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Information/Data Quality as an Element of "Good Regulatory Practice": The Implications for International Trade

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International Trade and Environment Committees
Co-Convened Panel

Does TTIP's Regulatory Cooperation Approach to Resolving EHS Non-Tariff Trade Barriers Present a Viable Model for Asia?

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I. Introduction

1. WTO Sanitary and Phytosanitary (SPS) and Technical Barriers to Trade (TBT) Agreements focus on food safety, human health and environmental protection, and consumer protection issues triggered by technical regulations and product standards relating to agricultural and industrial products.
   a. Both agreements seek to prevent unnecessary obstacles to trade (no disguised protectionism)/use of least trade-restrictive alternative available to fulfill/achieve a legitimate objective/appropriate level of protection. TBT Art. 2.2; SPS Art. 5.6.
2. The Trans-Pacific Partnership ("TPP") and Transatlantic Trade and Investment Partnership ("TTIP") agreements reflect a new generation of trade agreements that focus largely on regulatory coherence/regulatory cooperation.
   a. Both agreements seek to prevent unnecessary regulatory divergences.
3. The TPP & TTIP are **'deep integration initiatives' focusing on regulatory and non-tariff barriers.**
4. TPP & TTIP also deal with national security vis-à-vis BRICS (especially China).
5. TPP & TTIP each contains a horizontal chapter that focuses on the process by which regulations are developed, reviewed and implemented. TTIP goes further than TPP given that U.S. and EU regulatory processes are more closely aligned than those of Asian nations.

II. TPP "Regulatory Coherence" Chapter Overview

1. The TPP chapter on regulatory coherence will be about the ***institutional framework for coherence***.[1]
2. The **goal** of regulatory coherence is **to ease the conditions and costs of trade** between TPP countries while affirming the rights of TPP countries to regulate their economies to promote legitimate policy objectives."[2] In other words, to:
   a. improve regulatory practices;
   b. eliminate unnecessary barriers;
   c. reduce regional divergence in standards;
   d. promote transparency;
   e. conduct regulatory processes in a more trade-facilitative manner;
   f. eliminate redundancies in testing and certification; and
   g. promote cooperation on specific regulatory issues."[3]

ENDNOTES

[1] *See* Ian F. Fergusson, Mark A. McMinimy and Brock R. Williams, *The Trans-Pacific Partnership (TPP) Negotiations and Issues for Congress*, Congressional Research Service (CRS), R42694 (March 20, 2015), at p. 43, available at: https://www.fas.org/sgp/crs/row/R42694.pdf.

[2] *Id.*, at p. 42.

[3] *Id.*, at pp. 42-43, citing *Trans-Pacific Partnership (TPP) Trade Ministers' Report to Leaders* (Nov. 12, 2011), available at: https://ustr.gov/about-us/policy-offices/press-office/press-releases/2011/november/trans-pacific-partnership-tpp-trade-ministers%E2%80%99-re; Deborah Kay Elms, *The Trans-Pacific Partnership Agreement: Looking Ahead to the Next Steps*, Asia Development Bank Institute (ADBI) Working Paper No. 447 (Dec. 2013), at p. 4 (2013), available at: http://www.adbi.org/files/2013.12.20.wp447.trans.pacific.partnership.looking.ahead.pdf. *See also* Asia-Pacific Economic Cooperation, *2011 Leaders' Declaration, Annex D - Strengthening Implementation of Good Regulatory Practices*, (Honolulu, HI, Nov. 13, 2011), available at: http://www.apec.org/Meeting-Papers/Leaders-Declarations/2011/2011_aelm/2011_aelm_annexD.aspx ("Since its inception, APEC has promoted the use of good regulatory practices and worked to reduce the negative impact of regulatory divergences on trade and investment.") *Id.*

3. Contained in standalone chapter, and SPS, TBT, etc. chapters.
4. TPP partner countries "endeavor" to **establish *domestic* regulatory structures similar to the U.S. Office of Information and Regulatory Affairs in the Office of Management and Budget**, a venue to vet proposed regulations, and their compliance with domestic law and policy, as well as with trade agreements and other international obligations." (Congressional Research Service)[4]
   a. Seek to assure regulatory consistency among various domestic agencies;
   b. Encouraged to conduct regulatory impact assessments (RIAs) that would assess the need for a given regulation, conduct cost-benefit analysis, and assess alternatives to regulation;
   c. Seek to assure transparency, openness and accountability in the rule-making process.[5]

III. TPP Regulatory Coherence Chapter (leaked version Oct. 2010)[6]

1. **Have and Use Domestic Process or Mechanisms** – Generally
   a. To increase inter-ministerial consultation and coordination for developing and reviewing new ('covered') regulatory measures of general application;
      i. "**Regulatory Measures**" – "measures of general application in proposed or final form adopted by regulatory bodies of the **central level of government** with which compliance **is mandatory**. Art. X.7.

