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על שם אני ופול ינוביץ'



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TAKING FOREIGN PREFERENCES INTO ACCOUNT: THE RULEMAKING PROCESS IN THE UNITED STATES AND THE EUROPEAN UNION

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Taking Foreign Preferences into Account: The Rulemaking Process in the United States and the European Union

Ayelet Berman*

Abstract

In our globalized economy, policies and regulations issued by one country are increasingly having significant effects on third states and foreigners. In most cases such national regulations do not cause a breach of international law, but simply affect the interests of such outsiders, say of a social or economic nature. What does international law say about the accountability states have towards such third states and foreigners? While certain rules or best practices exist in specific areas, a general rule of international law does not exist. Be the legal situation as it may, in practice, the U.S. and EU rulemaking processes are opening up towards third states and foreigners. They may participate in notice and comment procedures, and regulatory impact assessments take impacts on them into account. In the absence of any international legal obligation, the paper argues that there are two main rationales behind this U.S. and EU practice: Their enlightened self interest in improving market-openness, and a sense of moral obligation towards poor countries. Finally, these principles of openness towards foreigners now having been embedded in OECD best practice suggests that they will find their way into the domestic regulatory systems of other countries (if they haven't done so yet).

1. Introduction

In our globalized economy, policies and regulations issued by one country may have significant effects on third states and foreigners (be they individuals, businesses or other entities that live or operate in such third states). While not the direct addressees of the regulations, in these times of interconnectedness and interdependence, they may be affected. It suffices to think of the recent Ebola outbreak and some states' decisions to restrict trade and travel to and from Ebola affected countries, and the consequent effects on the health stricken and the economy in those countries.¹ Also seemingly more mundane regulations have

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¹ Eyal Benvenisti, *The Ebola Outbreak as "A Threat to International Peace and Security" – The Precedential Significance of Security Council Resolution 2177*, GLOBAL TRUST, <http://globaltrust.tau.ac.il/the-ebola-outbreak-as-a-threat-to-international-peace-and-security-the->

significant effects, such as regulations concerning the safety of products that may be imported and the consequent effects on producers in third countries wishing to export, financial regulations and their spill over effects on the financial systems of other countries,² or regulations concerning employment migration and their effect on third country migrants – just to name a few. While such effects have always been present, with globalization and the increased movement of goods, services, information, people and funds, such effects have become more significant.

In most cases such national regulations do not cause a breach of international law (such as human rights law³ or WTO law), nor do they cause physical injury or damage. Thus, they do not evoke state responsibility or state liability under international law. Nevertheless, they affect the interests, say of a social or economic nature, of third states and foreigners. Foreign stakeholders may have an interest in, for example, lower costs or protecting their health, but they do not have any legal right protected under international law.

How does international law, if at all, regulate such activities? There is no general obligation under International Law that requires states to be accountable towards outsiders whose interests have been affected. The situation is fragmented and uneven with certain specific obligations in treaties and other agreements such as in the ILC Articles on Trans-boundary Harm or the 2012 OECD Recommendation on Regulatory Policy. The topic has also only sporadically been dealt with in the literature, with Benvenisti being an exception. He proposes a reconceptualization of the notion of sovereignty and argues that as “trustees of humanity” states need to be accountable towards third states and foreigners, which means taking their interests into account, and hearing them.

While the accountability of states towards third states and foreigners has largely not been dealt with in the literature and remains underdeveloped in international law, the discussion as to the accountability of global governance bodies towards their ‘external’ stakeholders – which shares many similarities with the debate here – has, in contrast, received much more attention and is more thoroughly developed: In what has become quite a significant group of international scholars – more accountability in the sense of more transparency, participation and oversight towards external stakeholders– is being demanded of global

precedential-significance-of-security-council-resolution-2177/#more-1352 (last visited Mar. 13, 2015).

² For example, Eyal Benvenisti, *Vice Chairman of the US Federal Reserve: The Fed Must Take Action to Maintain Order in International Capital Markets*, GLOBAL TRUST, <http://globaltrust.tau.ac.il/vice-chairman-of-the-us-federal-reserve-the-fed-must-take-action-to-maintain-order-in-international-capital-markets/> (last visited Mar. 13, 2015).

³ On domestic policies with extraterritorial effects that cause violations of human rights obligations see Lorand Bartels, *The EU's Human Rights Obligations in Relation to Policies with Extraterritorial Effects*, 25(4) EUROPEAN JOURNAL OF INTERNATIONAL LAW 1071 (2014) .

governance.⁴ Moreover, in practice, we also witness the opening up of many global bodies towards external stakeholders (e.g. receiving opportunity for notice and comment, participating as observers, or setting up complaints mechanisms). Due to its similarities, the work done in that context may inform our work on the accountability of states towards foreigners.

Be the international legal situation as it may, what is clear is that it is lagging behind state practice. As this paper demonstrates, the U.S. and the EU, in their rulemaking processes, are taking the interests of foreigners and third states into account. It demonstrates, first, how their notice and comment procedures are open to third countries and foreigners; and, second, how the regulators take impacts on third states and foreigners into account in their regulatory impact assessments.

As to the drivers behind these practices, the paper argues that – in the absence of international legal obligations to this end – that there are two main drivers that explain the open rulemaking processes in the U.S. and EU. First, is their desire to align diverging regulations (leading to market openness and economic growth), and second, a sense of moral obligation towards developing countries. Thus, in the absence of an international legal obligation, U.S. and EU practice is best explained by their enlightened self-interest, and by their sense that their (regulatory) power demands accountability towards poor countries.

That said, open regulatory processes and consideration of impacts on foreigners now embedded as a OECD best practice, it may well find its way into domestic regulatory systems of other countries that undertake regulatory reform in line with OECD principles (if they haven't done so yet). Thus, while the U.S. and EU, being the big trading countries that they are, have largely been driven by economic interests, smaller countries may find themselves adopting such reforms out of pressure or desire to align themselves with OECD best practices.

The paper is organized as follows: It begins with examining the accountability towards external stakeholders in international law (section 2). It then moves on to lay out the practice. Section 3 describes the involvement of foreigners in the rulemaking process, and section 4 sets out the background on regulatory impact assessments. Then it discusses how international impacts are taken into account in the impact assessments (section 5), and how foreigners are given voice in impact assessment (section 6). Section 7 discusses the rationales, and section 8 concludes.

⁴ E.g. GAL Project, INSTITUTE FOR INTERNATIONAL LAW AND JUSTICE, <http://www.iilj.org/gal/> (last visited Mar. 13, 2015); The Exercise of International Public Authority Project, MAX-PLANCK-INSTITUT FÜR AUSLÄNDISCHES ÖFFENTLICHES RECHT UND VÖLKERRECHT, http://www.mpil.de/de/pub/forschung/forschung_im_detail/projekte/voelkerrecht/ipa.cfm (last visited Mar. 13, 2015); INLAW Project, <HTTP://WWW.HIIL.ORG/PROJECT/INFORMAL-INTERNATIONAL-LAW-MAKING-AND-ACCOUNTABILITY> (last visited Mar. 13, 2015).

2. Accountability towards External Stakeholders in International Law

In this age of globalization, policies or regulations of one state may have effects on third states, and on foreign individuals, businesses or other entities that live or operate in such third states. Such foreigner stakeholders are what this paper refers to as “external stakeholders”. “External stakeholders” covers individuals, entities or third states that are affected by the policies of a state, but are not members (i.e. not citizens or registered companies) of the state concerned. Such external stakeholders are not the direct addressees of the regulations, but in these times of interconnectedness and interdependence, they are affected by them. Think say of a regulation which restricts immigration into the EU and its consequent effects on non-EU individuals living outside of the EU; regulations concerning the quality of food that may be imported into the U.S. and the consequent effects on food producers in non-U.S. countries wishing to export to the US, or the consequences of environmental policies on global warming.⁵ The point is that in this time and age, national policies increasingly cause “external effects” in third states or on foreigners, and with the increased movement of goods, services and people, these effects are quite significant.

If such national regulations were to cause a breach of applicable rules of international law, say human rights law or WTO law, this could lead to findings of state *responsibility* for breaches of international law. Or if state actions were to cause physical injury or damage, that could raise issues of *liability* under international law.⁶ But what happens if a state does not breach any law, or infringe any rights, or cause any physical injury or damage? Regulations issued in one state will, in fact, rarely affect a legal right that a person or entity in a third state is entitled to have protected by law, nor will they cause physical harm. Rather, the regulation may simply affect the interests, say of a social or economic nature of others (bearing on matters such as the quality of life, living conditions, prices of regulated products), and such interests do not have the status of law.⁷ The respective external stakeholders may have an interest in, for example, reducing costs, protecting their health or their environment, but they do not have any legal entitlement or rights to this end.

⁵ E.g. Eyal Benvenisti, *Quixotic Altruism or an Effective Investment? On Unilateral Measures to Mitigate Climate Change*, GLOBAL TRUST, <http://globaltrust.tau.ac.il/quixotic-altruism-or-an-effective-investment-on-the-incentives-and-concerns-with-unilateral-measures-to-mitigate-climate-change/> (last visited Mar. 13, 2015).

⁶ See e.g. JAMES CRAWFORD, *INTERNATIONAL LAW COMMISSION'S ARTICLES ON STATE RESPONSIBILITY: INTRODUCTION, TEXT AND COMMENTARIES* (2002).

⁷ In the national context, see Daphne Barak-Erez, *The Administrative Process as a Domain of Conflicting Interests*, 6 *THEORETICAL INQUIRIES IN LAW* 193 (2005).

How does international law, if at all, regulate such activities? Do states need to be *accountable*, in the sense that they need to be responsive,⁸ towards such foreign, external stakeholders for the effects they create? Do they need to take such interests into account in their policy making? Do they need to give external stakeholders a voice, or an opportunity to comment before they make policies?

There is no general obligation under International Law that requires states to be accountable towards their external stakeholders and take their interests into account. There are, however, specific obligations in treaties and other agreements. For example, The ILC Articles on the Prevention of Trans-boundary Harm From Hazardous Activities recognize the right of third states to be notified and consulted if a state act will affect them. This right is, however, limited to physical harm: The Articles oblige states to take “all appropriate measures” to prevent trans-boundary harm or to minimize the risk of it, and harm is defined as limited to physical consequences.⁹ As part of this prevention duty, in the case of a risk of causing significant physical harm to a third state, states are under an obligation to notify, provide information and receive comments from or consult with the affected state.¹⁰ Thus, International Law recognizes the rights of third states to be notified and to be able to respond before action is put into force. This recognition is limited, however, to significant physical harm, and applies only between states. World Trade Organization (WTO) law also sets out requirements towards foreigners that have been affected. For example, the Agreement on Agriculture determines that “Where any Member institutes any new export prohibition or restriction on foodstuffs... [it] shall give due consideration to the effects of such prohibition or restriction on importing Members’ food security”, and that “before any Member institutes an export prohibition or restriction, it shall give notice in writing, as far in advance as practicable...”.¹¹

⁸ Anne-Marie Slaughter, *Global Government Networks, Global Information Agencies, and Disaggregated Democracy*, 24 MICHIGAN JOURNAL OF INTERNATIONAL LAW 1041, 1053 (2002-2003); Richard B. Stewart, *Accountability, Participation, and the Problem of Disregard in Global Regulatory Governance (Draft Paper)* IILJ INTERNATIONAL LEGAL THEORY COLLOQUIUM: INTERPRETATION AND JUDGMENT IN INTERNATIONAL LAW, NYU LAW SCHOOL, 2008, <http://www.iilj.org/courses/documents/2008Colloquium.Session4.Stewart.pdf> (last visited Mar. 13, 2015).

⁹ Prevention of Transboundary Harm from Hazardous Activities, Art. 3 and Commentary thereto, *Official Records of the General Assembly, Fifty-sixth Session, Supplement No. 10*, U.N. Doc. A/56/10.

¹⁰ Art. 8(1) provides that “the state of origin shall provide the state likely to be affected with timely notification of the risk...and shall transmit to it the available technical and all other relevant information on which the assessment is based.” The Commentary to art. 8 provides “Article 8 calls on the State of origin to notify states likely to be affected by the planned activity...The requirement of notification is an indispensable part of any system designed to prevent transboundary harm or at any event to minimize the risk thereof.”

¹¹ Agreement on Agriculture, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, art 12.

Further, the Aarhus Convention¹² provides the right to take part in domestic environmental decision making to those “affected or likely to be affected by, or having an interest in, environmental decision-making”. This right was extended by the Aarhus Compliance Committee to foreign citizens residing outside the country. Another relevant document is the 2012 OECD Recommendation on Regulatory Policy and Governance. It recommends that members should “[i]n developing regulatory measures, give consideration to all relevant international standards and frameworks for cooperation in the same field and, where appropriate, [to] their likely effects on parties *outside the jurisdiction*”.¹³ And that “Processes of consultation on regulatory proposals should be open to receiving submissions from *foreign* and domestic interests.”¹⁴ While highly relevant, this Recommendation is of a soft law character and limited to OECD members.

Thus, the situation in international law is largely fragmented and uneven. In search of a more encompassing international law obligation Benvenisti argues that International Law should apply more stringent requirements on states whose activities or regulations affect third states and foreigners. In his work on “sovereigns as trustees of humanity” Benvenisti argues that states, in their roles as sovereigns, are “trustees of humanity”. As such, and given individuals’ “equal moral worth” they have obligations not only towards their own citizens, but also towards foreigners situated beyond national boundaries and need to take their interests into account, when the latter are affected by their policies or actions. To this end, states should be obliged under international law to give, as a minimum, voice to affected foreign stakeholders.¹⁵ He bases this argument on a new conceptualization of the notion of sovereignty. Sovereignty not only includes – as traditionally understood – a self-definitional and protective component, but rather – in this time and age of interconnectedness – also an ‘other regarding’ component. As such, states should be obliged under international law to give voice to affected external stakeholders. A different approach has been suggested by McCrudden. He argues that “enlightened self-interest” is a justification for accountability of states towards foreigners. That is, that persons who act to further the interests of others (or the interests of the group or groups to which they belong), ultimately serve their own self- interest.¹⁶

¹² UNECE Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters, Jun. 25, 1998, 2161 U.N.T.S. 447.

¹³ Organization for Economic Cooperation and Development (OECD), *Recommendation of the Council on Regulatory Policy and Governance*, 5 and 19 (Recommendation 12) (2012), <http://www.oecd.org/gov/regulatorypolicy/49990817.pdf> (last visited Mar. 13, 2015).

¹⁴ Recommendation 12.7.

¹⁵ Eyal Benvenisti, *Sovereigns as Trustees of Humanity: On the Accountability of States to Foreign Stakeholders* 107 AMERICAN JOURNAL OF INTERNATIONAL LAW 295 (2013).

¹⁶ See Christopher McCrudden, *AJIL Symposium: Comment on Eyal Benvenisti, Sovereigns as Trustees of Humanity*, OPINIO JURIS (July 25, 2013), <http://opiniojuris.org/2013/07/25/ajil->

As becomes clear, there remains much place for international legal development as to the accountability of states towards foreign, external stakeholders. Interestingly, a similar discussion has been taking place for some time now regarding the accountability of *global bodies* (e.g. Intergovernmental organizations, transgovernmental regulatory networks, public private partnerships etc.) towards their external stakeholders. As global bodies such as the WTO, the Basel Committee, the Global Fund or the International Conference on Harmonization (to name just a few) reach decisions and undertake actions that have an effect on many people, entities and states around the world, scholars and practitioners have been dealing with questions of their accountability, and whom such bodies need to be accountable to. Both debates are similar in that they are both concerned with accountability towards outsiders that are not members (or citizens), but are nevertheless affected by a decision. Hence, the work on the accountability of global bodies may be a source to inform future work on the accountability of states.

In the global context, the Seattle protests against the WTO were one of the first times these accountability concerns received global public attention. The problem had been that traditionally global bodies such as the WTO and World Bank were only accountable towards their member states, being as they were, those that authorized their activities.¹⁷ But people grew wary of this limited approach. The decisions and actions of global bodies have enormous impact on the lives of individuals, companies and countries around the world. And while most of the global bodies' decisions are not in breach of international law (nor do they cause physical damage) they are nevertheless quite significant. Examples are abundant: Think, say, of the WHO's recommendation to purchase swine flu vaccines (leading countries to spend money on drugs, and benefiting the companies selling those drugs), the UN Security Council's decision to list suspected terrorists and sanction them, or the World Bank's project funding (e.g. funding of a dam project in developing countries involves resettling the local population).¹⁸ Further, more

symposium-comment-on-eyal-benvenisti-sovereigns-as-trustees-of-humanity/ (last visited Mar. 15, 2015).

