of proof’ which clearly assigns to stakeholders the burden of establishing that each regulatory difference they want eliminated (through harmonisation or mutual recognition, in whole or in part) is truly ‘unnecessary.’

Finally, Executive Order 13,609 articulates a persuasive set of guiding principles for the exercise: “to identify approaches that are at least as protective [of public health, safety, environment and economic security] as those that are or would be adopted in the absence of such cooperation ... [and to] reduce, eliminate, or prevent unnecessary differences in regulatory requirements.”¹⁴⁶

Conclusion

In thinking about how to ‘mesh’ two major legislative and regulatory systems to promote coherence and cooperation, it is helpful to understand how those systems work separately, in their present form.

We have seen that the legislative and regulatory processes in the EU and US both require that important governmental regulatory measures undergo detailed impact assessment, and both sides seek to incorporate public input into their consideration of policy measures. But they do so at different points and in different ways.

The “formative” stage of legislation – in which draft legislation is conceived and crafted – is more reliably open and inclusive in the EU than the US, at least for important legislation. All legislative proposals considered by the EP and Council must originate in the European Commission and all major legislation that goes from the Commission to the European Parliament and Council is the product of an elaborate administrative process that will generally include extensive stakeholder consultations, Impact Assessment (IA), Inter-Service Consultation (ISC), and final adoption by the EU College of Commissioners. No comparable process is required for draft US legislation, which may be introduced by any Member and need not be subject to any formal assessment or stakeholder input prior to introduction.

By contrast, in the “deliberative” stage of the legislative process – in which draft measures are debated, amended, and ultimately enacted or rejected – the Council and the Parliament engage in a deliberative interaction that is roughly analogous to that of the US House of Representatives and Senate, with two major exceptions: i) most proposals submitted by the Commission are enacted, whereas most bills submitted by Members of Congress fail to pass; and ii) the US House and Senate have plenary authority to amend draft legislation by majority vote, whereas the Council cannot, without a unanimous vote, adopt a measure containing amendments with which the Commission disagrees.

¹⁴⁵ Ibid. § 3(c) and (d).

¹⁴⁶ Ibid. § 1.

On both sides of the Atlantic, legislation is required before regulators may act. However, EU legislation generally tends to be more detailed and prescriptive than its US counterpart, which often contains broad grants of discretionary authority allowing federal regulators to make policy within broad bounds.

In the formative or pre-proposal phase of regulatory design and drafting, both sides favour informal processes aimed at ensuring a wide-ranging discussions and a free flow of information. *Ex parte* contacts between agency and members of the public are generally accepted on both sides, in the interest of promoting a free flow of information, but there is no rigorous or mandatory disclosure of agency thinking at this stage.

The deliberative (post-proposal) stage for implementing and delegated acts in the EU remains less transparent than for US rulemaking - despite the commitment of the EU Commission and co-legislators in recent years to expanding the use of public consultation and impact assessment of non-legislative measures. US federal agencies are required by law to give public notice, to allow public comment on draft rules and draft impact assessments of major rules, and to respond to those comments that are significant - though US agencies often treat EU and foreign co-regulators just like any other commenter. The EU system *allows* the European Commission to adopt a comparable process for significant rules, but it does not *require* Impact Assessment or public consultation as a matter of course, at this stage, and only a few Impact Assessments have been carried out, thus far, for delegated and implementing acts.

Besides adopting quite different regulatory processes, the two systems also endow their respective regulators with quite different powers and constraints on power. For example, EU legislation may empower regulators to adopt “delegated acts” that modify legislative acts in “non-essential” ways, whereas it is a point of constitutional principle in the United States that no agency may ever modify an act passed by Congress.

“Delegated acts” promulgated by the European Commission are subject to legislative veto by either the EP or the Council, whereas the US Supreme Court has held legislative vetoes to be unconstitutional in the United States.

“Implementing rules” in the EU merely implement legislative acts without amending them and thus are more like US regulations, but they too are subject to veto, this time by Examination Committees composed of Member State representatives. There is no counterpart to this political veto power in US administrative process.

Whereas EU regulations are more vulnerable than their US counterparts to reversal by other political bodies, US regulations are much more frequently challenged in court. In fact, US regulations are subject to searching judicial review on matters of law, fact, and analysis, and it is not uncommon for agency rules to be reversed and remanded for reconsideration after judicial review. In the EU, by contrast, strict rules on *locus standi* and the rather deferential standard of review exercised by EU courts has meant that only a few acts – be they legislative or non-legislative – are challenged and struck down by courts every year.

US and EU regulators thus work within very different institutional and legal frameworks, following different processes under rather different constraints. Still, both sides recognise and express in their systems a commitment to transparency, openness, public participation and public accountability, though that commitment is expressed in different ways and at different times.

The challenge for TTIP negotiators is to find an effective mechanism for enabling these two disparate systems to work more effectively, efficiently, and cooperatively together. That exploration will be aided by a clear understanding of how the two legislative and regulatory systems work currently in their separate spheres. We hope this report will contribute to that understanding.

Annex: Process for developing laws and regulations in the EU and the US