   and

   b. To facilitate central collection and wide dissemination of information on regulatory measures. Art. X.2.1.
2. **Domestic Process or Mechanism at Central Level of Government** – Specifically, shall endeavor:
   a. To issue publicly available administrative documents specifying institutional elements; Art. X.2.2.a.
   b. To review covered regulatory measures to determine the extent to which the development of such measures adheres to **Good Regulatory Practices**;" Art. X.2.2.b.
   c. To advance transparency disciplines; Art. X.2.2.c.
   d. To strengthen coordination and consultation among ministries within the government so as to minimize overlap and duplication, prevent the creation of inconsistent requirements across ministries; Art. X.2.2.d.
   e. To make recommendations for systemic regulatory reform;" Art. X.2.2.e.
   f. To periodically report on its regulatory activities. Art. X.2.2.e.
3. **National Coordinating Body, Process or Mechanism** –
   Should seek to **maintain channels of communication** with:

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[4] *See* Ian F. Fergusson, Mark A. McMinimy and Brock R. Williams, *The Trans-Pacific Partnership (TPP) Negotiations and Issues for Congress*, Congressional Research Service (CRS), R42694 (March 20, 2015), *supra*, at p. 43.
[5] *Id*.
[6] *See Draft Trans-Pacific Partnership (TPP) Agreement, Chapter on Regulatory Coherence* (March 4, 2010), available at: http://www.citizenstrade.org/ctc/wp-content/uploads/2011/10/TransPacificRegulatoryCoherence.pdf.

a. central government regulatory authorities; *and*
b. relevant subcentral government bodies. Art. X.2.3.

4. **Good Regulatory Practices = Conducting Regulatory Impact Assessments** –Each Party, consistent with their domestic law, *should* generally encourage relevant regulatory authorities **to conduct regulatory impact assessments (RIAs)** when developing 'covered' regulatory measures that exceed a threshold of economic impact established by a Party;" Art. X.3.1.

   a. RIAs should identify:
      i. the problem and the policy objective that the regulatory authority intends to address…;" Art. X.3.1.a.1.
      ii. "reasonably feasible alternatives to achieve the policy objective;" Art. X.3.1.a.2.
      iii. "where appropriate, the grounds for concluding that the selected alternative achieves the policy objectives in a way that maximizes net benefits;" X.3.1.a.3.
         A. "Net Benefits" – "the differences between a planned regulatory action's anticipated benefits and costs." FN2.
   b. "The RIA *should* include:
      i. "a consideration of […the…] need to regulate to achieve the policy objective [or] whether an objective can be met by non-regulatory and/or voluntary means;" Art. X.3.1.b.1.
      ii. "an assessment […] of the costs and benefits of each available alternative, including not to regulate…" Art. X.3.1.b.2.
      iii. "an explanation why the alternative selected is superior to the other available alternatives identified;" Art. X.3.1.b.3.
      iv. "decisions based on the best reasonably obtainable scientific, technical, economic, and other information;" Art. X.3.1.b.4.

5. ***Other* "Good Regulatory Practice concepts"** that may be **relevant to an RIA analysis** are reflected in:
   a. The [2005] **APEC-OECD Integrated Checklist on Regulatory Reform**;[7]
      i. "Regulatory reform refers to changes that improve **regulatory quality** to enhance the economic performance, cost-effectiveness, or legal quality of regulations and related government formalities. It can include:
         A. Revising a single regulation;
         B. Scrapping and rebuilding of an entire regulatory regime and its institutions;
         C. Improving processes for making regulations and managing reform; or
         D. Deregulation - complete or partial elimination of regulation in a sector to improve economic performance."[8]

[7] *See* Organization for Economic Cooperation and Development, *APEC-OECD Integrated Checklist on Regulatory Reform* (2005), available at: http://www.oecd.org/regreform/34989455.pdf.
[8] *Id.*, at p. 6.

and

b. The **APEC Information Notes on Good Practices for Technical Regulation**."[9] Art. X.3.2.

   i. Provide (APEC) member economies with resource materials for reference when preparing, adopting or reviewing their regimes for the regulation of products according to the *Principles and Features of Good Practice for Technical Regulation* compiled by the APEC Sub-Committee on Standards and Conformance (SCSC);

   ii. Intended to assist (APEC) member economies in the adoption of efficient regulatory arrangements, which should lead to reductions in regulatory barriers to trade;

   iii. Should be considered as one of the means for assisting (APEC) member economies in meeting their international obligations under the WTO TBT Agreement and their commitment under the APEC Bogor Declaration (*inter alia* to continue to reduce barriers to trade and investment to enable goods, services and capital to flow freely among our economies).[10]

c. ***Good Regulatory Practices*** ("GRPs") –

"GRPs include **administrative procedures that govern *intra*governmental coordination of rulemaking activity, impact assessment, regulatory transparency, participation, and accountability**."[11]

d. ***Regulatory Quality*** – **World Bank Governance Indicators (WGI)/Millennium Challenge Corporation (U.S.)**

   i. "[C]aptures perceptions of ***the ability of the government to formulate and implement sound policies and regulations that permit and promote private sector development***."[12]

   ii. Most countries have provided list of principles and regulatory priorities documents to make the notion of regulatory quality more concrete."[13]

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[9] *See* Asia-Pacific Economic Cooperation, *APEC Information Notes on Good Practices for Technical Regulation* (Sept. 2000), available at: http://www.apec.org/~/media/Files/MinisterialStatements/Annual/2000/00_scsc3_017.doc.