¹⁷ Traditionally, accountability was based on the principal-agent model, or what Keohane and Grant have referred to as the "delegation" model of accountability – that is, those delegating power to global bodies, may hold them accountable. See Ruth W. Grant & Robert O. Keohane, *Accountability and Abuses of Power in World Politics* 1 AMERICAN POLITICAL SCIENCE REVIEW 29, 33 (2005). See also, Robert A. Dahl, *Can International Organizations be Democratic? A Skeptic's View*, DEMOCRACY'S EDGES 530 (Ian Shapiro & Casiano Hacker-Cordon eds., Cambridge University Press, 1999); KAREL WELLENS, REMEDIES AGAINST INTERNATIONAL ORGANIZATIONS (2002). Anne Peters, *Membership in the Global Constitutional Community* THE CONSTITUTIONALIZATION OF INTERNATIONAL LAW 210 (Jan Klabbers et al. eds., Oxford University Press, 2009).

¹⁸ Daniel Bradlow, *Private Complaints and International Organizations: A Comparative Study of the Independent Inspection Mechanisms in International Financial Organizations* 36

than 100 States and their banks have implemented the Basel Committee on Banking Supervision Accords to a greater or lesser degree, despite not being members of the organization,¹⁹ with significant effects on their local banking industries. Or the adoption in developing countries of guidelines issued by the International Conference on Harmonization (ICH), a club of drug regulatory agencies from developed countries, which has undermined the development of drugs for neglected diseases in developing countries,²⁰ and possibly the availability of essential medicines to the local populations.²¹

Consequently, in the past two decades, many have been calling for a change – leading to a reassessment of the accountability of global institutions. A contemporary approach has emerged whereby global bodies are expected not only to be accountable towards their members but also towards all those outside of the body, who are affected by their actions or decisions – that is, towards “external stakeholders”.²² Such external stakeholders, it is argued, should have a voice in the decisions affecting them. For example, Kingsbury and others argue that “[Global Administrative Law – which provides procedural rights to affected stakeholders] ... is meant to level the playing field, ensuring that global regulatory bodies are responsive to the interests of all of those upon whom their activities impact.”²³ The International Law Association (ILA) Final Report on the Accountability of International Organizations says that “the constituency entitled

GEORGETOWN JOURNAL OF INTERNATIONAL LAW 408 (2005). Sabine Schlemmer-Schulte, *The Impact of Civil Society on the World Bank, the International Monetary Fund and the World Trade Organization: The Case of the World Bank*, 7 ILSA JOURNAL OF INTERNATIONAL AND COMPARATIVE LAW 413 (2000-2001).

¹⁹ Mario Savino, *An Unaccountable Transgovernmental Branch: The Basel Committee*, GLOBAL ADMINISTRATIVE LAW: CASES, MATERIALS, ISSUES 67 (Sabino Cassese et al. eds., Institute for International Law and Justice: NYU School of Law and Istituto di Ricerche sulla Pubblica Amministrazione, 2008).

²⁰ Trudi Lang et al., *Clinical Research: Time for Sensible Global Guidelines*, 377 THE LANCET 1553 (2011); Trudie Lang et al., *Clinical Research in Resource-Limited Settings: Enhancing Research Capacity and Working Together to Make Trials Less Complicated*, 4 PLOS NEGLECTED TROPICAL DISEASES 619 (2010).

²¹ Ayelet Berman, *Reining in the Regulators: Transnational Regulatory Networks and Accountability* (PhD Thesis, 2014, Graduate Institute of International and Development Studies) 176-183.

²² See e.g. Keohane, Robert O. *Global Governance and Democratic Accountability* (Miliband Lectures, London School of Economics, 2002) <http://www2.lse.ac.uk/publicEvents/pdf/20020701t1531t001.pdf> at 14-15, 28-29.

Keohane and Grant have referred to this kind of accountability as the “participation model” of accountability, whereby the performance of global actors is evaluated by those affected by their actions. See also International Law Association Committee on the Accountability of International Organizations, *Final Report on the Accountability of International Organizations* 5 (2004), <http://www.ila-hq.org/en/committees/index.cfm/cid/9> (last visited Mar. 13, 2015) (“accountability is linked to the authority and power [of an IO], and that power entails accountability, that is the duty to account for the exercise of power”).

²³ Benedict Kingsbury, Nico Krisch, and Richard B. Stewart, *The Emergence of Global Administrative Law*, LAW AND CONTEMPORARY PROBLEMS 32-35 (2005).

to raise the accountability of IOs consists of all component entities of the international community at large provided their interests or rights have been or may be affected by acts, actions or activities of IOs.”²⁴ The One World Trust similarly argues that accountability should not only be towards “individuals or groups that are formally part of the organization”, but also towards “individuals or groups that are affected by an organization’s decisions and activities”.²⁵

In practice, global bodies are increasingly embracing external accountability and involving external, societal voices in their decision-making. In the past two decades IOs have moved away from being the exclusive preserve of member governments and have significantly opened up towards non-state actors of a commercial and non-commercial nature.²⁶ Tallberg demonstrates, how from the 1990s onwards we observe a very sharp increase in the formal access by non-state actors to IOs. For example, the WTO has introduced improvements that allow for greater civil society and NGO participation in its work.²⁷ Other IOs such as the OECD, ILO and WHO have also introduced procedures for the involvement of civil society.²⁸ Further, the World Bank set up an “Inspection Panel”, which receives complaints regarding World Bank projects from people that are “directly affected” by the violation of Bank policies and procedures.²⁹ Further examples are the compliance committee of the Aarhus Convention, which may receive communications brought forward by members of the public, including NGOs and individuals;³⁰ and the notice and comment procedures introduced by the Basel Committee.³¹ And the list goes on.

²⁴ International Law Association Committee on the Accountability of International Organizations, *Final Report on the Accountability of International Organizations*, *supra* at 5.

²⁵ One World Trust, *Pathways to Accountability: The Global Accountability Project (GAP) Framework* 19 (2005), http://www.oneworldtrust.org/index.php?option=com_docman&task=doc_view&gid=210&tmpl=component&format=raw&Itemid=55 (last visited Mar. 13, 2015).

²⁶ Jonas Tallberg, *Non-State Access to International Organizations: Patterns and Explanations* (NGOs in Global Governance, Geneva, 2012) (on file with author). Jonas Tallberg et. al, *Explaining the Transnational Design of International Organizations International Organization* 68(4) INTERNATIONAL ORGANIZATION 741-774 (2014)

²⁷ Maria Perez Esteve, *WTO Rules and Practices for Transparency and Engagement with Civil Society Organizations (Working Paper)* IISD WORKSHOP IN CIVIL SOCIETY AND WTO ACCOUNTABILITY 2011, http://www.iisd.org/pdf/2011/wto_accountability_rules_transparency.pdf (last visited Mar. 13, 2015).

²⁸ BUILDING GLOBAL DEMOCRACY (Jan Aart Scholte ed., Cambridge University Press, 2011). Further, the WHO is currently (2015) undertaking a reform on its cooperation with non-state actors.

²⁹ Ayelet Berman, *The World Bank Inspection Panel* (2008) (on file with the Graduate Institute of International and Development Studies Library).

³⁰ UNECE Convention on Access to Information, Public Participation in Decision Making and Access to Justice in Environmental Matters, Art 2(4).

³¹ Michael S. Barr & Geoffrey P. Millar, *Global Administrative Law: The View from Basel* 17(1) EUROPEAN JOURNAL OF INTERNATIONAL LAW 15, 31 (2006).

To conclude, the debate concerning the accountability of global bodies towards external stakeholders has significantly developed and is constantly evolving in law and in practice towards more openness. In contrast, the question as to the accountability of states towards external stakeholders has barely drawn any attention in the literature, and is significantly underdeveloped in international law. In view of developing the latter, the work done in the former may be a helpful source for informing future work.

The purpose of the following part is to fill this gap and to demonstrate that in practice, much is already underway and that states are in the process of opening up towards foreign stakeholders. We next zoom in on the U.S. and EU rulemaking process and demonstrate how they are taking the interests of foreigners stakeholders into account, and are giving them voice.

3. The Rulemaking Process in the U.S. and EU

The rulemaking process is the process whereby regulatory agencies promulgate regulations. In general, legislatures first set statutes, and then agencies create more detailed regulations. Regulations add scientific, economic or other expertise to policy, and flesh out the broad mandate of the authorizing statute. For example, the legislature will issue a statute that determines that pharmaceuticals sold need to be safe and the agency will issue a regulation that details the specific scientific standards for the assessment of safety.

In the U.S., the Congress has the sole power to make statutes and there are many federal agencies such as the U.S. Food and Drug Administration and the U.S. Environmental Protection Agency. In the U.S. the governing law for federal rulemaking is the Administrative Procedure Act of 1946 (APA). The APA sets out a “notice and comment” procedure whereby the public is notified about a proposed regulation, and can then comment on it, and the agency in turn is required to reason its decisions before it issues the final regulation. In addition, whenever a proposed regulation is considered to be significant, regulators are required to undertake Impact Assessments that assess the effectiveness of the proposed rule.

The legislative and regulatory processes in the U.S. and EU are different. In the EU, the aims set out in EU treaties are detailed in several kinds of acts, some being legally binding and some non-binding: regulations,³² directives,³³

³² A regulation is a binding legislative act.

³³ A directive is a legislative act that sets out a goal that all EU countries must achieve, but it is up to each individual country to decide how.

decisions,³⁴ recommendations,³⁵ and opinions.³⁶ The EU lacks an APA law, but the Commission has developed, pursuant to the principles set out in the White Paper on Governance, “Minimum Standards” on Consultation, which set out similar standards of notice and comment. It too undertakes an Impact Assessment for significant policies.

As noted above, regulations issued in one country may have an impact on third countries or foreigners. In the following section we take a closer look at how the rulemaking process, especially the notice and comment procedure, takes international impacts of regulation into account.

A. Flagging the International Impact of Regulation

In the U.S., Executive Order 13609 on “Promoting International Regulatory Cooperation”³⁷ introduced in 2012 new notification requirements in the rulemaking process where proposed regulations are thought to have an “international impact”. The Executive Order defines international impact narrowly, as related to trade. It says that it is “a direct effect that a proposed or final regulation is expected to have on international trade and investment, or that otherwise may be of significant interest to the trading partners of the United States.”³⁸

The Executive Order introduces notification requirements when a proposed regulation is expected to have an international impact, but such requirements do not apply to every proposed regulation. The proposed regulation must in itself be a “significant regulation” (significant regulations are generally regulation that have an effect of \$100 million or more on the economy in any one year, or adversely affects in a material way the economy)³⁹ and the expected impact must be significant too. In such cases, the Order demands that the international impact “be highlighted to the public” and agencies need to “ensure that significant regulations that the agency identifies as having significant international impact are

³⁴ A decision is binding on those to whom it is addressed.

³⁵ A recommendation is not binding.

³⁶ An opinion is non-binding.

³⁷ Executive Order 13609: Promoting International Regulatory Cooperation 77 FR 26413 (2012).

³⁸ *Id.*, sec. 4(b).

³⁹ Sec. 3(f)(1), Executive Order 12866: Regulatory Planning and Review 58 FR 51735 (1993); Office of Management and Budget, Office of Information and Regulatory Affairs, *2006 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities* (2006), http://www.whitehouse.gov/sites/default/files/omb/assets/omb/inforeg/2002_report_to_congress.pdf (last visited Mar. 14, 2015).

designated as such in the Unified Agenda of Federal Regulatory and Deregulatory Actions, on RegInfo.gov and on Regulations.gov.”⁴⁰

What is the Unified Agenda? The Unified Agenda reports on all regulatory activities under development throughout the federal government, and includes all regulations under development from all federal entities, be it departments, agencies or commissions.⁴¹ The Reginfo.gov site is a searchable database of the Unified Agenda,⁴² and as such, allows the public to find information on all regulations under development throughout the federal government.⁴³ The website gives the ability to search for those entries of particular interest, based on selection of criteria. Following the Executive Order, the Office of Information and Regulatory Affairs (OIRA) added a data element on “international impacts” to the online database and so this criteria can be searched for. Users of the website can check a box to search for rules that have international impact. The purpose of this addition was to facilitate comments from foreign regulators and stakeholders by making it easier to search rules that have an international impact, thereby facilitating transparency and comments from foreign regulators and stakeholders.⁴⁴

Have the Order’s requirements been followed in practice? A search on the reginfo.gov website suggests an affirmative answer. A search conducted on the 6 November 2014 shows that there are 1974 records in the system, which have been designated as having an international impact (though some may be referring multiple times to different stages in the same rule).⁴⁵ It should be noted that the

⁴⁰ Sec. 3(c), Executive Order 13609: Promoting International Regulatory Cooperation 77 FR 26413 (2012).

⁴¹ For more information about the Unified Agenda, see *About the Unified Agenda*, OFFICE OF INFORMATION AND REGULATORY AFFAIRS, http://www.reginfo.gov/public/jsp/eAgenda/StaticContent/UA_About.jsp (last visited Mar. 13, 2015) (The Unified Agenda provides uniform reporting of data on regulatory and deregulatory activities under development throughout the Federal Government, covering approximately 60 departments, agencies, and commissions. Each edition of the Unified Agenda includes regulatory agendas from all Federal entities that currently have regulations under development or review.)

⁴² See *How to Use the Unified Agenda*, OFFICE OF INFORMATION AND REGULATORY AFFAIRS, http://www.reginfo.gov/public/jsp/eAgenda/StaticContent/UA_HowTo.jsp (last visited Mar. 13, 2015).

⁴³ See OFFICE OF INFORMATION AND REGULATORY AFFAIRS, RegInfo.gov (last visited Mar. 13, 2015) for Federal regulatory information. The public can use this site to search the Unified Agenda of Regulatory and Deregulatory Actions and Regulatory Plan, as well as current and past OIRA regulatory reviews in accordance with Executive Order 12866: Regulatory Planning and Review 58 FR 51735 (1993).

⁴⁴ *International Regulatory Cooperation, 20 Years Later: Updating ACUS Recommendation 91-1 (19 October 2011)*, ADMINISTRATIVE CONFERENCE OF THE UNITED STATES, <http://www.acus.gov/report/international-regulatory-cooperation-final-report> (last visited Mar. 13, 2015), at 17.

⁴⁵ Unified Agenda And Regulatory Plan Search Results, <http://www.reginfo.gov/public/do/eAgendaAdvancedSearch> (last visited Mar. 13, 2015).

definition of international impact is slightly broader in the Unified Agenda, than the definition set out in the Executive Order, in that it is not limited to effects on trade. It understands “international impact” to mean “ this regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest”.⁴⁶

Based on a search of the Unified Agenda on Reginfo.gov the determination that a regulation under development has international impacts has been made across the board, by different federal departments and agencies in different policy areas. Examples, amongst many others, include the Department of Agriculture (e.g. the Farm Service Agency)⁴⁷ the Department of Commerce (e.g. the Foreign Trade Zones Board),⁴⁸ the Department of Defense,⁴⁹ Department of Energy⁵⁰ Department of Health and Human Services (e.g. the FDA’s Foreign Supplier Verification Program)⁵¹ the Department of Homeland Security,⁵² Department of Interior (e.g. Fish and Wildlife Service),⁵³ the Department of Labor (e.g. ETA),⁵⁴ the Securities and Exchange Commission,⁵⁵ Federal Trade Commission,⁵⁶ the

⁴⁶ See the records on OFFICE OF INFORMATION AND REGULATORY AFFAIRS, reginfo.gov (last visited Mar. 13, 2015).

⁴⁷ For example, *Disaster Declaration and Designation (2011)*, DEPARTMENT OF AGRICULTURE (USDA), <http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201110&RIN=0560-AH17> (last visited Mar. 13, 2015).

⁴⁸ For example, *Foreign-Trade Zones in the United States (2009)*, DEPARTMENT OF COMMERCE, <http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=200904&RIN=0625-AA81> (last visited Mar. 13, 2015).

⁴⁹ For example, *Restriction on Ball and Roller Bearings (2010)*, DEPARTMENT OF DEFENSE, <http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201004&RIN=0750-AG57> (last visited Mar. 13, 2015).

⁵⁰ For example, *Acquisition Regulation: Export Control (2013)*, DEPARTMENT OF ENERGY, <http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201304&RIN=1991-AB99> (last visited Mar. 13, 2015).

⁵¹ *Foreign Supplier Verification Program*, FDA, <http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201404&RIN=0910-AG64> (last visited Mar. 13, 2015); *Food Labeling: Revision of the Nutrition and Supplement Facts Labels (2012)*, HHS/FDA, <http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201210&RIN=0910-AF22> (last visited Mar. 15, 2015).

⁵² For example, *Authorization for Certain H-4 Dependent Spouses (2014)*, DEPARTMENT OF HOMELAND SECURITY (DHS)/USCIS, EMPLOYMENT, <http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201404&RIN=1615-AB92> (last visited Mar. 13, 2015).

⁵³ For example, *Injurious Wildlife Evaluation; Constrictor Species from Python, Boa, and Eunectes Genera*, DEPARTMENT OF INTERIOR/FISH AND WILDLIFE SERVICE, <http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=200910&RIN=1018-AV68> (last visited Mar. 13, 2015).

⁵⁴ *Wage Methodology for the Temporary Nonagricultural Employment H-2B Program (2011)*, DOL/ETA, <http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201110&RIN=1205-AB61> (last visited Mar. 13, 2015).

⁵⁵ For example, Amendments to Regulation D, Form D and Rule 156 under the Securities Act (2014), SECURITIES AND EXCHANGE COMMISSION,

Department of State (e.g. amendments to rules concerning international adoptions,⁵⁷ rules regarding au pairs,⁵⁸ or passport classification)⁵⁹ the Department of Treasury (e.g. amending existing rules concerning “African Growth and Opportunity Act and Generalized System of Preferences and Trade Benefits under AGOA,⁶⁰ or amending Customs and Border Protection Regulations that implement trade benefits for Sub-Saharan African countries contained in the African Growth and opportunity Act)⁶¹, Agency for International Development (e.g. loan guarantees to Israel,⁶² or assistance under USAID)⁶³ and many more.⁶⁴

Thus, the search function on [reginfo.gov](http://www.reginfo.gov) has definitely made it easier to search for proposed rules that have an international impact, making it easier to bring this to the awareness of third countries or foreign stakeholders. Stakeholders can then look up these proposed rules in [regulations.gov](http://www.regulations.gov) and comment on them there (we talk about that next). That said, it should be pointed out that this flagging requirement does not apply to all proposed regulations, but is limited to “significant” regulations that have ‘significant’ international impact.

<http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201404&RIN=3235-AL46> (last visited Mar. 13, 2015).

⁵⁶ For example, *Business Opportunity Rule (2011)*, DOL/ETA, <http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201110&RIN=3084-AB04> (last visited Mar. 13, 2015).

⁵⁷ *Adoptions: Regulatory Change to Clarify the Application of the Accreditation Requirement and Standards in Cases Covered by the Intercountry Adoption Universal Accreditation*, DEPARTMENT OF STATE, Act <http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201404&RIN=1400-AD45> (last visited Mar. 13, 2015).

⁵⁸ *Exchange Visitor Program – Au Pairs*, DEPARTMENT OF STATE, <http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201404&RIN=1400-AC82> (last visited Mar. 13, 2015).

⁵⁹ *Classification Symbols*, DEPARTMENT OF STATE, <http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201404&RIN=1400-AD52> (last visited Mar. 13, 2015).

⁶⁰ See OFFICE OF INFORMATION AND REGULATORY AFFAIRS, <http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201404&RIN=1515-AD47> (last visited Mar. 13, 2015).

⁶¹ OFFICE OF INFORMATION AND REGULATORY AFFAIRS, <http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201404&RIN=1515-AD50> (last visited Mar. 13, 2015). The Interim Final Rule is Department of Treasury (TREAS) Trade Benefits Under the African Growth and Opportunity Act 68 FR 13820 (2000).

⁶² *Israel Loan Guarantees Issued Under the Emergency Wartime Supplemental Appropriations Act, 2003--Standard Terms and Conditions*, AGENCY FOR INTERNATIONAL DEVELOPMENT (AID), <http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201404&RIN=0412-AA72> (last visited Mar. 13, 2015).

⁶³ Partner Vetting in USAID Assistance, AID, <http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201404&RIN=0412-AA71> (last visited Mar. 13, 2015).

⁶⁴ Unified Agenda And Regulatory Plan Search Results, OFFICE OF INFORMATION AND REGULATORY AFFAIRS, <http://www.reginfo.gov/public/do/eAgendaAdvancedSearch> (last visited Mar. 13, 2015).

In the EU the situation is different and there isn't any such "international impact" flagging requirement in the rulemaking process (though it is required in the Impact Assessment – we discuss that further below).

To the extent a proposed regulation has an international impact – what can a foreigner or third state do about it? Are they allowed to voice their concerns? In the next section we investigate whether foreigners have a say in the notice and comment procedure of the rulemaking process.

B. Foreign Participation in Notice and Comment

If foreigners and third states are concerned about a regulation being developed in the U.S. or EU, do they have access to the domestic rulemaking process? Yes they do. As will be laid out in this section, foreigners and third states are allowed to comment in the U.S. and EU notice and comment procedures.

1. The United States

In the United States, the Administrative Procedures Act (APA)⁶⁵ guarantees that interested stakeholders will have a voice in the regulatory process. The APA established the "notice and comment" rulemaking process where all proposed regulations must be published and the public is given a chance to comment. All regulations out for comment are available on www.regulations.gov, the website for all commenting on federal regulations that are out for notice and comment. The public can use this site to send their comments electronically to agencies on Federal regulations published for comment in the Federal Register. The Office of Management and Budget (OMB) Good Guidance Practices sets out a similar "notice and comment" procedure for the development of guidelines (i.e. legally non binding rules).⁶⁶

Can foreigners and third states participate in the notice and comment process? Section 553(c) of the APA determines that under notice and comment rulemaking "the agency shall give interested persons an opportunity to participate in the rule making through submission of written data views, or arguments". Neither the APA nor the courts have explicitly defined the term "interested persons". Further, Executive Order 13563 on "Improving Regulation and Regulatory Review"

⁶⁵ Administrative Procedure Act 5 U.S.C. 552 (1946).

⁶⁶ Memorandum for the Heads of Executive Departments and Agencies and Independent Regulatory Agencies: Issuance of OMB's "Final Bulletin for Agency Good Guidance Practices" M-07-07 (Jan. 18, 2007), Office of the U.S. Trade Representative and Office of Information and Regulatory Affairs, available at <http://www.whitehouse.gov/sites/default/files/omb/memoranda/2011/m11-23.pdf> (last visited Mar. 14, 2015).

(2011) which reinforced the importance of public participation in the regulatory process,⁶⁷ remained silent on the participation of foreigners or third states. Nevertheless, the U.S regulatory process has in practice been open to foreigners. As early as the 1990s, the approach was that “nothing prevents active foreign participation in regulatory decision-making. In practice, both domestic and foreign firms are afforded ample and non-discriminatory opportunities to shape the regulatory process from proposed to final rule. Foreign firms can and do make active use of these procedures.”⁶⁸

This openness towards foreigners has recently been reinforced. A 2011 United States Trade Representative (USTR) and OIRA memorandum to the Heads of Executive Departments, Agencies and Independent Regulatory Agencies entitled “Export and Trade Promotion, Public Participation, and Rulemaking” instructs that the regulatory process must be open to both domestic and foreign stakeholders.⁶⁹ It states that “consistent with Executive Order 13563, Federal agencies should provide the public with timely access to regulatory analyses and supporting documents ...as well as meaningful opportunities for comment. To that end, agencies should ...publish information online...Public access via the Internet ensures that rules, analyses, and supporting documents are available to, and allow comment by, **both domestic and foreign stakeholders**, this promoting exports and trade.”⁷⁰

In practice, while domestic stakeholders make up the lions share of commenting, foreign stakeholders have been commenting too. A search in regulations.gov – the website which houses all comments to proposed rules –demonstrates that foreign and international bodies – based physically outside of the U.S. – are commenting. (There are many multinationals or international non-profit NGOs that have arms or physical representations in the U.S., which submit comments. We do not include them here.)

⁶⁷ Sec. 2 (“Public Participation”) (stating that “Regulations shall be adopted through a process that involves public participation. To that end, regulations shall be based....on the open exchange of information and perspectives among State, local and tribal officials, experts in relevant disciplines, affected stakeholders in the private sector, and the public as a whole.”)

⁶⁸ OECD, *Regulatory Reform in the United States: Enhancing Market Openness through Regulatory Reform* (1999), 6, 10, <http://www.oecd.org/dataoecd/23/46/2756360.pdf> (last visited Mar. 14, 2015).

⁶⁹ *Memorandum for the Heads of Executive Departments and Agencies and Independent Regulatory Agencies: Export and Trade Promotion, Public Participation, and Rulemaking, M-11-23 (19 May 2011)*, OFFICE OF THE U.S. TRADE REPRESENTATIVE AND OFFICE OF INFORMATION AND REGULATORY AFFAIRS, <http://www.whitehouse.gov/sites/default/files/omb/memoranda/2011/m11-23.pdf> (last visited Mar. 14, 2015).

⁷⁰ *Id.*, 3.

Comments have been made by different kinds of foreign and international stakeholders – governments, NGOs, individuals, commercial, non –profit and academic bodies. Just to get a sense, here are several examples: On a FDA proposed rule on Food Labeling comments were submitted by an international association of scientists (International Scientific Association for Probiotics and Prebiotic)⁷¹, governments (e.g. Australian government),⁷² foreign business associations (e.g. Chileans Avocado Importers Association).⁷³ On a Fish and Wildlife Service proposed rule regarding the “Threatened Status of the African Lion”⁷⁴ comments were received from international and foreign NGOs such as PETA International Science Consortium (an international non-profit NGO for the protection of animals)⁷⁵ and Living Systems Research (a London based NGO), as well as the Czech Republic.⁷⁶ Regarding the Department of Transportation’s proposed rule on an aviation topic, comments were received by foreign aircraft carriers from South America (Avianca Carriers),⁷⁷ the Caribbean,⁷⁸ or Switzerland (Swiss Air Lines).⁷⁹ Foreign governments have also used this system

⁷¹ International Scientific Association for Probiotics and Prebiotics, *Comment Re: Docket No. FDA-2012-N-1210-0132; Proposed Rules on Food Labeling: Revision of the Nutrition and Supplement Facts Labels and Serving Sizes of Foods That Can Reasonably Be Consumed at One-Eating Occasion (30 July 2014)*, <http://www.regulations.gov/#!documentDetail;D=FDA-2012-N-1210-0318> (last visited Mar. 14, 2015).

⁷² *Comments from the Australian Government to the Government of the United States of America: Food Labeling Revision of the Nutrition and Supplement facts Labels as notified in G/TBT/N/USA/893*, <http://www.regulations.gov/#!documentDetail;D=FDA-2012-N-1210-0181> (last visited Mar. 14, 2015).

⁷³ Chileans Avocado Importers Association, *RE: Docket No. FDA-2012-N-1210 and RIN 0910-AF22. Comments on Food Labeling: Revision of the Nutrition and Supplement Facts Labels (19 August 2014)*, <http://www.regulations.gov/#!documentDetail;D=FDA-2012-N-1210-0358> (last visited Mar. 14, 2015).

⁷⁴ See for all comments: <http://www.regulations.gov/#!docketBrowser;rpp=25;po=0;dct=PS;D=FWS-R9-ES-2012-0025> (last visited Mar. 14, 2015).

⁷⁵ See also PETA International Science Consortium, *Re: Office of the Commissioner; Request for Comments on the Food and Drug Administration Fiscal Year 2014–2018 Strategic Priorities Document; Request for Comments, Docket FDA–2014–N–0833*, <http://www.regulations.gov/#!documentDetail;D=FDA-2014-N-0833-0003> (last visited Mar. 14, 2015).

⁷⁶ For a comment submitted by London based organization “Living Systems Research”, see <http://www.regulations.gov/#!documentDetail;D=FWS-R9-ES-2012-0025-2890> (last visited Mar. 14, 2015); from Czech Republic see <http://www.regulations.gov/#!documentDetail;D=FWS-R9-ES-2012-0025-0420> (last visited Mar. 14, 2015).

⁷⁷ Comments of the Avianca carriers (Colombia, El Salvador) in response to the U.S. Department of Transportation’s Notice of Proposed Rulemaking, “Transparency of Airline Ancillary Fees and Other Consumer Protection Issues,” 79 FR 29970 (May 23, 2014) (Posted on 30 September 2014), <http://www.regulations.gov/#!documentDetail;D=DOT-OST-2014-0056-0722> (last visited Mar. 14, 2015).

⁷⁸ Comments of Insel Air International and Inselair Aruba N.V. in the Matter Of Transparency of Airline Fees and Other Consumer Protection Issues (Posted on 30 September 2014), <http://www.regulations.gov/#!documentDetail;D=DOT-OST-2014-0056-0737> (last visited Mar. 14, 2015).

⁷⁹ Comments of Swiss International Airlines Ltd. In the matter of Transparency of Airline Ancillary Fees Docket No. OST-2014-0056 and Other Consumer Protection Issues (Posted 29

to comment and in 2014 alone these included, inter alia, comments from the Governments of Canada,⁸⁰ Government of South Korea,⁸¹ Honduras⁸² Japan,⁸³ and Indonesia.⁸⁴

2. The European Union

The EU has no equivalent to the APA, but the European Commission has adopted “Minimum Standards” of consultation⁸⁵ that set out guidelines which the Commission must follow in its consultations. The Commission is currently in the process of clarifying and updating the Minimum Standards and developing new “stakeholder consultation guidelines”,⁸⁶ but at the time of writing the Minimum Standards remain the most relevant document. The Commission’s Minimum Standards on consultation determine that consultations are open to all interested parties, including third countries and stakeholders within such countries. They determine that “Depending on the issues at stake, consultation is intended to provide opportunities for input from representatives of regional and local authorities, civil society organizations, undertakings and associations of undertakings, the individual citizens concerned, academics and technical experts,

September 2014), <http://www.regulations.gov/#!documentDetail;D=DOT-OST-2014-0056-0708> (last visited Mar. 14, 2015).

⁸⁰ Government of Canada Comments on the FDA’s Methodology for Identifying High Risk Foods (Posted 15 September 2014), <http://www.regulations.gov/#!documentDetail;D=FDA-2014-N-0053-0028> (last visited Mar. 14, 2015).

⁸¹ Comments from the Government of the Republic of Korea on Accreditation of Third Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue (Posted 11 September 2014), <http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0146-0137> (last visited Mar. 14, 2015).

⁸² Comments from the Government of Honduras (regarding the impact of proposed FDA regulations on premium cigars) (posted 29 August 2014), <http://www.regulations.gov/#!documentDetail;D=FDA-2014-N-0189-79285> (last visited Mar. 14, 2015).

⁸³ Comments by the Government of Japan with regard to section 156.602(e)(2) and 156.604(d) in the Centers for Medicare Medicaid Services proposed rule (posted 22 April 2014), <http://www.regulations.gov/#!documentDetail;D=CMS-2014-0036-0060> (last visited Mar. 14, 2015).

⁸⁴ Government of Indonesia, Comments on the USTR 2014 Special Review of Countries that do not Provide Adequate Protection of Intellectual Property Rights (Posted on 16 February 2014), <http://www.regulations.gov/#!documentDetail;D=USTR-2013-0040-0063> (last visited Mar. 14, 2015).

⁸⁵ European Commission, *Communication from the Commission: Towards a reinforced Culture of Consultation and Dialogue: General Principles and Minimum Standards for Consultation of Interested Parties by the Commission*, COM(2002) 704 final (11 December 2002) <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2002:0704:FIN:EN:PDF> (last visited Mar. 14, 2015).

⁸⁶ European Commission, *Stakeholder Consultation Guidelines 2014 – Public Consultation Document*, 1, http://ec.europa.eu/smart-regulation/impact/docs/scgl_pc_questionnaire_en.pdf (last visited Mar. 14, 2015).

and *interested parties in third countries*.⁸⁷ The minimum standards determine that target groups to be consulted should be “those affected by the policy” and that in determining the relevant parties for consultation, the Commission should create proper balance, inter alia, between the “organizations in the European Union and *those in non-member countries* (e.g. in the candidate or *developing countries or in countries that are major trading partners of the European Union*.”)⁸⁸

And indeed, in practice, consultations have been open to foreign and international bodies. The EU’s Transparency Register registers “all organizations and self-employed individuals engaged in activities carried out with the objective of directly or indirectly influencing the formulation or implementation of policy and decision-making processes of the EU institutions”⁸⁹ Thus, all entities commenting on EU regulations (except for public authorities)⁹⁰ are expected to register. A search of the Transparency Register reveals many listed international and foreign bodies. International organizations listed include the International Organization of Migration (IOM)⁹¹, the United Nations Human Settlements Programme,⁹² the Universal Postal Code.⁹³ Many foreign and International NGOs or think tanks and research or academic institutions are listed, including the United Nations Association of the United States Middle East,⁹⁴ a U.S. NGO based in Israel,

⁸⁷ European Commission, *Communication from the Commission: Towards a reinforced Culture of Consultation and Dialogue: General Principles and Minimum Standards for Consultation of Interested Parties by the Commission*, COM(2002) 704 final (11 December 2002), Sec. II (“Overall rationale of the Commission’s consultation process”), [http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2002:0704:FIN:EN:PDF_\(last visited Mar. 14, 2015\)](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2002:0704:FIN:EN:PDF_(last%20visited%20Mar.14,2015)).