[10] *See* Asia-Pacific Economic Cooperation, *1994 APEC Economic Leaders' Declaration of Common Resolve - Bogor Declaration* (Nov. 15, 1994), available at: http://www.apec.org/Meeting-Papers/Leaders-Declarations/1994/1994_aelm.aspx.

[11] *See* Kent Shigetomi, *Global Trends in Good Regulatory Practice*, Office of the U.S. Trade Representative (Oct. 5, 2014), at p. 4, available at: http://www.mincetur.gob.pe/newweb/Portals/20/Documentos/eventos/2014/octubre/05_global_trends_in_good_regulatory_practice_Kent_SUSTR.pdf.

[12] *See* Daniel Kaufmann, Aart Kraay and Massimo Mastruzzi, *The World Governance Indicators - Methodology and Analytical Issues*, World Bank Development Research Group (Policy Research Working Paper 5430) (Sept. 2010), at p. 4, available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1682130; World Bank Group, *WGI-Regulatory Quality*, available at: http://info.worldbank.org/governance/wgi/pdf/rq.pdf. *See also* Millennium Challenge Corporation of the United States of America, *Regulatory Quality Indicator*, available at: https://www.mcc.gov/pages/selection/indicator/regulatory-quality-indicator.

[13] *See* World Bank Group, *Better Regulation for Growth – Governance Frameworks and Tools for Effective Regulatory Reform: Regulatory Quality Indicators* (2010), at p. 3, available at: https://www.wbginvestmentclimate.org/uploads/OverviewRegulatoryQualityIndicators.pdf.

iii. Indicators of regulatory quality, performance measures of regulatory governance and targets for ***the reduction of paperwork and administrative burdens*** have become prominent items on the reform agenda of governments and international organizations."[14]

iv. Must distinguish between:

A. the quality of the regulatory tools governments employ (e.g., regulatory impact assessment, consultation, simplification plans, codification exercises, plans to reduce administrative burdens, regulatory cost-ceilings for departments and agencies);

B. the quality of the overall process to produce regulations through different administrative requirements (e.g., (administrative procedure acts, freedom of information acts, notice-and-comment, and obligation to respond to the received comments); and

C. quality of the regulations as experienced by firms and citizens." [15]

6. **Transparency** –
Each Party should ensure that relevant regulatory authorities ***provide appropriate public access to*** covered regulatory measures and their ***supporting documentation, regulatory analyses, data***, and, where practicable, make this information available online for viewing and reproducibility;" Art. X.3.4.

7. **Periodic Review of Significant Regulatory Measures** –
"Each Party should establish or maintain procedures for it to **review […] significant regulatory measures** to determine whether specific regulatory measures should be modified, streamlined, expanded, or repealed so as to make the Party's regulatory program more effective in achieving the policy objective(s) pursued." Art. X.3.5.

8. **Annual Publication of Regulatory Agenda** –
"Each Party should publish, on an annual basis, a regulatory agenda which includes any covered regulatory measure that it reasonably expects its regulatory authorities to issue within no less than the following twelve-month period;" Art. X.3.6.

9. **Methods of Collaborating With Other Parties** –
"Each Party should consider […] methods [to **collaborate** with other Parties and their stakeholders], including:
a. "Information Exchanges;" Art. X.3.7.a-b.
b. "Coordinating Regulatory Activities;" Art. X.3.7.c.
c. "Share Best Practices and **harmonize relevant regulatory approaches, standards and related procedures**," including in the development of regulatory measures. Art. X.3.7.d.

10. **Regular Consultations** –
"[T]he Parties shall **consult regularly** on the implementation and operation of sectoral regulatory coherence provisions in other chapters…" Art. X.4.

11. **Establish Committee on Regulatory Coherence** –
"[T]o consider issues associated with implementation and operation of this Chapter and

[14] *Id*., at p. 1.
[15] *Id*., at p. 4.

to identify future priorities, including potential sectoral initiatives, for cooperative activities related to regulatory coherence among the Parties…" Art. X.5.1.

a. Consensus-based decisionmaking yearly or biannually. Art. X.5.1.
b. Development of a work plan. Art. X.5.3.
c. Consider developments in the areas of **Good Regulatory Practices** *and* **Best Practices** in maintaining national coordinating bodies, processes or mechanisms, and Parties' experience in implementing Good Regulatory Practices. Art. X.5.4.

12. **TPP Dispute Settlement** –

Limited to:

a. the obligation to have "processes or mechanisms to facilitate central coordination and review of certain new regulatory measures."
   i. "**To establish an actionable breach of this obligation** […] a Party must demonstrate that the other Party (1) violated the obligation ***and*** (2) that such violation adversely affected trade and investment between those Parties." Art. X.8.