⁸⁸ European Commission, *Communication from the Commission: Towards a reinforced Culture of Consultation and Dialogue: General Principles and Minimum Standards for Consultation of Interested Parties by the Commission*, COM(2002) 704 final (11 December 2002), Sec. B (“Consultation Target Groups”), [http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2002:0704:FIN:EN:PDF_\(last visited Mar. 14, 2015\)](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2002:0704:FIN:EN:PDF_(last%20visited%20Mar.14,2015)).

⁸⁹ European Parliament and European Commission, *Transparency Register – Frequently Asked Questions* (Version 2, 4 October 2012), Sec. 2, <http://ec.europa.eu/transparencyregister/info/your-organisation/faq.do?locale=en> (last visited Mar. 14, 2015).

⁹⁰ European Parliament and European Commission, *Transparency Register – Frequently Asked Questions* (Version 2, 4 October 2012), Sec. 8, <http://ec.europa.eu/transparencyregister/info/your-organisation/faq.do?locale=en> (last visited Mar. 14, 2015).

⁹¹ *Transparency Register, EUROPEAN UNION*, <http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=14074813668-09> (last visited Mar. 14, 2015).

⁹² *Transparency Register, EUROPEAN UNION*, <http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=48501899660-66> (last visited Mar. 14, 2015).

⁹³ *Transparency Register, EUROPEAN UNION*, <http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=81947973709-24> (last visited Mar. 14, 2015).

⁹⁴ *Transparency Register, EUROPEAN UNION*, <http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=653759214387-79> (last visited Mar. 14, 2015).

Waste Management Norway, a Norwegian NGO,⁹⁵ the American Pontifical Catholic University,⁹⁶ the Asian Social Institute, a research centre based in the Philippines.⁹⁷ Assembly of Scientists and Experts of Afghanistan, Drugs for Neglected Diseases Initiative (DNDi),⁹⁸ the Global CCS Institute, a NGO based in Australia,⁹⁹ Global Research Alliance, an Indian NGO,¹⁰⁰ the International Institute for Sustainable Development, a NGO based in Geneva,¹⁰¹ South Centre, a NGO based in Geneva,¹⁰² the Canadian Health Sciences Institute,¹⁰³ the Israeli Center for Assistive Technology and Aging¹⁰⁴ Universum Academy Switzerland,¹⁰⁵ WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies at Health Economics Department of Gesundheit Österreich GmbH (Austrian Health Institute)¹⁰⁶, the African Diplomatic

⁹⁵ *Transparency Register, EUROPEAN UNION,*
<http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=479517112355-55> (last visited Mar. 14, 2015).

⁹⁶ *Transparency Register, EUROPEAN UNION,*
<http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=161655011700-04> (last visited Mar. 14, 2015).

⁹⁷ *Transparency Register, EUROPEAN UNION,*
<http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=168024811535-96>
 and
<http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=593340211015-96> (last visited Mar. 14, 2015).

⁹⁸ *Transparency Register, EUROPEAN UNION,*
<http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=66666589895-96> (last visited Mar. 14, 2015).

⁹⁹ *Transparency Register, EUROPEAN UNION,*
<http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=378142414263-73> (last visited Mar. 14, 2015).

¹⁰⁰ *Transparency Register, EUROPEAN UNION,*
<http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=613866814651-58> (last visited Mar. 14, 2015).

¹⁰¹ *Transparency Register, EUROPEAN UNION,*
<http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=737088911290-60> (last visited Mar. 14, 2015).

¹⁰² *Transparency Register, EUROPEAN UNION,*
<http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=36929146308-92> (last visited Mar. 14, 2015).

¹⁰³ *Transparency Register, EUROPEAN UNION,*
<http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=12118929197-69> (last visited Mar. 14, 2015).

¹⁰⁴ *Transparency Register, EUROPEAN UNION,*
<http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=34131776858-24> (last visited Mar. 14, 2015).

¹⁰⁵ *Transparency Register, EUROPEAN UNION,*
<http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=543788113294-07>

¹⁰⁶ *Transparency Register, EUROPEAN UNION,*
<http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=54082565857-79> (last visited Mar. 14, 2015).

Academy,¹⁰⁷ Action for Green Earth, an Indian NGO,¹⁰⁸ American Diplomatic Mission for World Peace, an American NGO¹⁰⁹ and so forth.

The webpage “Your Voice in Europe” is the commenting platform for all EU policy proposals. All consultations are published there. A search through comments that are publicly available on the website reveals that while most comments are submitted by EU stakeholders, foreigners and international bodies submit comments too. For example comments on the Commissions’ consultation regarding the ‘Paper on the Setting of Maximum and Minimum Amounts for Vitamins and Minerals in Foodstuffs’,¹¹⁰ received comments from ASEAN¹¹¹ Turkish Manufacturers¹¹² U.S trade associations,¹¹³ and South African trade associations,¹¹⁴ Comments are also being submitted by global bodies. In its consultation regarding responsible sourcing of minerals originating from conflict areas¹¹⁵ the Commission received comments from manufacturers and trade associations from the U.S., and businesses from Congo, Rwanda and

¹⁰⁷ *Transparency Register, EUROPEAN UNION,*
<http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=7769830145-83>
(last visited Mar. 14, 2015).

¹⁰⁸ *Transparency Register, EUROPEAN UNION,*
<http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=200422813062-07>
(last visited Mar. 14, 2015).

¹⁰⁹ *Transparency Register, EUROPEAN UNION,*
<http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=484297511523-62>
(last visited Mar. 14, 2015).

¹¹⁰ European Commission Health and Consumers, *Food Supplements – Responses to the Discussion Paper on the Setting of Maximum and Minimum Amounts for Vitamins and Minerals in Foodstuffs*,
http://ec.europa.eu/food/food/labellingnutrition/supplements/resp_discus_paper_amount_vitamins.htm
(last visited Mar. 14, 2015).

¹¹¹ ASEAN Alliance of Health Supplement Associations (AAHSA) *Comments on Discussion Paper on the Setting of Maximum and Minimum Amounts for Vitamins and Minerals in Foodstuffs* (28 September 2006),
http://ec.europa.eu/food/food/labellingnutrition/supplements/documents/aahsa_en.pdf (last visited Mar. 14, 2015).;

¹¹² Besbesder, *Comments from Besbesder: Discussion Paper on the Setting of Maximum and Minimum Amounts for Vitamins and Minerals in Foodstuffs*,
http://ec.europa.eu/food/food/labellingnutrition/supplements/documents/besbesder_en.pdf (last visited Mar. 14, 2015).

¹¹³ *Comment by Council for Responsible Nutrition,*
http://ec.europa.eu/food/food/labellingnutrition/supplements/documents/crn_en.pdf (last visited Mar. 14, 2015).

¹¹⁴ *Comments from Health Products Association of Southern Africa, Paper on the Setting of Maximum and Minimum Amounts for Vitamins and Minerals in Foodstuffs* (June 2006),
http://ec.europa.eu/food/food/labellingnutrition/supplements/documents/hpa_en.pdf (last visited Mar. 14, 2015).

¹¹⁵ European Commission Trade – Consultations, *Public Consultation on a Possible EU Initiative on Responsible Sourcing of Minerals Originating from Conflict-Affected and High-Risk Areas*,
http://trade.ec.europa.eu/consultations/index.cfm?consul_id=174 (last visited Mar. 14, 2015).

Switzerland.¹¹⁶ On EU drug policy¹¹⁷ the Commission received comments from international NGOs such as the International Drug Policy Consortium¹¹⁸ or the World Federation Against Drugs.¹¹⁹ Or the International Baby Food Action Network (IBFAN) an international NGO, submitted comments regarding the Commission's consultation regarding the revision of its directive on infant formulae.¹²⁰ And during the consultation regarding the 2014 revision of the Commission's impact assessment guidelines the Commission received comments from individuals from Tunisia¹²¹ as well as the U.S. government.¹²² Foreigners have also been able to comment in the guideline development process. For example, the European Medicines Agency (EMA) Guideline Development Procedures opens the procedure to foreigners.¹²³

Thus, to conclude, it is now common in the U.S. and EU for notice and comment processes to be open towards foreigners and third states. We next take a look at Regulatory Impact Assessments and how impacts on third states and foreigners are considered there.

4. Regulatory Impact Assessment: Background

It is now common in many OECD countries to conduct as part of the rulemaking process a Regulatory Impact Assessment (often also referred to as Impact Analysis—henceforth we refer to both as “RIA”) in the development of

¹¹⁶ *European Commission DGIT – IPM*, <http://ec.europa.eu/yourvoice/ipm/forms/dispatch?userstate=DisplayPublishedResults&form=EuM> in (last visited Mar. 14, 2015).

¹¹⁷ European Commission DG Justice, Public Consultation on the Communication, *Towards a Stronger European Response to Drugs (3 March 2012)*, http://ec.europa.eu/justice/newsroom/anti-drugs/opinion/111027_en.htm (last visited Mar. 14, 2015).

¹¹⁸ International Drug Policy Consortium, *IDPC Response to the European Commission Consultation on Communication “Towards a Stronger European Response to Drugs”*, http://ec.europa.eu/justice/newsroom/anti-drugs/opinion/files/contributions_110227/ngo/idpc_en.pdf (last visited Mar. 14, 2015).

¹¹⁹ World Federation Against Drugs, *European Commission Public Consultation on the Communication “Towards a Stronger European Response to Drugs”*, http://ec.europa.eu/justice/newsroom/anti-drugs/opinion/files/contributions_110227/ngo/wfad_en.pdf (last visited Mar. 14, 2015).

¹²⁰ European Commission Health and Consumers, *Consultation: Revision of Commission Directive 91/321/EEC on infant formulae and follow – on formulae*, http://ec.europa.eu/food/consultations/comments_en.htm (last visited Mar. 14, 2015).

¹²¹ Hella Ben Brahim Neji (Tunisia), *Comments for the Impact Assessment Consultation Guidelines*, http://ec.europa.eu/smart-regulation/impact/docs/contributions/o_ben_brahim_ia_en.pdf (last visited Mar. 14, 2015).

¹²² *Comments of the United States Government on the 2014 Revision of Commission Impact Assessment Guidelines – Public Consultation Document (30 September 2014)*, http://ec.europa.eu/smart-regulation/impact/docs/contributions/o_usa_ia_en.pdf (last visited Mar. 14, 2015).

¹²³ Ayelet Berman, *The Role of Domestic Administrative Law in the Accountability of IN-LAW: The Case of the ICH*, *INFORMAL INTERNATIONAL LAWMAKING*, 468-499 (J. Pauwelyn, R. Wessel, J. Wouters eds., Oxford, University Press, 2012).

significant regulation.¹²⁴ In addition to the notice and comment procedure (which apply in the development of any kind of regulation), RIA is a tool that is used at the early stage of the policy circle, when *significant* regulatory proposals are being developed. The goal of the RIA is to ensure that the proposed regulation is being prepared on the basis of comprehensive and balanced evidence on the nature of the problem addressed, the added value of regulatory action and the costs and benefits of alternative course of action.¹²⁵ By conducting such *ex ante* analysis of likely impacts of regulatory actions, and helping policy makers to consider the best regulatory approaches, it improves the quality of the policy.¹²⁶

In this section we focus on RIAs in the U.S. and EU, and the extent to which they take impacts on third states and foreigners into account, as well as the role foreigners have in the RIA process. Before looking at these issues in more detail, it is important to understand, as already pointed out above, that there are differences in the legislative and regulatory process between the U.S. and the EU. These differences are important for understanding the different approaches to RIAs. Due to the differences in the systems, RIAs are produced at different stages in the process. We next provide a general overview of the different approaches to RIAs in the U.S. and the EU.

A. United States

For what kind of regulatory proposals are RIA's carried out?

RIA's are carried out for all "economically significant" rules issued by non-independent agencies within the Executive Branch of the U.S. Federal government. "Economically significant" rules is understood, generally, as a rule that has an effect of \$100 million or more on the economy in any one year, or adversely affects in a material way the economy.¹²⁷ Thus, and this should be kept in mind, not all regulations in the U.S. are accompanied by a RIA.

What is the legal framework for RIAs?

The basic legal framework on RIAs is set out in OMB Circular A-4 and the Executive Order (EO) 12866 of 1993 on 'Regulatory Planning and Review',

¹²⁴ Office of Management and Budget, Office of Information and Regulatory Affairs, *2006 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities* (2006), *supra*.

¹²⁵ *2014 Revision of the European Commission Impact Assessment Guidelines – Public Consultation Document*, 2, http://ec.europa.eu/smart-regulation/impact/docs/iag_pc_questionnaire_en.pdf (last visited Mar. 14, 2015).

¹²⁶ OECD, *Recommendation of the Council on Regulatory Policy and Governance* (2012), *supra* at 25.

¹²⁷ Sec. 3(f)(1), Executive Order 12866: Regulatory Planning and Review 58 FR 51735 (1993); Office of Management and Budget, Office of Information and Regulatory Affairs, *2006 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities* (2006), *supra* at 73.

which set out the basic criteria against which RIAs are required. Executive Order 12866 requires federal agencies to implement laws or primary legislation “in the most cost-beneficial way”. Specifically, it requires executive branch agencies to assess all costs and benefits of available regulatory alternatives, and select the approach that maximizes net benefits. Circular A-4 applies RIAs to “economically significant” proposed and final rules.¹²⁸ In 2011 President Obama signed Executive Order 13563 “Improving Regulation and Regulatory Review” which adds to the legal basis for RIAs. It reinforces that agencies “must choose among alternative regulatory approaches, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity).”¹²⁹

Several U.S. laws also require impact assessment in specific contexts. For example, the National Environmental Policy Act of 1969¹³⁰ requires federal agencies to consider the environmental impacts of their proposed regulatory actions and reasonable alternatives to those actions. To meet this requirement, federal agencies prepare an Environmental Impact Statement (EIS).¹³¹

What is the nature of the RIA?

The essence of the RIA consists of a cost-benefit analysis. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives, and when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). International impacts also need to be taken into account (we discuss that separately below). The RIA takes all such impacts into account but integrates them within a *cost-benefit analysis* or cost-effectiveness analysis.¹³² All impacts are *quantified and monetized* into an overall assessment of costs and benefits of the proposed and alternative regulation proposals. That said, it has been acknowledged that there are benefits and costs that are difficult, if not impossible, to monetize. Such costs and benefits are also taken into account.¹³³

¹²⁸ *Id.*

¹²⁹ Sec. 1(b), Executive Order 13563: Improving Regulation and Regulatory Review 76 FR 3821 (2011).

¹³⁰ National Environmental Policy Act 1969, Pub. L. No. 91-190, as amended, 42 U.S.C. §§ 4321-4347.

¹³¹ The Regulatory Flexibility Act 1980, 5 U.S.C. 601-612, the Unfunded Mandates Reform Act 1995, 2 U.S.C. 25, the Paperwork Reduction Act 1980, 44 U.S.C. §§ 3501–3521 also set out specific RIA requirements.

¹³² Office of Management and Budget, Office of Information and Regulatory Affairs, *2006 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities* (2006), *supra*.

¹³³ Circular A-4 says that officials should use their professional judgment in deciding whether there are significant non-quantifiable costs and benefits that could change the outcome of the analysis based on what is quantifiable; Executive Order 13563: Improving Regulation and

B. European Union

For what kind of proposals are RIA's carried out?

RIAs are carried out for a broad range of policy proposals in the European Commission. They are prepared for Commission initiatives that are expected to have significant direct economic, social or environmental impacts. These can be legislative proposals,¹³⁴ non-legislative initiatives¹³⁵ which define future policies, implementing measures and delegated acts¹³⁶ As regards legislative initiatives, the most common procedure for adopting legislation is the co-decision procedure. According to this procedure, the European Commission puts forward a legislative proposal before the European Parliament and the Council. Since the Commission initiates the legislation, it produces the Impact Assessments before the proposal gets examined by the Parliament and Council.

What is the legal framework for RIAs?

The EU's impact assessment system is based on political commitments made by the Commission in a range of documents, e.g. the Lisbon Agenda (2000), the Gothenburg Council Conclusions, the White Paper on Governance and the Sustainable Development Strategy the New Initiative for Growth and Jobs (2005), and the Interinstitutional 'Common Approach to Impact Assessment' (2005) between the Commission, the Council and the European Parliament. The specific guidelines are set out in the European Commission's Impact Assessment Guidelines which were first issued in 2002, but have been revised and extended in 2005, and then again in 2009. Overall the RIA process has undergone strengthening over the years with the revision of guidelines and the establishment of the IA Board in 2006.

What is the nature of the RIA?

The RIA consist of assessing three types of impacts: economic, social and environmental, and gives equal consideration to each of these impacts. Rather than quantifying the costs and benefits (as is the case in the U.S.), the purpose is

Regulatory Review 76 FR 3821. Sec. 1(a) says that our regulatory system must "take into account benefits and costs, both quantitative and qualitative". Sec 1(c) provides: "In applying these principles, each agency is directed to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible. Where appropriate and permitted by law, each agency may consider (and discuss qualitatively) values that are difficult or impossible to quantify, including equity, human dignity, fairness, and distributive impacts."

¹³⁴ Those included in the Commission Legislative and Work Programme (CLWP) as well as those which are not

¹³⁵ Such as White Papers, Action Plans, expenditure programmes and negotiating guidelines for international agreements.

¹³⁶ European Commission, *Impact Assessment Guidelines (15 January 2009)*, available at http://ec.europa.eu/smart-regulation/impact/commission_guidelines/docs/iag_2009_en.pdf (last visited Mar. 14, 2015).

to clearly identify impacts in each of these pillars, and to show any likely trade offs between them. International impacts need also be assessed – and we talk about that separately below.

We next take a closer look at the assessment of international impacts in the RIAs. First in the U.S. and then in the EU.

5. Assessing International Impacts in RIAs

RIAs were first introduced in the 1990's. The economy being still domestically focused, the legal framework in both the U.S. and EU does not make much, if at all, mention to international impacts. Nevertheless, in practice, international effects, at least to some extent, were assessed. In the past decade or so this is changing and the assessment of international effects is becoming an increasingly important aspect of RIAs in the U.S. and EU. As we shall see below, in both the U.S. and EU it is now common to assess international impacts as part of the RIAs.

A. Assessing International Impacts in U.S. RIAs

1. Until 2008

The basic legal framework for RIAs, as mentioned above, is set out in Executive Order 12866 (Regulatory Review and Planning) of 1993 and OMB Circular A-4, as well as EO 13563 (Improving Regulation and Regulatory Review) of 2011. In promulgating a new economically significant regulation, agencies are directed to assess the costs and benefits of regulatory alternatives and select the alternative that maximizes net benefits.¹³⁷

EO 12866 was issued in 1993 and as such is largely directed towards domestic impacts of regulation, but it has been understood as requiring agencies to consider international trade impacts for economically significant rules:¹³⁸ Section 6(a)(3)(C)(ii) states that agencies, for economically significant regulatory actions,¹³⁹ have an obligation to provide an assessment of “any adverse effects on the efficient functioning of the economy, private markets (including productivity, employment, and competitiveness) health, safety, and the natural environment),

¹³⁷ Office of Management and Budget and the Secretariat General of the European Commission, *Review of the Application of EU and US Regulatory Impact Assessment Guidelines on the Analysis of Impacts on International Trade and Investment – Final Report and Conclusions* (May 13, 2008), 11, available at http://ec.europa.eu/smart-regulation/impact/key_docs/docs/joint_paper_sg_oira_050808.pdf (last visited Mar. 14, 2015).

¹³⁸ *Id.*

¹³⁹ As defined in Sec. 3(f)(1), Executive Order 12866: Regulatory Planning and Review 58 FR 51735 (1993).

together with, to the extent feasible, a quantification of these costs”.¹⁴⁰ International trade being a key component of the efficient functioning of private markets, the OMB has considered agencies as having an obligation to consider trade impacts in their RIAs of economically significant rules.¹⁴¹

OMB Circular A-4, issued in 2003 further elaborated on these requirements of EO 12866 for economically significant regulations. It states that “The role of the Federal Government in facilitating U.S participation in global markets should be considered...Concerns that new U.S. rules could act as non-tariff barriers to imported goods should be evaluated carefully.”¹⁴² It also states that “Where you choose to evaluate a regulation that is likely to have effects beyond the borders of the United States, these effects should be reported separately.”¹⁴³ Circular A-4, however, did not set out clear instructions as to how to consider the international trade and investment effects of U.S. regulation.

Further, Circular A-4 states that an IA “should focus on benefits and costs that accrue to citizens and residents of the United States.”¹⁴⁴ Analyzing the impact on foreign entities outside of the U.S. is, hence, not required by the Circular. Finally, Executive Order 13563 also does not mention explicitly international effects or effects on third countries.

Nevertheless, even in the absence of clear instructions, acknowledging that many impacts on foreign entities are passed on to the U.S. economy such impacts have been taken into account.¹⁴⁵ If a regulation increases the cost of importing a product, and this raises domestic prices, the costs to domestic consumers or producers would be considered in the IA; or generally if the rule would impose a cost on foreign entities that would be felt on the U.S. economy. Therefore, an analysis of the direct costs on foreign entities has been often used as a proxy of the costs on the U.S. economy, and so many IAs incorporate that¹⁴⁶

¹⁴⁰ Executive Order 12866: Regulatory Planning and Review 58 FR 51735 (1993) (as amended by Executive Order 13422, 72 FR 14 (2007)).

¹⁴¹ Office of Management and Budget and the Secretariat General of the European Commission, *Review of the Application of EU and US Regulatory Impact Assessment Guidelines on the Analysis of Impacts on International Trade and Investment – Final Report and Conclusions*, supra.

¹⁴² *Id.*, at 6.

¹⁴³ *Id.*, at 15.

¹⁴⁴ Circular A-4 (17 September 2003), p. 15.

¹⁴⁵ Office of Management and Budget and the Secretariat General of the European Commission, *Review of the Application of EU and US Regulatory Impact Assessment Guidelines on the Analysis of Impacts on International Trade and Investment – Final Report and Conclusions*, supra. Office of Management and Budget, Office of Information and Regulatory Affairs, *2006 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities*, supra at 78.

¹⁴⁶ Office of Management and Budget and the Secretariat General of the European Commission, *Review of the Application of EU and US Regulatory Impact Assessment Guidelines on the Analysis*

For example, the U.S. Federal Aviation Administration (FAA) proposed in 2005 a rule that would require operators and manufacturers of airplanes in operation in the U.S. to make certain technical adjustments in their fuel tanks.¹⁴⁷ The direct regulatory impact on Airbus, a foreign manufacturer, was estimated at about \$436 million as, among others, Airbus' production costs would increase. The FAA did not perform a separate analysis of the trade impacts of this regulation, but did assume that such costs were direct costs of the regulation to be compared against benefits.¹⁴⁸ In another case the U.S. Customs and Border Protection of the Department of Homeland Security proposed a rule that would affect U.S. and non-U.S. aircraft carriers and considered the costs to non-U.S. carriers.¹⁴⁹ In another case the FDA proposed a regulation that required domestic and foreign facilities that deal with food intended for human and animal consumption in the U.S. to register with the FDA.¹⁵⁰ In the RIA, the FDA assessed the costs it would impose on foreign facilities.¹⁵¹ A final example is a proposed rule by the U.S. Department of Agriculture that applied phytosanitary measures on Mexican avocado growers seeking to export to the U.S.¹⁵² It was assessed that the costs related to these measures would be small and not significantly influence the supply or price of Mexican avocados.

of Impacts on International Trade and Investment – Final Report and Conclusions, supra at 13; Office of Management and Budget, Office of Information and Regulatory Affairs, *2006 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities, supra* at 78.

¹⁴⁷ U.S. Federal Aviation Administration (FAA), Reduction of Fuel Tank Flammability in Transport Category Airplanes, Proposed Rule, 71 FR 70921 (2005).

¹⁴⁸ Office of Management and Budget and the Secretariat General of the European Commission, *Review of the Application of EU and US Regulatory Impact Assessment Guidelines on the Analysis of Impacts on International Trade and Investment – Final Report and Conclusions, supra* at 18.

¹⁴⁹ U.S. Customs and Border Protection of the Department of Homeland Security, Advance Electronic Transmission of Passenger and Crew Member Manifests for Commercial Aircraft and Vessels 72 FR 48319 (2007); Office of Management and Budget and the Secretariat General of the European Commission, *Review of the Application of EU and US Regulatory Impact Assessment Guidelines on the Analysis of Impacts on International Trade and Investment – Final Report and Conclusions, supra* at 20.

¹⁵⁰ U.S. Food and Drug Administration (FDA), Registration of Food Facilities under the Public Health Security and Bioterrorism Preparedness and Response Act, Interim Final Rule, 68 FR 58894 (2003).

¹⁵¹ FDA: Registration of food facilities under the Public Health and Security and Bioterrorism Preparedness and Response Act, Interim Final Rule 66 FR 58894; Office of Management and Budget and the Secretariat General of the European Commission, *Review of the Application of EU and US Regulatory Impact Assessment Guidelines on the Analysis of Impacts on International Trade and Investment – Final Report and Conclusions, supra* at 22.

¹⁵² U.S. Department of Agriculture (USDA), Mexican Hass Avocado Import Program, 69 FR 69748 (2004).

In addition, U.S. agencies also normally consider whether a proposed rule is in line with U.S. international obligations (e.g. with the Convention on International Civil Aviation, or with WTO and NAFTA Agreements).¹⁵³

Thus, in practice, while the legal framework does not mention international impacts, in practice, agencies have assessed two types of international impacts: Impacts on foreign entities in terms of the costs the proposed regulation incurred on them, as well as whether the regulation complies with international legal obligations.

2. After 2008

In 2008 the U.S. and EU agreed to modify their respective RIAs, to better incorporate international trade impacts into their impact assessments. They issued a joint report entitled the ‘Review of the Application of EU and US Regulatory Impact Assessment Guidelines on the Analysis of Impacts on International Trade and Investment’ (The 2008 U.S. – EU Report).¹⁵⁴ The background to their understanding was that “As explicit barriers, such as tariffs, to international trade fall, in an increasingly global marketplace, domestic policies are more likely to affect trading partners. Because of this, OMB and the European Commission are considering whether our respective regulatory analysis approaches should be modified to better incorporate international trade impacts into the analysis of regulation. An evaluation of the effect of regulation on trade may help to ensure that regulatory policy does not become a tool for establishing unnecessary barriers to trade.”¹⁵⁵

Following this report and in view of implementing the understandings, the OIRA issued a memorandum to the agencies that provides new guidance as to how agencies should analyze the international effects of regulation in RIAs.¹⁵⁶ The memorandum defines ‘international effects’ in a narrow fashion, as effects on ‘international trade and investment’. It states that agencies should consider effects of domestic regulation on international trade and investment as part of the

¹⁵³ U.S. Federal Aviation Administration (FAA), Reduction of Fuel Tank Flammability in Transport Category Airplanes, Proposed Rule, 71 FR 70921 (2005); U.S. Food and Drug Administration (FDA), Registration of Food Facilities under the Public Health Security and Bioterrorism Preparedness and Response Act, Interim Final Rule, 68 FR 58894 (2003).

¹⁵⁴ Office of Management and Budget and the Secretariat General of the European Commission, *Review of the Application of EU and US Regulatory Impact Assessment Guidelines on the Analysis of Impacts on International Trade and Investment – Final Report and Conclusions*, *supra*.

¹⁵⁵ *Id.*, at 14.

¹⁵⁶ Office of Management and Budget, Office of Information and Regulatory Affairs, *2006 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities* (2006), *supra* at 72 (A separate guidance to incorporate guidance with respect to the obligations of agencies to consider international impacts has not been developed, and the OMB considers the memorandum to be sufficient to lie out the obligation).

IA.¹⁵⁷ And so while the EO 12866 and Circular A-4 do not mention international impacts expressly, the 2008 OMB memorandum guides agencies how they should incorporate trade impacts into the RIA.¹⁵⁸

As regards how to technically assess the impact in terms of costs and benefits, it determines that agencies should consider international trade as a “private market where economic exchange takes place across national boundaries.”¹⁵⁹ “Just as a regulation may impose costs on private domestic markets, a regulation may have the effect of interfering with, and shrinking, the level of international trade. Since this aspect of regulation is presumptively harmful to overall economic welfare in each nation, the size of this harmful effect should be considered in regulatory analysis and compared, along with other regulatory costs, to the benefits generated by the regulation to determine whether regulations maximize the net benefits to society.” When considering how this cost should be considered, the 2008 OMB memorandum refers back to Circular A-4 that states that the analysis “should focus on benefits and costs that accrue to citizens and residents of the United States.” It then goes on to demonstrate how a trade impact could lead to impact on US citizens (such as in the examples mentioned above).¹⁶⁰

It further states that where a regulation may have a significant effect on international trade and investment, existing international standards or regulatory approaches, if applicable, should be analyzed as an explicit regulatory alternative. This is also consistent with the requirements established by OMB Circular A-119 and the National Technology Transfer and Investment Act, which require US agencies to evaluate and consider private sector standards, including international standards, as one alternative when developing regulations.¹⁶¹

In 2011 further developments took place. Following the Executive Order on Promoting International Regulatory Cooperation, a second OIRA memorandum was issued in which it instructs that when “effects, including adverse effects on the ability of American *companies to compete in domestic and foreign markets* are reasonably anticipated, agencies should provide a publicly available assessment.”¹⁶²

¹⁵⁷ *Id.*, at iv, 70.

¹⁵⁸ *Id.*, at 71.

¹⁵⁹ *Id.*

¹⁶⁰ *Id.*, 72-73.

¹⁶¹ *Id.*, 73.

¹⁶² Office of the U.S. Trade Representative and Office of Information and Regulatory Affairs, *Memorandum for the Heads of Executive Departments and Agencies and Independent Regulatory Agencies: Export and Trade Promotion, Public Participation, and Rulemaking, M-11-23 (19 May 2011)*, *supra* at 2.

To conclude this point, OIRA has now expressly instructed the agencies to assess international impacts. However, it is limited in that it essentially focuses on two specific kinds of impacts: *impacts on international trade and investment*, and *impacts on international obligations* (and not any kind of impact, say of an economic, social or environmental impact on foreigners or third states as is the case in the EU –see the discussion below). Moreover, in quantifying the effect, it ultimately narrows it down to *quantifying how the impact on international trade will ultimately impact U.S citizens/residents and businesses* (rather than how it will effect foreigners *per se*). Thus, the IA remains, ultimately, interested in the costs and benefits that accrue to the U.S..

We next take a look at how international impacts are assessed in the EU RIAs.

B. Assessing International Impacts in EU RIAs: Background

The RIA system in the EU has been gradually strengthened in the past decade. As part of this process, the assessment of international effects has also, gradually, received much more attention. We distinguish between two main periods: 2002 through 2009, and 2009 and onwards.

I. 2002-2009

The IA guidelines were introduced in 2002 and consisted of assessing three types of impacts: economic, social and environmental impacts. With the revision of the IA guidelines in 2005, assessment of international effects received much more attention. In 2005 they were revised in a manner that strengthened the assessment of economic effects, especially in the context of global economic relations:¹⁶³ The revised Guidelines required that all impacts be assessed, irrespective of where they are likely to materialize or whom they are likely to affect. They also specifically required that “*impacts on international trade and relations*”, as well as “*impacts on third countries or international agreements*” be taken into account.¹⁶⁴ Among other things, this required an assessment of whether the policy proposal places EU companies at an advantage or disadvantage vis-à-vis non –EU competitors, or how trade and investment will be affected.

In practice, since the introduction in 2005 of the requirement to assess international impacts, the EU has indeed been assessing these impacts more and

¹⁶³ Office of Management and Budget and the Secretariat General of the European Commission, *Review of the Application of EU and US Regulatory Impact Assessment Guidelines on the Analysis of Impacts on International Trade and Investment – Final Report and Conclusions*, *supra* at 4.