III. TTIP "Regulatory Cooperation" Chapter (leaked version March 2015)[16]

1. **Scope** –
   a. Covers – 'regulatory acts' at **central level** (U.S. Federal and EU Regional) ***and*** **sub(non)-central level** (U.S. States & EU Member states);
2. **Policy Objectives** –
   a. "**To reduce unnecessarily burdensome, duplicative or divergent regulatory requirements affecting trade or investment**;" Sec. I, Art. 1.1b.
   b. "To promote an effective, pro-competitive […] transparent and predictable […] regulatory environment;" Sec. I, Art. 1.1.c.
   c. "To further the development, adoption and strengthening of "international instruments," and their timely implementation and application […in furtherance of] consistent regulatory outcomes;" Sec. I, Art. 1.1.d.i. "International Instruments" – (e.g., UNECE United Nations Economic Commission Europe), OECD, IMDRF (International Medical Device Regulators Forum) or the ICH (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use);
      i. Documents adopted by international bodies or fora in which both Parties' regulators and competent authorities at central level participate, including as observers, and which provide requirements or related procedures, recommendations or guidelines on the supply or use of a service [(e.g.,] authorization, licensing, qualification) or on characteristics or related production methods, presentation or use of a product." Sec. I, Art. 2.d.

[16] *See* European Commission, *RECONSTRUCTED: Draft sent 26/3-15 from the Commission to the Trade Policy Committee CHAPTER [ ] Regulatory Cooperation* (March 26, 2015), available at: http://corporateeurope.org/sites/default/files/reconstructed_ec_proposal_regulatory_cooperation_march_2015_0.pdf. *Cf.* European Commission, *Initial Textual Proposal for a Draft Chapter on Regulatory Cooperation in TTIP* (Feb. 10, 2015), available at: http://trade.ec.europa.eu/doclib/docs/2015/february/tradoc_153120.pdf; http://epthinktank.eu/2015/02/17/ttip-regulatory-cooperation/.

d. To provide a framework for possible cooperation among regulators and **encourages** the application of **Good Regulatory Practices**.
   i. Does **not** entail any obligation to achieve any particular regulatory outcome.
   ii. Does **not** restrict the right of each Party to maintain, adopt and apply measures to achieve legitimate public policy objectives […] at the level of protection that it considers appropriate…;" Sec. I, Art. 1.2.

e. To reaffirm their shared commitment to good regulatory principles and practices, as laid down in the **OECD Recommendation of 22 March 2012 on Regulatory Policy and Governance**." Sec. I, Art. 1.3.
   i. **"2012 Recommendation of the OECD Council on Regulatory Policy and Governance**[17]
      A. [Recognized] the importance of sound regulatory frameworks as a basic condition for well-functioning markets and societies, protecting the environment and the promotion of economic growth."[18]
      B. Recommended that governments should "[r]egularly publish reports on the performance of regulatory policy and reform programmes and the public authorities applying the regulations."[19]
      C. "**6.2 *Design and assess data collection and information management strategies to ensure that the necessary high-quality information is available for the preparation of reports while avoiding the imposition of unnecessary administrative burdens***."[20] **[DATA QUALITY]**
      D. "**6.3 *Promote an external review function*, including input by stakeholders and civil society**."[21] **[PEER REVIEW]**

3. **Definitions** –
   a. "***Regulatory Act at Central Level***" –
      i. EU regulations; directives; and delegated and implementing acts;
      ii. U.S. federal statutes; federal agency or executive branch entity rules (5 USC § 551 (4)); orders (5 USC § 551 (6)); guidance documents (Executive Order 12,866 § 3(g)) issued by any federal agency, government corporation, government controlled corporation or other executive branch establishment (covered under FOIA - 5 USC § 552 (f) (1)) [promulgations

[17] *See* Organization for Economic Cooperation and Development, *Recommendation of the Council on Regulatory Policy and Governance* (adopted March 22, 2012), available at: http://www.oecd.org/governance/regulatory-policy/49990817.pdf.
[18] *Id*., at pp. 5, 10.
[19] *See* Organization for Economic Cooperation and Development, *Recommendation of the Council on Regulatory Policy and Governance – Annex to the Recommendation of the Council on Regulatory Policy and Governance* (2012), *supra* at Sec. 6, p. 13.
[20] *Id*., at Sec. 6.2, p. 13.
[21] *Id*., at Sec. 6.3, p. 13.

covered under the Administrative Procedure Act]; executive orders and other executive documents laying down general rules or mandating conduct by government bodies; Sec. I, Art. 2.a.

b. "***Regulatory Acts at Non-Central Level***" –
   i. Laws & regulations adopted by EU Member State central national authorities, but not including EU Member State laws transposing EU regional acts into domestic law;
   ii. Laws & regulations adopted by the central authorities of a U.S. State.

c. "***Regulatory Acts***" –
   i. Those that "determine requirements or related procedures for the supply, or use of a *service* (e.g., authorization, licensing or qualification);" Sec. I, Art. 3.1.a *or*
   ii. Those that "determine requirements or related procedures applying to *goods* […] concerning their characteristics or related production methods, their presentation or their use." Sec. I, Art. 3.1.b. *and*
   iii. Those "**that have or are likely to have a significant impact on trade or investment between the Parties**."
   iv. Those concerning matters covered by [specific or sectoral provisions concerning goods and services, to be identified] fall in within the scope of this Chapter. Sec. I, Art. 3.3.

d. "***Regulators and Competent Authorities at Non-Central Level***" –
   i. EU Member central government authorities;
   ii. U.S. State governmental authorities. Sec. II, Art. 2.d.