¹⁶⁴ Annex to *European Commission Impact Assessment Guidelines* at p. 29, 33

more rigorously,¹⁶⁵ and there has been a growing awareness of the need to assess the international effects of policy proposals.¹⁶⁶ The Impact Assessment Board, set up in 2006 (whose role is to review draft IAs), has also emphasized the need to strengthen the analysis of international impacts.¹⁶⁷

The Impact Assessments have in particular taken two kinds of effects into account: effects on international trade (e.g. effects on third countries' exports),¹⁶⁸ and compliance with international obligations (e.g. whether in compliance with WTO rules).¹⁶⁹

2. 2009- to date

In 2009, and following its 2008 understanding with the U.S. alluded to above, the EU revised its Impact Assessment Guidelines in 2009 (The 2009 IA Guidelines).¹⁷⁰ The revised guidelines strengthen the importance of assessing international effects as part of the RIA process. The goal of the revision has been to ensure that in the assessment of future regulations, due account of international impacts be taken.¹⁷¹ The Guidelines now determine that: "The IA report should reflect how and to what extent the evaluation of international impacts has been

¹⁶⁵ Office of Management and Budget and the Secretariat General of the European Commission, *Review of the Application of EU and US Regulatory Impact Assessment Guidelines on the Analysis of Impacts on International Trade and Investment – Final Report and Conclusions*, *supra*, at 6.

¹⁶⁶ European Commission impact assessments are available at http://ec.europa.eu/smart-regulation/impact/index_en.htm (last visited Mar. 14, 2015).

¹⁶⁷ Office of Management and Budget and the Secretariat General of the European Commission, *Review of the Application of EU and US Regulatory Impact Assessment Guidelines on the Analysis of Impacts on International Trade and Investment – Final Report and Conclusions*, *supra* at 6.

¹⁶⁸ European Commission, *Commission Staff Working Paper – Tobacco Regime – Extended Impact Assessment* (COM (2003) 554final SEC(2003)) 1023 (23 September 2003), available at http://ec.europa.eu/smart-regulation/impact/ia_carried_out/docs/ia_2003/sec_2003_1023_en.pdf (last visited Mar. 14, 2015).

¹⁶⁹ European Commission, *Commission Staff Working Document Accompanying document to the Proposal for a Directive of the European Parliament and of the Council on the Coordination of Procedures for the Award of Certain Public Work Contracts, Public Supply Contracts and Public Service Contracts in the Fields of Defense and Security – Impact Assessment* (COM(2007) 766 final SEC(2007) 1599, SEC(2007) 1598) (5 December 2007), available at http://ec.europa.eu/smart-regulation/impact/ia_carried_out/docs/ia_2007/sec_2007_1598_en.pdf (last visited Mar. 14, 2015); European Commission, *Commission Staff Working Paper Accompanying Document to the Proposal for a Directive of the European Parliament and of the Council on the Coordination of Procedures for the Award of Certain Public Work Contracts, Public Supply Contracts and Public Service Contracts in the Fields of Defense and Security – Summary of the Impact Assessment* (COM(2007) 766 final SEC(2007) 1598), available at [http://www.europarl.europa.eu/registre/docs_autres_institutions/commission_europeenne/sec/2007/1599/COM_SEC\(2007\)1599_EN.pdf](http://www.europarl.europa.eu/registre/docs_autres_institutions/commission_europeenne/sec/2007/1599/COM_SEC(2007)1599_EN.pdf) (last visited Mar. 14, 2015).

¹⁷⁰ Office of Management and Budget and the Secretariat General of the European Commission, *Review of the Application of EU and US Regulatory Impact Assessment Guidelines on the Analysis of Impacts on International Trade and Investment – Final Report and Conclusions*, *supra*.

¹⁷¹ *Id.*, at 2.

taken into account in the comparison of options.” The Commission is currently in the process of updating the IA Guidelines and new guidelines are expected soon.

The focus, in assessing international impacts, is on impacts on international trade and investment (including impacts on international obligations), and impacts on developing countries: The Guidelines determine that “Every IA should establish whether proposed policy options have an impact on relations with third countries. In particular they should look at: the competitiveness of European businesses; trade relations with third countries – some policies may affect trade or investment flows between the EU and third countries; the IA should analyze how different groups (foreign and domestic businesses and consumers) are affected; impact on WTO obligations; impacts on developing countries – initiatives that may affect developing countries should be analyzed for their coherence with the objectives of the EU development policy. This includes an analysis of consequences (or spill overs) in the longer run in areas such as economic, environmental, social or security policy.”¹⁷²

We next look at the specific instructions set out in the 2009 IA Guidelines with respect to the assessment of impacts on international trade and investment, and impacts on developing countries.¹⁷³

C. EU RIAs: Impact on International Trade and Investment and on Developing Countries

1. Impact on International Trade and Investment

In assessing the impact on International Trade and Investment, the 2009 IA Guidelines require to assess the impact on international trade and investment in the EU, third states and foreigners outside of the EU. The main concern in assessing the economic impact of the proposal is whether/what effect this impact will have on EU competitiveness in comparison with foreign countries and enterprises.¹⁷⁴ Accordingly, the 2009 IA Guidelines suggest posing questions such as: How does the option affect trade or investment flows between the EU and third countries? Does the option affect specific groups (foreign and domestic businesses and consumers)?¹⁷⁵ Will it increase or reduce differences between the regulatory regime faced by EU companies and competitors in non-EU countries?

¹⁷² *European Commission Impact Assessment Guidelines* (15 January 2009), *supra* at 42.

¹⁷³ Part III: Annexes to *European Commission Impact Assessment Guidelines* (15 January 2009), at 29.

¹⁷⁴ *Id.*, at 38.

¹⁷⁵ *European Commission Impact Assessment Guidelines* (15 January 2009), *supra* at 34.

Will it place EU firms at an advantage or disadvantage compared to their international competitors? Will it contribute to the relocation of economic activity to or from non-EU countries? Will a ‘first-mover’ advantage be generated with other countries likely to follow?¹⁷⁶

The 2009 IA Guidelines also instruct to assess the impact of the proposed policy on international obligations or areas of international cooperation (posing questions such as: How does it affect EU trade policy and its international obligations, including in the WTO? Does the option concern an area in which international standards, common regulatory approaches or international regulatory dialogues exist? What are the impacts on third countries with which the EU has preferential trade arrangements?)¹⁷⁷ It further instructs to assess whether the proposed rule is in line with other EU policies (e.g. does it affect EU foreign policy and EU/EC development policy?)

2. *Impact on Developing Countries*

The 2009 IA Guidelines devote an entire new section and upgrade the guidelines in that they now require assessing impacts on developing countries.¹⁷⁸ The framework for assessing impacts on developing countries is, however, not only set out in the 2009 IA Guidelines, but also in the EU Policy Coherence for Development. We look at each next.

a) The 2009 IA Guidelines

The 2009 IA Guidelines include an entire new section on assessing impacts on developing countries.¹⁷⁹ The guideline requires that economic, environmental and social impacts on developing countries be assessed:

“EU policies can affect developing countries in a number of areas. From an economic point of view, impacts on different sectors (agriculture, extractive industries, manufacturing and services) should be distinguished where relevant. Relevant economic variables include: GDP growth, GDP per capita, current account balances, business climate, macroeconomic stability, terms of trade, export revenue, tax revenue, and inflation rates. In the social and environmental areas the Millennium Development Goals indicators (health, education, food

¹⁷⁶ Part III: Annexes to *European Commission Impact Assessment Guidelines* (15 January 2009), *supra* at 38.

¹⁷⁷ *European Commission Impact Assessment Guidelines* (15 January 2009), *supra* at 34.

¹⁷⁸ Part III: Annexes to *European Commission Impact Assessment Guidelines* (15 January 2009), *supra* at 39.

¹⁷⁹ *Id.*

security, environment) should be used. “ It further states that “EU policies can also have unintended economic, social and environmental impacts. Often, the fact that a EU policy is changed may present a challenge for a developing country when it needs to align its policy to comply with new standards. Many developing countries have weak administrations and find it difficult to adapt to changing regulations.”

In line with these concerns, the 2009 IA Guidelines pose questions pertaining to the economic impacts of the proposed policy in developing countries (such as: Does it affect developing countries at different stages of development (least developed and other low-income and middle income countries) in a different manner? Does the option impose adjustment costs on developing countries? Does the option affect goods or services that are produced or consumed by developing countries? Does it increase poverty in developing countries or have an impact on income of the poorest populations?);¹⁸⁰ pertaining to the social impact on developing countries (e.g. Does the option have a social impact on third countries that would be relevant for overarching EU policies, such as development policy?), pertaining to environmental impacts (e.g. What is the impact of the proposed policy on the environment in third countries that would be relevant for overarching EU policies, such as development policy.),¹⁸¹ and pertaining to international development obligations (e.g. Does it affect international obligations and commitments of the EU arising from e.g. the ACP-EC Partnership Agreement or the Millennium Development Goals?)¹⁸²

b) European Development Policy and the Policy for Coherence

In line with the EU’s Policy Coherence for Development (PCD),¹⁸³ the IA must also assess the proposed policy for coherence with the EU’s development policy. This means that in the assessment of the impact of a proposed policy on developing countries, the initiatives must also be analyzed for their consistency with EU development policy objectives.

The background to this requirement is as follows:

¹⁸⁰ *European Commission Impact Assessment Guidelines* (15 January 2009), *supra* at 34.

¹⁸¹ *Id.*, at 38.

¹⁸² *Id.*, at 36.

¹⁸³ European Commission Development and Cooperation—Europeaid, *Policy Coherence for Development*, available at https://ec.europa.eu/europeaid/policies/policy-coherence-development_en (last visited Mar. 14, 2015).

Under the EU's Policy Coherence for Development (PCD),¹⁸⁴ the EU seeks to take account of development objectives in all of its policies that are likely to affect developing countries. What underlies the PCD is the acknowledgement that all EU policies, also non-development policies, have an external impact,¹⁸⁵ and the PCD aims at minimizing contradictions and building synergies between different EU policies to benefit developing countries and increase the effectiveness of development cooperation.

It has always been the EU approach that it must take into account in the policies that it implements effects on developing countries: The legal basis to the Policy Coherence Approach was first integrated in EU law in the Treaty of Maastricht in 1992 (Art. 130v – saying that “The Community shall take account of the objectives [of development cooperation] in the policies that it implements which are likely to affect developing countries”), and further reinforced in the Treaty of Lisbon (Art. 208 TFEU—which reaffirms that “the Union shall take account of the objectives of development cooperation in the policies that it implements which are likely to affect developing countries”).

While the PCD commitment exists for over twenty years, its actual implementation has been slow, becoming more effective in the 2000s.¹⁸⁶ Since then, the EU has gradually strengthened its work on PCD procedures, instruments and mechanisms, including its' inclusion in impact assessments.¹⁸⁷ This is reflected in the growth of political commitments to this end, and nowadays the awareness is much higher.¹⁸⁸ There are several political documents that reflect this development:

The political commitment to the PCD is embedded in the European Consensus on Development (2006),¹⁸⁹ a document reflecting a shared consensus of the

¹⁸⁴ *Id.*

¹⁸⁵ See, for example, European Parliament, *European Parliament Resolution of 13 March 2014 on the EU 2013 report on Policy Coherence for Development*, 2013/2058(INI) (13 March 2014), available at <http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P7-TA-2014-0251> (last visited Mar. 14, 2015).

¹⁸⁶ James Mackie (EU External Action Programme), *The European Experience on PCD – Lessons Learned and Challenges for the Future* (12 June 2014), 4, available at http://ec.europa.eu/europeaid/sites/devco/files/presentation-european-experience-on-pcd-20140612_en_0.pdf (last visited Mar. 14, 2015).

¹⁸⁷ European Commission Development and Cooperation—Europeaid, *Policy Coherence for Development*, *supra*.

¹⁸⁸ *The European Experience on PCD – Lessons Learned and Challenges for the Future* (12 June 2014), *supra* at 23.

¹⁸⁹ European Commission Development and Cooperation—Europeaid, *European Consensus on Development*, available at <https://ec.europa.eu/europeaid/node/1364> (last visited Mar. 14, 2015); Joint Statement by the Council and the Representatives of the Governments of the Member

Commission, Parliament and the Council, which introduced the name “Policy Coherence for Development”. The Consensus is a policy statement that commits the EU to eradicating poverty and building a fairer and more stable world. It considers that the EU has a responsibility in poverty eradication and sustainable development in developing countries, including pursuit of the Millennium Development Goals (MDGs).¹⁹⁰ It considers this responsibility not only a moral obligation, but also necessary in building “a more stable, peaceful, prosperous and equitable world, reflecting the interdependency of richer and poorer countries.”¹⁹¹ It identifies three values and principles – reducing poverty, democratic values and nationally led development - which the EU must implement in its development policies.¹⁹²

In line with this responsibility, the EU reaffirms in the European Consensus on Development that it has a “commitment to promoting policy coherence for development”. Acknowledging that non-development policies may have effects that undermine the development goals, it states that “It is important that non-development policies assist developing countries’ efforts in achieving MDGs. The EU shall take account of the objectives of development cooperation in all policies that it implements which are likely to affect developing countries. To make this commitment a reality, the EU will strengthen policy coherence for development procedures, instruments and mechanisms at all levels, and secure adequate resources and share best practice to further these aims. This constitutes a substantial additional EU contribution to the achievement of the MDGs.”¹⁹³

While there are different mechanisms to promote PCD, Impact Assessment is one of them.¹⁹⁴

And so in view of promoting policy coherence, IAs are now required to assess the coherence of proposed policies with the European/MDG development goals. This requirement is set out in a series of documents:

Statutes meeting with the Council, the European Parliament and the Commission on European Union Development Policy: ‘The European Consensus’, 2006 O.J. (C46/1).

¹⁹⁰ MDGs are intended to eradicate extreme poverty and hunger, achieve universal primary education, promote gender equality and empower women, reduce the mortality rate of children, improve maternal health, combat HIV/AIDS, malaria and other diseases, ensure environmental sustainability and develop a global partnership for development.

¹⁹¹ Joint Statement by the Council and the Representatives of the Governments of the Member States meeting with the Council, the European Parliament and the Commission on European Union Development Policy: ‘The European Consensus’, *supra* at 1.

¹⁹² *Id.*

¹⁹³ *Id.*, at Sec. 6 (“Policy Coherence for Development (PCD)”) and Section 1(9) (under “Common Objectives”), and Sec. 44 (under Part II: The European Community Development Policy”).

¹⁹⁴ James Mackie (EU External Action Programme), *The European Experience on PCD – Lessons Learned and Challenges for the Future (12 June 2014)*, *supra* at 8, 10.

In 2005 the Council issued its conclusions regarding EU's contribution to the MDGs.¹⁹⁵ In this document it reinstated its commitment to policy coherence, stating that “the EU recognizes the importance of non-development policies for assisting developing countries in achieving MDGs. Building on the existing Treaty obligation for the Community, the EU shall take account of the objectives of development cooperation in all policies that it implements which are likely to affect developing countries. The EU will make a specific effort to promote and enhance Policy Coherence for Development in the context of the Global Partnership for Development under MDG 8...”¹⁹⁶ and the Council “will assess internal procedures, mechanisms and instruments to strengthen the effective integration of development concerns in its decision making procedures on non-development policies. ...the Council invites the Commission to further reinforce its existing instruments *notably its Impact Assessment tool* and consultations with developing countries during policy formulation, and consider new ones when necessary in support of a strengthened Policy Coherence for Development.”¹⁹⁷

Then, in 2009, in view of improving PCD within the EU,¹⁹⁸ a new document stressed that the impact assessments have an important role in ensuring ex-ante mainstreaming of PCD.¹⁹⁹

This commitment to improving EU action on PCD was then reaffirmed in the 2011 Agenda for Change,²⁰⁰ a reform that had been introduced to make the EU's

¹⁹⁵ Council of the European Union, *Millennium Development Goals: EU Contribution to the Review of the MDGs at the UN 2005 High Level Event – Conclusions of the Council and the Representatives of the Governments of the Member States Meeting within the Council*, 9266/05 DEVGEN 91 RELEX 256 ONU 60 FIN 181 (24 May 2005), available at <http://register.consilium.europa.eu/doc/srv?l=EN&f=ST%209266%202005%20INIT> (last visited Mar. 14, 2015).

¹⁹⁶ *Id.*, at 9. It defines twelve policy areas that it would follow up on (trade, environment, climate change, security, agriculture, fisheries, social dimension of globalization, employment, decent work, migration, research and innovation, information society, transport and energy).

¹⁹⁷ *Id.*, at 10.

¹⁹⁸ Council of the European Union, *Council Conclusions on Policy Coherence for Development (PCD)*, 2974TH EXTERNAL RELATIONS COUNCIL MEETING (17 November 2009), available at http://www.consilium.europa.eu/uedocs/cms_Data/docs/pressdata/en/gena/111278.pdf (last visited Mar. 14, 2015).

¹⁹⁹ Council of the European Union, *Council Conclusions on Policy Coherence for Development* (12 December 2013), 2, available at http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/EN/foraff/140063.pdf (last visited Mar. 14, 2015). The Council defined five areas of priority: 1) Trade and Finance, 2) Addressing climate change, 3) Ensuring global food security, 4) Making migration work for development, and 5) Strengthening the links and synergies between security and development in the context of a global peace building agenda.

²⁰⁰ European Commission Development and Cooperation—Europeaid, *Agenda for Change*, available at <https://ec.europa.eu/europeaid/node/1365> (last visited Mar. 14, 2015); *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions—Increasing the Impact of EU Development Policy: And Agenda for Change*, COM (2011) 637 final (Oct. 13, 2011).

development policy more strategic and targeted.²⁰¹ Finally, in 2014, the European Parliament stressed once again the need to improve impact assessment so as to improve the PCD and emphasized “the need to improve the Commission’s impact assessment system by featuring PCD explicitly and ensuring that development becomes a forth element of the analysis, alongside the economic, social and environmental impacts.”²⁰²

Have these requirements been implemented in practice? Further research would need to be undertaken on this question, but it appears that in practice only a small number of IAs on initiatives with a potential impact on developing countries actually included analysis of those aspects. In fact, studies have shown that the IA has not functioned as an effective instrument for the implementation of the PCD in non-EU countries.²⁰³ Thus, despite the formal requirements, PCD and development objectives are not yet given sufficient weight in the IA process. The Commission is, therefore, currently looking at ways of raising the profile and awareness of the PCD requirement in the IA guidelines and strengthening analytical capacity for assessing development impacts of non-development policies.²⁰⁴

To conclude, RIAs in both the U.S. and EU are assessing international impacts, but they remain of a different in nature. The U.S. focuses on impacts on trade and investment and monetizes costs and benefits. The EU undertakes a more profound analysis by also assessing (economic, social and environmental) impacts on developing countries. Be that as it may, to the extent such an impact is identified, what can foreigners and third states do about it? Can they voice their concerns? Do they have any access to the RIA process? We look at that question next.

²⁰¹ European Commission Development and Cooperation—Europeaid, *EU Communication on the Agenda for Change*, 11, https://ec.europa.eu/europeaid/policies/european-development-policy/agenda-change_en (last visited Mar. 14, 2015).

²⁰² European Parliament, *European Parliament Resolution of 13 March 2014 on the EU 2013 report on Policy Coherence for Development*, 2013/2058(INI), at Sec. 6, (Mar. 13, 2014), available at <http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P7-TA-2014-0251> (last visited Mar. 14, 2015).

²⁰³ Jacopo Torriti, Fredric Boudier and Ragnar Lofstedt, *Comments on the Joint Draft Report prepared by the Office of Management and Budget and the Secretariat General of the European Commission: “Review of the Application of EU and US Regulatory Impact Assessment Guidelines on the Analysis of Impacts on International Trade and Investment”* (14 January 2008), 2, available at <http://www.whitehouse.gov/sites/default/files/omb/assets/omb/inforeg/trade/1.pdf> (last visited Mar. 14, 2015).

²⁰⁴ European Commission, *EU 2013 Report on Policy Coherence for Development*, 24, available at https://ec.europa.eu/europeaid/sites/devco/files/pcd-report-2013_en.pdf (last visited Mar. 14, 2015).

6. Impact Assessments: Participation of Foreign Stakeholders

To the extent an international impact has been identified in the RIA—foreigners and third states have access to the rulemaking process in the U.S. and EU.

In the U.S. consultation requirements are not specifically spelled out in the Executive Orders or Circular A-4, and they continue to be governed by the APA, which applies to all proposed regulations, including economically significant regulations that undergo RIAs. Thus, as mentioned above, foreigners may comment as part of the normal notice and comment process.

In the EU, consulting interested parties is an obligation for every IA and it must follow the Commission's "Minimum Standards" on consultation (mentioned above).²⁰⁵ Such consultations are open to all interested parties, including interested parties in third countries.²⁰⁶

This requirement was further reinforced with the 2008 U.S.-EU Report. There the parties agreed that it was important to have transparent RIA procedures that are accessible to the public, and that public consultation and notice and comment procedures should be open to governments, businesses and citizens of the EU, U.S. and third countries.²⁰⁷ They further agreed that policy proposals and accompanying IAs should be made public, which would allow foreign governments and stakeholders to voice their concerns.²⁰⁸ Also planned legislative or regulatory proposals would be made public and the parties would already indicate already at this stage whether the proposal might have an international impact or be of interest to third countries.²⁰⁹ This enables potential stakeholders to foresee possible contributions. Indeed, the Commission publishes roadmaps outlining upcoming impact assessments,²¹⁰ and the U.S. gives notices of future regulations in the Unified Agenda (discussed above).

²⁰⁵ *European Commission Impact Assessment Guidelines* (15 January 2009), *supra* at 19. European Commission, *Communication from the Commission: Towards a reinforced Culture of Consultation and Dialogue: General Principles and Minimum Standards for Consultation of Interested Parties by the Commission*, COM(2002) 704 final (11 December 2002), available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2002:0704:FIN:EN:PDF> (last visited Mar. 14, 2015).

²⁰⁶ *Id.*, at 4.

²⁰⁷ Office of Management and Budget and the Secretariat General of the European Commission, *Review of the Application of EU and US Regulatory Impact Assessment Guidelines on the Analysis of Impacts on International Trade and Investment – Final Report and Conclusions*, *supra* at 26.

²⁰⁸ *Id.*

²⁰⁹ *Id.*

²¹⁰ For example, European Commission, *Impact Assessment – 2014 Roadmaps at Impact Assessment – 2014*, available at http://ec.europa.eu/governance/impact/planned_ia/roadmaps_2014_en.htm (last visited Mar. 15, 2015).

The EU 2009 IA Guidelines implemented these understandings and expressly instruct that the Commission must “always include [in the consultation] all target groups and sectors which will be significantly affected by or involved in policy implementation, *including those outside the EU*”.²¹¹ They also stress the importance of ensuring that stakeholders in third countries participate in the consultation process.²¹² Thus, the consultations regarding the RIAs are fully open to all interested parties, including third country stakeholders.²¹³ Moreover, the Impact Assessment Secretariat General can ensure that potentially affected third countries participate in the RIA consultation process, and international policy dialogues can also be used as a means of exchanging information with third countries and external stakeholders.

7. The Rationale for Increased Openness towards Foreign Interests

The paper has demonstrated how the rulemaking process in the U.S. and EU has opened up towards third states and foreigners. Regulators are flagging their regulations for international impacts, assessing international impacts as part of their RIAs, and foreigners can freely participate in their notice and comment procedures. In the absence of an international legal obligation underlying these practices – what factors explain them?

A. Enlightened Self Interest: Economic Growth

This paper argues that the driver behind the openness towards foreigners and their interests is the desire of market economies to improve market openness by aligning diverging regulations. Thus, states are acting out of their “enlightened self interest”,²¹⁴ as the removal of diverging regulations should lead to better growth.

Explicit barriers, such as tariffs, to international trade have largely fallen with trade liberalization in the past couple of decades. But countries still have diverging regulations – and these regulations create barriers to trade. Regulations may diverge for different reasons. Sometimes they are different for non-important reasons. Say when regulators share common goals and methods of regulation, but

²¹¹ Part III: Annexes to *European Commission Impact Assessment Guidelines* (Jan. 15, 2009), *supra* at 14.

²¹² *European Commission Impact Assessment Guidelines* (Jan. 15, 2009), *supra*, at 42.

²¹³ *Id.*

²¹⁴ Christopher McCrudden, *AJIL Symposium: Comment on Eyal Benvenisti, Sovereigns as Trustees of Humanity* (Opinio Juris, July 25, 2013), *supra*.

for historical or other reasons, regulations remain inconsistent. Sometimes regulations differ for more substantive issues, and may be legitimate to protect appropriate national interests in health, safety or the environment. Be that as it may, such diverging regulations disrupt trade and have been termed the “3rd generation barriers to trade,”²¹⁵ Think say of different food labeling requirements which require food producers that sell in different countries to pack the food differently, depending on the market, or different safety requirements for automobiles that require manufacturers to conduct different testing. These regulatory differences not only prevent economies of scale, they also increase costs and create delays. As the EU has pointed out: “[t]he nature of barriers to trade in the global economy has changed. Where market access once focused on border tariffs, non-tariff and other “behind the border” barriers in the markets of our trading partners are increasingly important.”²¹⁶

The big trading economies, have recognized that the most important remaining trade barriers are due primarily to such regulator differences, and not due to tariffs.²¹⁷ They want to remove them as that will help lower costs for businesses,

²¹⁵ Mauro Petriccione, *Reconciling Transatlantic Regulatory Imperatives with Bilateral Trade*, TRANSATLANTIC REGULATORY COOPERATION: LEGAL PROBLEMS AND POLITICAL PROSPECTS 205-221 (George Bermann et al. eds., Oxford University Press, 2001).

²¹⁶ *Id.*, at 3. See also *Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions; Global Europe: Competing in the World: A Contribution to the EU's Growth and Jobs Strategy*, COM(2006) 567 final, 5 (Oct. 4, 2006), available at http://eur-lex.europa.eu/LexUriServ/site/en/com/2006/com2006_0567en01.pdf (last visited Mar. 14, 2015) (this report, which aimed to contribute to the Lisbon Growth and Jobs Strategy, underlined the contribution trade policy has to stimulating growth and creating jobs in Europe, and stressed (among others) the need to focus on nontariff barriers to trade, especially in emerging countries).

²¹⁷ Office of Management and Budget, Office of Information and Regulatory Affairs, *2006 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities* (2006), *supra*. International Trade Administration Department of Commerce, *Notice on Removal of Non Tariff Barriers between the US, Mexico and EU: Request for Public Comments Concerning Regulatory Cooperation Activities That Would Help Eliminate or Reduce Unnecessary Regulatory Divergences in North America That Disrupt U.S. Exports*, 76 FR 11760 (Mar. 3, 2011). (“the main impediments to greater trade and investment – and more open foreign markets for U.S. exporters and investors – are not tariffs or quotas, but rather unnecessary differences in product regulations that increase costs for producers and consumers...”). See also APEC, *6th Conference on Good Regulatory Practice (GRP); Report to the Subcommittee on Standards and Conformance (SCSC)*, (Mar. 5, 2011), http://www.whitehouse.gov/sites/default/files/omb/oira/irc/scsc_6th_conference_on_good_regulatory_practice_march_2011.pdf (last visited Mar. 14, 2015). *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions; Global Europe: A Stronger Partnership to Deliver Market Access for European Exporters*, COM(2007) 183 final, 3 (Apr. 18, 2007), available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2007:0183:FIN:EN:PDF> (last visited Mar. 14, 2015). (with respect to the “changing nature of barriers to trade” that “[w] hile high border tariffs still hamper trade in some sectors and must be tackled ..., non-tariff barriers (NTBs) in the markets of our trading partners are increasingly important.... NTBs ... are becoming more important than the traditional policy-based trade constraints of import tariffs and duties.”) (and at 3 “[t]he nature of barriers to trade in the global economy has changed. Where market access once

increase exports and further economic growth and job creation.²¹⁸ Against this background market economies have been increasingly working towards the reduction of regulatory barriers to trade through alignment of diverging regulations,²¹⁹ and this has been receiving even more attention following the 2008 financial crisis.²²⁰ For example, the U.S.-EU Free Trade Agreement currently being negotiated under the TTIP focuses on regulatory convergence of non-tariff barriers to trade rather than on easing tariffs (saying that “cutting unnecessary red tape would reduce the cost of doing business across the Atlantic by making it easier for companies to comply with both American and European laws”),²²¹ and international organizations such as the OECD’s Guiding Principles

focused on border tariffs, non-tariff and other “behind the border” barriers in the markets of our trading partners are increasingly important.”) See also *Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions; Global Europe: Competing in the World: A Contribution to the EU’s Growth and Jobs Strategy*, *supra*.

²¹⁸ U.S. Government Accountability Office, *International Regulatory Cooperation: Agency Efforts Could Benefit from Increased Collaboration and Interagency Guidance* (Aug. 1, 2013), available at <http://www.gao.gov/assets/660/656488.pdf> (last visited Mar. 15, 2015), at 6.

²¹⁹ *Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions; Global Europe: Competing in the World: A Contribution to the EU’s Growth and Jobs Strategy*, *supra*, (this global strategy is an essential part of the EU’s Lisbon Strategy for Growth and Jobs and sets an ambitious agenda for opening the markets that matter most, particularly in Asia). This strategy has been reiterated in the *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions; Global Europe: A Stronger Partnership to Deliver Market Access for European Exporters*, *supra*. The importance of this strategy to open markets was also recognized in the *Communication from the Commission to the Spring European Council: Strategic Report on the Renewed Lisbon Strategy for Growth and Jobs: Launching the New Cycle (2008-2010) Keeping Up the Pace of Change*, COM(2007) 803 (Dec. 11, 2007), available at [http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SPLIT_COM:2007:0803\(01\):FIN:EN:PDF](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SPLIT_COM:2007:0803(01):FIN:EN:PDF) (last visited Mar. 15, 2015). This has been the consistent approach, see: *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions On the External Dimension of the Lisbon Strategy for Growth and Jobs: Reporting on Market Access and Setting the Framework for more Effective International Regulatory Cooperation*, COM/2008/0874 final (Dec. 16, 2008), available at <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52008DC0874>, at 2, 3. (As part of the renewed Lisbon Strategy for Growth and Jobs, which is considered Europe’s response to the challenges of globalization, the EU adopted an “external agenda”, according to which the EU would act to “open up new opportunities for international trade and investment, improve market access focusing on countries and sectors where significant barriers remain, and promote international regulatory cooperation.”).

²²⁰ *Communication from the Commission to the European Council -- A European Economic Recovery Plan*, COM (2008) 800 final (Dec. 26, 2008), available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0800:FIN:EN:PDF> (last visited Mar. 15, 2015). See also OECD Public Governance and Territorial Development Directorate & Regulatory Policy Committee, *Stocktaking Paper on International Regulatory Cooperation XX*, 11, 16, GOV/RPC(2012)8 (Oct. 15, 2012), 6.

²²¹ EUROPEAN COMMISSION, *TRANSATLANTIC TRADE AND INVESTMENT PARTNERSHIP: THE REGULATORY PART* (2013).

for Regulatory Quality and Performance,²²² the APEC-OECD Integrated Checklist on Regulatory Reform,²²³ and the WTO and the World Bank are likewise encouraging members to work towards removal of non-tariff barriers to trade.²²⁴

In view of this goal, the U.S., EU and other OECD countries are now (since the mid 2000's but even more so following the 2008 financial crisis) working on improving their "international regulatory cooperation", that is, cooperation and communication between countries concerning regulation.²²⁵ In the U.S., the Administrative Conference of the United States issued a 2011 Recommendation supporting International Regulatory Cooperation as a method for removing diverging regulations, saying that "The Administrative Conference finds that improved international regulatory cooperation is *desirable* because it can help United States agencies accomplish their statutory regulatory missions domestically... International Regulatory cooperation can also *remove non-tariff barriers to trade and exports*, promoting global commerce and United States competitiveness."²²⁶ Following ACUS' recommendation, and within this context, President Obama issued in 2012 Executive Order 13609 on "Promoting International Regulatory Cooperation". The EO explains how international regulatory cooperation is a tool to remove diverging regulations, stating that "[t]he regulatory approaches taken by foreign governments may differ from those taken by U.S. regulatory agencies to address similar issues. In some cases, the differences between the regulatory approaches of U.S. agencies and those of their foreign counterparts might not be necessary and might impair the ability of

²²² Principle 6 in OECD, *The OECD 2005 Guiding Principles for Regulatory Quality and Performance* (2005), available at <http://www.oecd.org/fr/reformereg/34976533.pdf> (last visited 12 December 2014).

²²³ Comment to Principle D7, *id.*, 31.

²²⁴ APEC Subcommittee on Standards and Conformance, *Report to the Sub-Committee on Standards and Conformance (SCSC) / 6th Conference on Good Regulatory Practice (GRP)* (5 March 2011), available at http://www.whitehouse.gov/sites/default/files/omb/oira/irc/scsc_6th_conference_on_good_regulatory_practice_march_2011.pdf (last visited Mar. 15, 2015).