4. **Transparency** –
   a. Publication of list of planned regulatory acts at central level once each year; Sec. II, Art. 5.1.
   b. Make publicly available information on planning and timing leading to the adoption of planned regulatory acts at central level "undergoing impact assessment," including on planned stakeholder consultations and potential for significant impacts on trade or investment." Sec. II, Art. 5.2.
   c. Offer a reasonable opportunity for any interested natural or legal person, on a non-discriminatory basis, to provide input through a public consultation process, and ensure contributions are considered. Sec. II, Art. 6.1.

5. **Conduct Regulatory Impact Assessments** –
   a. For planned regulatory acts at central level." Sec. II, Art. 7.1.
   b. RIAs shall consider:
      i. "[R]elevant international instruments;"
      ii. "[T]he regulatory approaches of the other Party;"
      iii. "[I]mpact on int'l trade or investment." Sec. II, Art. 7.2.a-c.

6. **Regulatory Policy Instruments/Tools** –
   a. Publish RIAs at central level no later than the proposed or final regulatory acts;" Sec. II, Art. 7.3.a.
   b. Promote exchange of information on available relevant scientific and economic evidence and data as well as on [their practice to assess impacts on international trade and investment and], the methodology and economic assumptions applied in

regulatory policy analysis;" Sec. II, Art. 7.3.b.

c. Promote exchange of experience and share information on planned ex-post evaluations and retrospective reviews." Sec. II, Art. 7.3.c.

7. **Regulatory Cooperation** –
   a. Parties will establish a bilateral mechanism to **seek increased compatibility between their respective regulatory framework**s, where appropriate;" Sec. III, Art. 8.1.
   b. Each Party will designate a "Focal Point" (an office in its central administration) responsible for exchanging information about envisaged and existing regulatory acts at central level." Sec. III, Art. 8.3.
8. **Party Information Exchange** – (on regulatory acts at **central** level)
   a. Identify published planned regulatory acts at central level "that are likely to have a significant impact on international trade or investment, including […] between the Parties." Sec. III, Art. 9.1.
   b. Regularly inform about proposed regulatory acts at central level not originating from Executive Branch or included in most recent published list "that are likely to have a significant impact on international trade or investment, including […] between the Parties." Sec. III, Art. 9.2.
   c. Participate constructively in regulatory exchanges […u]pon the request of a Party…" Sec. III, Art. 9.3, 9.5.
   d. Communicate without delay to legislative authorities and via Focal Point specific written comments or statements received from the other Party concerning regulatory acts at central level which are being prepared or reviewed by those bodies." Sec. III, Art. 9.7.
   e. When requested, it shall start promptly, and may continue until the adoption of the regulatory act.. Sec. III, Art. 10.1-2.
   f. Shall not prejudice the right to regulate in a timely manner, particularly in cases or urgency or in accordance with deadlines in domestic law." Sec. III, Art. 10.3.
9. **Information and Regulatory Exchanges** (on regulatory acts at **non-central** level)
   a. In areas and sectors where there may be common interest. Sec. III, Art. 11.1.
   b. The regulators and competent authorities at central level of both Parties will coordinate the exchanges involving the regulatory authorities at non-central level responsible for the regulatory acts concerned, at one Party's request, via the other Party's Focal Point. Sec. III, Art. 11.2.
10. **Promoting Regulatory Compatibility By Proposing Joint Examinations – (at central level)**
    a. Where mutual benefits can be realised without compromising the achievement of legitimate public policy objectives." Sec. III, Art. 10.1.
    b. Must "duly substantiate" the proposal "as regards the choice of the method," and each response must be substantiated. Sec. III, Art. 10.3.
    c. A Joint Examination may be proposed to promote regulatory compatibility through one or more possible methods:
       i. "**Mutual recognition of equivalence of regulatory acts** based on evidence that the relevant regulatory acts achieve equivalent outcomes as regards the fulfilment of the public policy goals pursued by both Parties;" Sec. III, Art. 10.2.a.

ii. "**Harmonization of regulatory acts or their essential elements**" by applying existing international instruments, cooperating with Parties to develop new international instruments, or approximating them bilaterally. Sec. III, Art. 10.2.b.

iii. "**Simplification of regulatory acts**" [consistent with] shared legal or administrative principles and guidelines. Sec. III, Art. 10.2.c.

d. Alternatively, the Parties also may "agree to cooperate, in areas of common interest, with respect to pre-normative research, and to exchange scientific and technical information relevant for this purpose." Sec. III, Art. 10.4.

11. **Promoting International Regulatory Cooperation** –

a. Parties may cooperate between themselves and with third parties by:

i. Presenting joint initiatives, proposals and approaches in international bodies or fora, especially in areas where regulatory exchanges have been initiated or concluded;" Sec. III, Art. 13.1

ii. Implementing within their respective domestic systems those international instruments they have contributed to." Sec. III, Art. 13.2.