²²⁵ IRC has been defined by the OECD as "any agreement or organizational agreement, formal or informal, between countries (at the bilateral, regional or multilateral level) to promote some form of cooperation in the design, monitoring, enforcement, or ex post management of regulation. IRC is not restricted to its strict equivalence with international legal obligations, but also *includes non-binding agreements and voluntary approaches*. Consequently, IRC mechanisms may run from *voluntary* to legally binding agreements." OECD, Stocktaking Paper on International Regulatory Cooperation, *supra* at 8. President Obama's Executive Order in 2012 on "Promoting International Regulatory Cooperation" defines IRC as "referring to a bilateral, regional or multilateral process in which *governments engage in various forms of collaboration and communication with respect to regulations...*". Executive Order 13609: Promoting International Regulatory Cooperation 77 FR 26413 (2012).

²²⁶ Administrative Conference of the United States, *International Regulatory Cooperation, Administrative Conference Recommendation 2011-6* (8 December 2011), 2, available at http://www.acus.gov/sites/default/files/documents/Recommendation_2011-6_28InternationalRegulatoryCooperation29.pdf (last visited Mar. 15, 2015).

American businesses to export and compete internationally... International regulatory cooperation can also reduce, eliminate, or prevent unnecessary differences in regulatory requirements.”²²⁷

It is within this context that regulators are opening up their domestic rulemaking processes towards foreign regulators and foreign stakeholders. Seeking to align diverging regulations, and preventing the rise of new differences, domestic rulemaking processes must be open to foreign regulators and foreign stakeholders. They must be made aware of regulations that are in the pipeline, and they must be able to voice their comments to prevent such divergence. Such openness will prevent in due course the creation of new barriers and support the removal of existing ones. Moreover, in general, it has become “common wisdom” that there is a link between open regulatory procedures to economic growth,²²⁸ and it is this belief that also underlies this growing openness.²²⁹ Explaining why it is improving its assessment of international trade and investment impacts, the OMB states that: “Recent studies demonstrate the correlation between efficient regulations and economic growth. They suggest that a *regulatory regime that offers transparent rules...increases investment, economic growth, and consumer welfare ...*”²³⁰ This school of thought – correlating between transparent regulations and economic prosperity -- has been behind a lot of these developments.²³¹

To conclude, these developments, that is, the desire to improve market openness through removal of diverging regulations (and the involvement in more regulatory cooperation to this end) explain why we witness more openness towards foreign regulators and foreign stakeholders in the rulemaking process. Openness is considered a tool to this end. Indeed, the 2011 OIRA memorandum (which as mentioned above instructs agencies to open their rulemaking process to foreigners and to take interests on foreigners into account) says exactly that. It explains that the USTR and OIRA “are issuing this Memorandum to *promote U.S. exports and trade through increased transparency and openness in the rulemaking process*. Reducing unnecessary barriers to exports and trade will promote economic

²²⁷ Sec. 1.

²²⁸ For example, SIMEON DJANKOV, CARALEE MCLIESH, AND RITA ROMALHO, REGULATION AND GROWTH (World Bank, 2006), <http://www.enterprisesurveys.org/~media/GIAWB/EnterpriseSurveys/Documents/ResearchPapers/Regulation-and-Growth-2006.pdf> (last visited Mar. 15, 2015).

²²⁹ See, for example, Introductory Text in OECD, *Recommendation on Regulatory Policy* (2012), *supra*; OECD-APEC *Integrated Checklist for Regulatory Reform: A Policy Instrument for Regulatory Quality, Competition Policy and Market Openness*, *supra*.

²³⁰ 2008 U.S. –EU Report, p. 14

²³¹ See OECD, *Recommendation of the Council on Regulatory Policy and Governance* (2012), *supra*.

growth, entrepreneurship, job creation, and innovation.”²³² To conclude, states are opening up towards foreigners out of their “enlightened self interest”.

Further, in view of the desire of governments to open their regulatory processes so as to remove non tariff barriers to trade, and their belief that this will improve economic growth – some governments have reached agreements to improve their international regulatory cooperation, better incorporate international trade impacts into their impact assessments, and allow foreigners access to their rulemaking procedures:

For example, in 2005 the U.S., Canada and Mexico announced under the Security and Prosperity Partnership of North America (SPP) the SPP Regulatory Cooperation Framework. The aim of the framework is to improve international regulatory cooperation among the countries. In the Voluntary Cooperation Framework²³³ and the Common Regulatory Principles²³⁴ the parties agree to improve transparency and access to each others’ rulemaking process, agreeing that “*regulatory cooperation* should be strengthened on a systemic basis through *increased transparency* in the rulemaking process, exchanges of best practices, and information sharing among regulators.”²³⁵ Further, in view of increasing transparency of the rulemaking process, they agreed to “develop *intergovernmental “early alert” mechanisms* to systematically and proactively share information throughout the rule development process to avoid incompatibility issues.” And “On a systematic basis seek and provide an *opportunity to comment on each other’s regulatory proposals* that could have implications for the other Partners and consult throughout the process.”²³⁶ They also agree to take trade impacts on each other into account, agreeing to work “towards including assessment of *trade impact in the regulatory impact analysis* to reduce regulatory barriers to trade among the partners.”²³⁷ And to “ensure

²³² Office of the U.S. Trade Representative and Office of Information and Regulatory Affairs, *Memorandum for the Heads of Executive Departments and Agencies and Independent Regulatory Agencies: Export and Trade Promotion, Public Participation, and Rulemaking* M-11-23 (19 May 2011), *supra*.

²³³ Canada/United States/Mexico, *Security and Prosperity Regulatory Cooperation Framework* (Mar. 23, 2005), available at [http://www.spp-psp.gc.ca/eic/site/spp-psp.nsf/vwapj/RCF-eng.pdf/\\$FILE/RCF-eng.pdf](http://www.spp-psp.gc.ca/eic/site/spp-psp.nsf/vwapj/RCF-eng.pdf/$FILE/RCF-eng.pdf) (last visited Mar. 15, 2015).

²³⁴ *Security and Prosperity Partnership if North America, Common Regulatory Principles*, available at http://www.whitehouse.gov/sites/default/files/omb/oira/irc/spp_regulatory_cooperation_framework.pdf (last visited Mar. 15, 2015).

²³⁵ Canada/United States/Mexico, *Security and Prosperity Regulatory Cooperation Framework*, *supra*, at Section I on “Framework Goals”.

²³⁶ *Id.*, at Section III (A).

²³⁷ *Id.*, at Section III(Goal 3A).

transparent regulatory development and implementation, making regulations and regulatory impact analyses easily accessible”²³⁸

A further example is the U.S. – EU High Level Regulatory Forum, a forum of senior officials from different areas of government that discuss regulatory matters,²³⁹ and is headed by the OMB/OIRA and the European Commission²⁴⁰ which arrived in 2011 at a Common Understanding on Regulatory Principles and Best Practices. The parties agreed that in view of improving their regulatory cooperation when developing or changing regulatory measures” they would “highlight or “flag” domestic regulatory measures that may impact international trade and investment”.²⁴¹ They would include such “flagging” in planning documents such as the U.S. Unified Agenda or EU Roadmaps.²⁴² Further, “*Invitations to comment [on regulatory measures] should be open to all interested parties, including foreign governments, irrespective of their place of establishment or domicile.*”²⁴³ Moreover, they would “*solicit input from international stakeholders* in regulatory measures under development to help prevent unnecessary divergence, burdens and duplicative regulatory requirements, including (when feasible and appropriate) meetings with senior-level officials and international stakeholders.”²⁴⁴ Finally, they would “explore new ways to use planning tools and documents to enable more opportunities for cooperation and collaboration with foreign governments and external stakeholders, and to encourage more input with meaningful comments.”²⁴⁵

Moreover, the notion that the regulatory process needs to be open towards foreigners, and that international impacts need to be assessed, is part of a regulatory reform, which the OECD has encouraged in the past decade or so for better regulatory systems and regulatory quality. A central pillar of these reforms

²³⁸ Security and Prosperity Partnership of North America, *Common Regulatory Principles, supra* at Principle 9.

²³⁹ UNITED STATES-EUROPEAN UNION HIGH-LEVEL REGULATORY COOPERATION FORUM, *available at* http://www.whitehouse.gov/omb/oira_irc_europe (last visited Mar. 15, 2015).

²⁴⁰ As well as works under the auspices of the U.S.-EU High Level Cooperation Forum, *id.*

²⁴¹ UNITED STATES-EUROPEAN UNION HIGH-LEVEL REGULATORY COOPERATION FORUM, *10th Meeting* (7 and 8 June 2011), 1, *available at* http://www.whitehouse.gov/sites/default/files/omb/oira/irc/hlrcf_summary_report_june_2011.pdf (last visited Mar. 15, 2015).

²⁴² UNITED STATES-EUROPEAN UNION HIGH-LEVEL REGULATORY COOPERATION FORUM, COMMON UNDERSTANDING ON REGULATORY PRINCIPLES AND BEST PRACTICES (2011), 4, *available at* http://trade.ec.europa.eu/doclib/docs/2011/july/tradoc_148030.pdf (last visited Mar. 15, 2015).

²⁴³ *Id.*, at 1.

²⁴⁴ *Id.*, at 3.

²⁴⁵ *Id.*, at 4. Other examples include the US-EU TRANSATLANTIC ECONOMIC PARTNERSHIP, GUIDELINES ON REGULATORY COOPERATION AND TRANSPARENCY (2002) which require that the development of technical regulations be open to foreign parties for consultations, and generally allow comments by foreign parties on regulatory proposals.

is promoting open government, including transparency and participation of stakeholders, and integrating RIAs in the policy process.²⁴⁶ Regarding access of foreigners the “APEC–OECD Integrated Checklist for Regulatory Reform” (2005), a checklist of regulatory principles for the development of good regulatory governance principles requires that the development of rules be transparent and *accessible to foreign parties*, allowing them to comment, including on their access to appeal systems.²⁴⁷ In March 2012, the OECD reiterated this approach when it issued the “Recommendation on Regulatory Policy and Governance” mentioned above. It recommends that “[p]rocesses of consultation on regulatory proposals should be open to receiving submissions from *foreign* and domestic interests.”²⁴⁸

Regarding assessing international impacts, the OECD Recommendation also recommends there that members should “[i]n developing regulatory measures, give consideration to all relevant international standards and frameworks for cooperation in the same field and, where appropriate, [to] their likely effects on parties outside the jurisdiction”.²⁴⁹ This recommendation, hence, suggests that countries should take the impact of their proposed policy on foreigners into account. It explains that “[a]t a minimum, governments should ensure that systems for rule making take into account the potential impacts on parties outside of the national boundaries and provide opportunities for consultation with external partners on the development of regulations.” Further, the APEC-OECD Checklist stresses the rationale behind assessing trade and investment impacts, explaining that it will prevent diverging regulations and improve market openness: “Narrowly-defined and discriminatory regulation can, explicitly or indirectly, impede flow of trade and investment to the detriment of domestic economic efficiency and of consumers. Early consideration of trade issues, particularly in

²⁴⁶ OECD, *Recommendation of the Council on Regulatory Policy and Governance* (2012), *supra* at 3-4.

²⁴⁷ *OECD-APEC Integrated Checklist for Regulatory Reform: A Policy Instrument for Regulatory Quality, Competition Policy and Market Openness*, *supra* at 7 (Principle A6: “Are the policies, laws, regulations, practices, procedures and decision making transparent, consistent, comprehensible and accessible to users both inside and outside government, and to domestic as well as foreign parties?”), 11 (Principle A7: “It is important that foreign stakeholder and participants should not be disadvantaged in their access to the appeal systems), (Principle D4: “To what extent has the government established effective public consultation mechanisms and procedures ...and do such mechanisms allow sufficient access for all interested parties, including foreign stakeholders?), 16 (Principle B2: “Reviews of regulatory measures (primary laws or secondary regulations) should be conducted in a fashion that does not discriminate between domestic and foreign stakeholder[s] by, limiting opportunity for comment or participation.”), 17 (Principle B5: “Regulations should be developed in an open and transparent fashion, with appropriate and well-publicized procedures for effective and timely inputs from interested nations; and foreign parties, such as affected business, trade unions, wider interest groups such as consumer and environmental organizations, or other levels of government.”)

²⁴⁸ OECD, *Recommendation of the Council on Regulatory Policy and Governance* (2012), *supra* at 19 (Section 12.7 of the Recommendation).

²⁴⁹ *Id.*, at 5 and 19 (Recommendation 12).

the development and examination of alternative policy instruments, can prevent unnecessary restrictions on market openness...Systems of regulatory impact analysis should take sufficient account of market openness considerations.”²⁵⁰

To conclude, the U.S. and EU perceive open and transparent rulemaking processes as a tool for opening markets, improving competition and achieving economic growth. Thus, this openness is best explained by their “enlightened self-interest”. That said, these principles of open regulatory processes and consideration of impacts on foreigners as of recently clearly integrated in OECD Recommendations – reflecting best practice -- suggests that they may well make their way into domestic regulatory systems of other, smaller countries that undertake regulatory reform in line with OECD principles (if they haven’t done so yet). Thus, while the U.S. and EU, being the big trading countries that they are, have largely been driven by economic interests, smaller or weaker countries may find themselves adopting such reforms out of pressure or desire to align themselves with OECD best practices.

B. Moral Obligations towards Developing Countries

But enlightened self-interest is not the entire story, at least not in the case of the EU. There, as we have seen above, RIAs also consider the economic, social and environmental impacts on developing countries. The EU is concerned that its non-development policies may adversely impact developing countries. While in the long term its insistence on “policy coherence” should lead to a more stable, peaceful world, from which the EU itself would benefit too (and as such is in its enlightened self interest), the justification for acting responsibly towards developing countries is also based in moral considerations. The EU expressly considers that its Policy Coherence on Development is born out of its moral responsibility to eradicate poverty and building “a more stable, peaceful, prosperous and equitable world, reflecting the interdependency of richer and poorer countries.”²⁵¹

8. Conclusion

²⁵⁰ *OECD-APEC Integrated Checklist for Regulatory Reform: A Policy Instrument for Regulatory Quality, Competition Policy and Market Openness*, *supra* at 27, Principle D1.

²⁵¹ Joint Statement by the Council and the Representatives of the Governments of the Member States meeting with the Council, the European Parliament and the Commission on European Union Development Policy: ‘The European Consensus’, *supra*. European Commission Development and Cooperation—Europeaid, *European Consensus on Development*, *supra*.

In this age of interconnectedness and interdependence, policies and regulations issued in one country can have significant effects on third countries and foreigners. This raises questions regarding the accountability of states towards such third states and foreigners – accountability that goes beyond traditional state responsibility. Traditional international law is not very elaborate on this matter, with few exceptions, such as the ILC Articles on Trans-boundary Harm and the 2012 OECD Recommendation on Regulatory Policy. Further, not much, if at all, has been written about the accountability of states towards foreigners and third countries – Benvenisti being an exception.

Be the legal situation be as it may, in practice, international law is lagging behind the reality of state practice. This paper demonstrates that, in the very least the U.S. and EU, are moving away from a traditional sovereign understanding of themselves, and are considering the impact of their policies on foreigners and third states, and are also open to hearing them. Moreover, this practice is not only limited to the U.S. and EU but is actively being encouraged by the OECD as best practice for regulatory policy.

Specifically, regarding the U.S. and EU it demonstrates, first, that notice and comment procedures are open to foreigners and that foreigners take advantage of these procedures. It, second, demonstrates that RIAs take impacts on third states and foreigners into account. In the U.S., this is largely limited to impacts on international trade and development, and the impact is assessed in monetized terms of benefits or costs. The EU requires a more profound assessment of international impacts. It not only requires impacts on international trade and investment but is also concerned with social and environmental impacts, and most notably, the impacts on developing countries and whether the regulation is in line with the EU's/MDG's development policies.

In the absence of any international legal obligation to this end, the paper argues that there are two main drivers that explain this openness of the U.S. and EU towards foreigners and the readiness to take their interests into account. Most notably is the desire of the big trading partners to remove diverging regulations through regulatory cooperation. Transparent and open regulatory processes are perceived as advancing this goal as it gives foreigners and third states information about regulations in the pipeline, and open access to the rulemaking process, which in turn allows them to prepare and share information about the regulatory situation in their country, thereby preventing in due course new barriers, or allowing for the removal of new ones. In the case of the EU and its consideration of developing countries' interests more is at stake. The EU considers itself as having a moral responsibility to reduce poverty in developing countries.

Thus, in the absence of an international legal obligation, the U.S. and EU are driven largely by their enlightened self-interest, and in the case of the EU, also by moral considerations. Finally, while the U.S. and EU, being the big trading countries that they are, have largely been driven by economic interests, other countries may find themselves adopting such reforms out of pressure or desire to align themselves with OECD best practices.