12. **Establishment of Regulatory Cooperation Body (RCB)** –

a. RCB Functions:

i. To prepare and publish an Annual Regulatory Co-operation Programme reflecting common priorities and the outcomes of past or ongoing regulatory cooperation initiatives…" Sec. III, Art. 14.1, 14.2.a.

ii. To monitor the implementation of this Chapter's provisions, including the [specific or sectoral provisions concerning goods and services];" Sec. III, Art. 14.2.b.

iii. To consider new initiatives for regulatory co-operation proposed by either Party or their stakeholders; Sec. III, Art. 14.2.d.

iv. To prepare joint initiatives or proposals for international regulatory instruments…" Sec. III, Art. 14.2.e.

v. To ensure transparency in regulatory cooperation between the Parties;" Sec. III, Art. 14.2.f.

vi. To examine any other issue concerning application of this Chapter, or of [specific or sectoral provisions concerning goods and services] raised by a Party;" Sec. III, Art. 14.2.g.

vii. To create sectoral working groups and delegate certain tasks to them or to such other working groups as may be set up by the Joint Ministerial body;" Sec. III, Art. 14.4.

b. "The agenda and the minutes of RCB annual meetings of the RCB shall be made public." Sec. III, Art. 14.5.

i. Annual meetings should be open to stakeholders to exchange views on the Annual Regulatory Co-operation Programme prepared jointly by the co-chairs of the RCB [and] the co-chairs of the Civil Society Contact Groups…" Sec. III, Art. 15.1, 15.2.

ii. Participating stakeholders need NOT be directly affected by the items on the meeting agenda. Sec. III, Art. 15.2.

iii. Stakeholders shall be provided the opportunity to submit their general views and observations or to present to the RCB concrete suggestions for further regulatory co-operation between the Parties," which shall be given careful consideration. Sec. III, Art. 15.3.

iv. The RCB shall provide stakeholders with a written reply to 'substantial' proposals. Sec. III, Art. 15.3.

c. RCB Composition and Rules of Procedure –

i. Composed of representatives of both Parties;

ii. Co-chaired by senior representatives of regulators and competent authorities at central level for regulatory coordination activities.

iii. Shall invite the involvement of regulators and competent authorities at non-central level when considering regulatory acts at non-central level. Sec. III, Art. 16.1.

IV. Information/Data Quality

1. Is an aspect of "Regulatory Quality" which is a principle of OECD, World Bank and APEC "Good Regulatory Practices" referenced in both the TPP Regulatory Coherence and TTIP Regulatory Cooperation Chapters.

2. Ensuring information/data quality is among the "Good Regulatory Practice" functions performed by the U.S. Office of Information and Regulatory Affairs in the Office of Management and Budget.

3. The Information/Data Quality Act (IQA)[22]

a. Congress passed the IQA in 2000 (Pub. L. No. 106-554, 114 Stat. 2763, 2763A-153-154 (2000), § 515, codified at 44 U.S.C. § 3516 note)

i. IQA is a federal procedural statute which contributes to government accountability and transparency.

b. Implements and amends the Paperwork Reduction Act (PRA) (Publ. L. 104-13, 109 Stat. 163, 104th Cong. (May 22, 1995)).

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[22] *See* Lawrence A. Kogan, *Revitalizing the Information Quality Act as a Procedural Cure for Unsound Regulatory Science: A Greenhouse Gas Rulemaking Case Study*, Washington Legal Foundation Critical Legal Issues Working Paper Series No. 19 (Feb. 2015), available at: http://www.wlf.org/publishing/publication_detail.asp?id=2479. *See also* OIRAWatch, *Judicial Review of the Data Quality Act*, Center for Regulatory Effectiveness (Feb. 12, 2015), available at: http://www.thecre.com/oira/?p=3787; David LaRoss, EPA *Critics Float New Strategy To Challenge Agency Rules Using Data Law*, InsideEPA (Feb. 19, 2015), available at: https://nebula.wsimg.com/aad41051818e710eb5d3242de005e126?AccessKeyId=39A2DC689E4CA87C906D&disposition=0&alloworigin=1; David LaRoss, *Immigration Order Could Boost EPA Critics' Data Quality Suits Over Rules*, InsideEPA (March 02, 2015), available at: https://nebula.wsimg.com/4f5d3ba0d28c9f48f0762fb0d956dd5e?AccessKeyId=39A2DC689E4CA87C906D&disposition=0&alloworigin=1; Jonathan Rowland, *Challenging the Scientific Basis for Emissions Regulations*, WorldCoal.com (March 10, 2015), available at: http://www.worldcoal.com/power/10032015/Challenging-the-scientific-basis-for-emissions-regulations-coal2042/; Lawrence A. Kogan, *A Second Look at EPA Findings*, Forbes Opinion (March 5, 2015), available at: http://www.forbes.com/sites/realspin/2015/03/05/a-second-look-at-epa-findings/; Lawrence A. Kogan, When It Comes To Climate Policies, 'Trust But Verify', Forbes Opinion (March 27, 2015), available at: http://www.forbes.com/sites/realspin/2015/03/27/when-it-comes-to-climate-policies-trust-but-verify/; Lawrence A. Kogan, *U.S. Information Quality Act Filing Reveals Patent Assertion Entity Propaganda*, OIRAWatch.com (April 22, 2015), available at: http://www.thecre.com/oira/?p=4334.

c. Congress intended that the IQA, as an implementation of the PRA, protect the negative right of a designated class of persons not to be burdened, financially or otherwise, by poor quality science that agencies disseminate in support of major regulations.

d. Requires (dependent and independent Federal agencies (and White House Offices):

i. to ensure the quality (accuracy), objectivity, utility, and integrity of the scientific, technical, and statistical information that federal agencies adopt and disseminate to the public.

ii. to provide an administrative review mechanism that will allow affected entities (stakeholders) to seek correction of agency-disseminated information that was not adequately validated.

4. White House Office of Management and Budget (OMB) issued guidelines implementing the IQA.

a. Require that each federal agency develop and adhere to its own IQA guidelines, and set out minimum criteria for scientific peer review of agency-drafted and third -party studies and scientific assessments, as well as, criteria for the selection of peer reviewers.

5. Information/data quality is already an aspect of "Regulatory Quality," *but* the IQA is *not* expressly incorporated into the OECD World Bank and APEC "Good Regulatory Practices" referenced within the TPP and TTIP, as are other OMB-OIRA regulatory review mechanisms, such as regulatory impact assessment and economic cost-benefit analysis.[23]

a. This result obtains b/c:

i. The Obama administration does not enforce the IQA, and the EU is opposed to the IQA.

ii. These IQA opponents are EU Precautionary Principle proponents.

b. These IQA opponents are EU Precautionary Principle proponents,[24] *b/c*:

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[23] *See Presidential Executive Order 12866*, 58 FR 51735 (Oct. 4, 1993), available at: http://www.archives.gov/federal-register/executive-orders/pdf/12866.pdf; *Presidential Executive Order 13563*, 76 FR 3821 (Jan. 21, 2011), available at: http://www.gpo.gov/fdsys/pkg/FR-2011-01-21/pdf/2011-1385.pdf; The White House, *OMB Circular No. A-4, "Regulatory Analysis"* (M-03-21) (Sept. 17, 2003), available at: https://www.whitehouse.gov/omb/memoranda_m03-21/; https://www.whitehouse.gov/omb/circulars_a004_a-4/. *See also* White House, *Regulatory Impact Analysis: A Primer*, available at: https://www.whitehouse.gov/sites/default/files/omb/inforeg/regpol/circular-a-4_regulatory-impact-analysis-a-primer.pdf; John D. Graham, *Valuing the Future: OMB's Refined Position*, 74 U Chi L Rev 51 (2007), available at: https://lawreview.uchicago.edu/sites/lawreview.uchicago.edu/files/uploads/74.1/74_1_Graham.pdf ("Federal agencies are required by presidential executive order to prepare a regulatory impact assessment (RIA) in support of any economically significant regulatory action.[fn] An important feature of the RIA is a benefit-cost analysis.[fn]").

[24] *See* Institute for Trade, Standards and Sustainable Development, *Information Quality Act Opponents Are Post-Modern Precautionary Principle Proponents*, "ITSSD Programs—Theme #4 (2006-2013)—International Regulatory Transparency: Information Quality Act," available at: https://nebula.wsimg.com/46093c80df10130c677000d47b9fb3d7?AccessKeyId=39A2DC689E4CA87C906D&disposition=0&alloworigin=1.

i. Federal agency implementation of the IQA would deny agencies of their ability to employ adequate regulatory protections in implementation of Congress' precautionary intent gleaned (reinterpreted) from 1970's-era environmental, health and safety legislation.

ii. "The IQA threatens to undermine the precautionary approach mandated by Congress in such statutes by subjecting individual regulatory decisions to strict evidentiary standards"[25] that require quantitative in lieu of qualitative data, especially in the case of risk assessments.[26]

iii. Judicially reviewable agency IQA peer review practices could ultimately jeopardize the 'super deference' (i.e., judicial deference to agency interpretation of uncertainties in scientific evidence as well as ambiguous provisions in organic statutes) federal agencies have long enjoyed pursuant to the U.S. Supreme Court's decision in *Chevron U.S.A., Inc. v. Natural Resources Defense Council*, Inc., which imposes a rather high evidentiary threshold to show that disputed agency regulations based on third party scientific assessments were "arbitrary and capricious."[27]

c. The Post-Modern EU Precautionary Principle challenges the fundamental tenets of Enlightenment era empirical science, and sets forth a new evidentiary paradigm for scientific burdens and thresholds of proof. [28]

V. Comparing TTIP Regulatory Cooperation With TPP Regulatory Coherence

1. "[T]he regulatory provisions of a U.S.-EU agreement should build on the TPP Regulatory Coherence chapter and **go well beyond** to provide an additional set of tools to remove unnecessary divergences from the existing stock of regulations and prevent future divergences from developing."[29]

2. ***Regulatory Coherence v. Regulatory Cooperation***:

a. ***Regulatory Coherence*** – "is about ***good regulatory practices***, transparency, and

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[25] *See* Sidney A. Shapiro, Rena Steinzor and Margaret Clune, *Ossifying Ossification: Why the Information Quality Act Should Not Provide for Judicial Review, Center for Progressive Policy Reform*, CPR White Paper #601 (Feb. 2006), at p. 8, available at: http://www.progressivereform.org/articles/CPR_IQA_601.pdf.

[26] *See* Thomas O. McGarity, Sidney A. Shapiro, Rena I. Steinzor, Joanna Goger and Margaret Clune, Truth and *Science Betrayed, The Case Against the Information Quality Act*, Center for Progressive Reform (Feb. 2005), at p. 9, available at: http://thecre.com/pdf/20111110_iqa.pdf.

[27] *See* Emily Hammond Meazell, *Super Deference, the Science Obsession, and Judicial Review as Translation of Agency Science*, 109 MICH. L. REV. 733, 734 (2011), available at: http://www.michiganlawreview.org/assets/pdfs/109/5/meazell.pdf; *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).

[28] *See* Institute for Trade, Standards and Sustainable Development, *The Information Quality Act and the Post-Modern Modern Precautionary Principle*, "ITSSD Programs—Theme #4 (2006-2013)—International Regulatory Transparency: Information Quality Act," available at: https://nebula.wsimg.com/79d22b24f3e1149d2b0465789de113b0?AccessKeyId=39A2DC689E4CA87C906D&disposition=0&alloworigin=1.

[29] *See* U.S. Chamber of Commerce, *Technical Barriers to Trade (TBT) and Sanitary/Phyto-Sanitary (SPS) Concerns in an EU-U.S. Trade and Investment Agreement*, available at: http://ec.europa.eu/enterprise/policies/international/cooperating-governments/usa/jobs-growth/files/consultation/regulation/44-us-chamber-on-tbt-sps_en.pdf.

stakeholder engagement in a domestic regulatory process."[30]

i. "…[T]he function of **regulatory "coherence**" [is to] ensure[] the greatest possible **transparency** about measures under consideration, solicit[] as much **input** as possible, and ensure[] that all parts of **government** are **engaging** with one another."[31]

b. "***Regulatory Cooperation*** - is the process of interaction between U.S. and EU regulators, founded on the benefits regulators can achieve through closer partnership and greater ***regulatory interoperability***. […]

i. Regulatory cooperation […] can encourage regulators to **proactively consider cooperation**, direct the **manner in which regulators consult** with each other, speak to the importance of **assessing significant transatlantic impacts**, and where both feasible and desirable, facilitate the regulators' ability to enter into regulatory cooperation arrangements."[32]

ii. Regulatory cooperation can "encourage **a paradigm shift in the mindset of regulators to consider some of the broader international costs and benefits of what they are doing**. Done properly, it will actually enhance the ability of regulators to achieve their mandates, as it will allow them to become more efficient in addressing real risks, and thus effective in enforcing their laws."[33]

c. Regulatory Coherence is foremost concerned with establishing **compatible minimal regulation notification, development and review *processes***.

d. Regulatory Cooperation is concerned not only with establishing compatible regulation notification, development and review ***processes***, but also with establishing **compatible and interoperable *regulations and standards***.

3. It is critical that Asian nations pursue regulatory coherence as the first step to eventually eliminating unnecessary regulatory divergences, considering that most global manufacturing supply-chains are based in Asia.

VI. What is the Likelihood that Regulatory Coherence/Regulatory Cooperation Will Succeed in Reducing Non-Tariff Barriers to Trade?

1. **TTIP - CARVE-OUT from Chapter –** This chapter ***does not cover*** **legislation** at central *or* non-central level **which establishes public policy objectives**, such as acts determining the principles of [e.g.,] *inter alia*:

a. **competition**;

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[30] *See* U.S. Chamber of Commerce, *Regulatory Coherence & Cooperation in the Transatlantic Trade and Investment Partnership (TTIP)*, at p. 1, available at: https://www.uschamber.com/sites/default/files/regulatory_coherence_regulatory_cooperation_-chamber_ttip_paper-final_2.pdf.

[31] *Id*., at p. 5.

[32] *Id*., at p. 2.

[33] *Id*., at p. 10.

b. **consumer protection**;
c. **IPR protection**;
d. company incorporation and registration;
e. **personal data protection**; **or**
f. ***protection of the environment***. (General Note, par. 5).

2. **Dispute Settlement** –
Procedures for regulatory cooperation ***may not*** lend themselves to the application of dispute settlement rules. The Parties should consider other mechanisms (e.g., regulator monitoring and reporting, including to the political level (Joint Ministerial Body)." Gen'l Notes, par. 5.

3. **Cultural Preferences** –
It will be difficult to bridge **cultural differences/preferences**, which can serve not only as the legitimating bases for divergent regional and national laws, regulations and standards, as the EU's TTIP carve-out shows, but also as sources of what former WTO Director General, Pascal Lamy once characterized as 'good' trade protectionism.[34]
a. While this will be a long road to travel, the Parties have at least begun to talk about it.

[34] *See* Pascal Lamy, *Co-Existence Between Public Policy And Free Trade: Can We Achieve Good Protectionism*, Conference of the Greens/European Free Alliance at the European Parliament (Brussels, March 5, 2004), available at: http://trade.ec.europa.eu/doclib/docs/2004/march/tradoc_116156.pdf (distinguishing 'good' protectionism marked by "organising market opening in such a way as to uphold the varying collective preferences of different societies," i.e., "legitimate protection of social choices," from 'bad' protectionism "which means discriminating between imported and domestic products in a way that favours the latter, thus protecting domestic manufacturers.")