March 21, 2013

Via Electronic Mail and Facsimile

Mr. Paul Verkuil
Chairman
Administrative Conference of the United States
1120 20th St. NW
Suite 706 South
Washington, DC 20036

Re: Bias toward Industry in ACUS Project on International Regulatory Cooperation

Dear Mr. Verkuil:

We are writing to express our disappointment at the way ACUS has conducted its project on International Regulatory Cooperation (IRC) and to urge you to ensure greater balance in ACUS's continuing work on this and other projects. In general, ACUS has elevated business and trade concerns over health, safety, and environmental protections throughout its research project on IRC, from the development of its recommendations through the current implementation stage.

On several occasions, we have expressed concern about ACUS being overly responsive to industry groups, warning that such alliances would begin to tarnish ACUS's reputation as a neutral, independent organization and alienate the public interest groups that support its work.[1] We never received a response to our most recent letter of October 18, 2012, and yet we continue to feel that these issues require ACUS's prompt attention.

To that end, we encourage you to look back over the flaws in ACUS's project on IRC—a case study illustrating how the process enables industry groups and their ideological allies to gain control over a project. These interests effectively dominated the IRC project by (1) framing the discussion in ways that obscured any opposing points of view, and (2) taking advantage of the composition of ACUS decisionmaking bodies. Industry groups were able to enshrine their self-serving policy preferences in ACUS's final recommendations, which often prove influential among policymakers. Indeed, on May 1, 2012, President Obama signed Executive Order 13609 on

[1] *See* Letter from Tom McGarity and Rena Steinzor, Ctr. for Progressive Reform, to Paul Verkuil, Chairman, ACUS (Apr. 27, 2012), *available at* http://progressivereform.org/articles/ACUS_Letter_042712.pdf (objecting to ACUS's decision to co-host an implementation summit on "incorporation by reference" and IRC with the Chamber of Commerce); Letter from Tom McGarity and Rena Steinzor, Ctr. for Progressive Reform, to Paul Verkuil, Chairman, ACUS (Oct. 18, 2012), *available at* http://progressivereform.org/articles/Verkuil_ACUS_Bias_Letter_101812.pdf (expressing disappointment

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"Promoting International Regulatory Cooperation," based in part on ACUS's recommendations, and it perpetuates those same industry-driven priorities.[2]

The principal objective of IRC is to "harmonize" U.S. regulatory standards with those of other countries or international standard-setting organizations.[3] In the words of Executive Order 13609, IRC is intended to "reduce, eliminate, or prevent unnecessary differences in regulatory requirements."[4] There is always a danger that such harmonization efforts will become a deregulatory "race to the bottom" in which nations, at the urging of business groups, converge on the least protective standard in the interest of maximizing international trade.

The imprudent push toward IRC, as embodied in ACUS's recommendations and Executive Order 13609, encourages agencies to find "unnecessary differences" to eliminate in order to promote trade, without adequately grounding such efforts in the agencies' statutory missions to protect health, safety, and the environment. As a result, agencies may be pressured to make regulatory decisions solely on the basis of trade-related economic factors—which may be impermissible considerations under their statutes in many cases—even where those decisions compromise public safeguards. A more responsible program of regulatory cooperation would encourage only "upward" harmonization, directing agencies to (1) consider foreign or international approaches only if they would strengthen existing U.S. protections, and (2) work on lifting the standards of U.S. trading partners where they fall below those of the United States, recognizing that inadequate foreign regulatory systems pose serious threats to the health and safety of U.S. consumers in this globalized economy.

In our previous letters, we have objected to ACUS's practice of co-hosting events with industry groups, and now, ACUS's close relationship with the Chamber of Commerce has begun to affect how others perceive your organization as well. The Administrative Law Review (ALR) recently decided to withdraw from an IRC symposium it had planned to co-sponsor alongside ACUS and the Chamber of Commerce, originally scheduled for March 21, 2013. (It would have been the third joint event between ACUS and the Chamber on the subject of IRC.) The ALR felt compelled to pull out when the Chamber repeatedly refused to allow well-qualified public interest representatives to serve on the panels, thereby foreclosing any genuine debate on the implications of IRC.[5] The symposium was ultimately canceled in

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about ACUS's decision to co-sponsor an imbalanced workshop on chemical risk assessments with a large trade association (the American Chemistry Council) and several industry-biased think tanks).

[2] Exec. Order 13609, 77 FED. REG. 26413 (May 4, 2012), *available at* http://www.gpo.gov/fdsys/pkg/FR-2012-05-04/pdf/2012-10968.pdf. *See* International Regulatory Cooperation | ACUS, www.acus.gov/research-projects/international-regulatory-cooperation (Executive Order 13609 "based in part on Recommendation 2011-6"); David Hunter, *Executive Order Embraces International Regulatory Race to the Bottom as Official Administration Policy*, CPR Blog (May 2, 2012), http://progressivereform.org/CPRBlog.cfm?idBlog=0F52AD3D-CB5E-DB59-373FC982EEFE109C.

[3] IRC also encompasses a number of relatively innocuous measures, such as information-sharing among nations and coordinated enforcement efforts, but the harmonization of standards has always been the central goal of such efforts. In current discussions, these efforts are often described as regulatory "cooperation," "alignment," or "coordination," but that is only because the term "harmonization" has become too politically charged among both consumer and business organizations—the meaning remains essentially the same.

[4] Exec. Order 13609 § 1, 77 FED. REG. at 26413.

[5] The ALR is the official law journal of the American Bar Association (ABA) Section of Administrative Law & Regulatory Practice. This ABA Section has long been a vocal supporter of ACUS, and you yourself have served as its Chair in the past. *See* Letter from William Luneburg, Chair, ABA Section of Admin. Law & Regulatory Practice, to Michael Fitzpatrick, Acting Adm'r, Office of Info. & Regulatory Affairs (Aug. 18, 2009), *available at* http://www.americanbar.org/content/dam/aba/migrated/poladv/letters/adminlaw/2010may20_acus_l.authcheckdam.pdf (recommending topics for the reauthorized ACUS, eagerly awaiting its return); William Funk, *R.I.P. ACUS*, 21 ADMIN. & REG. L. NEWS 1 (1996), *available at* http://apps.americanbar.org/adminlaw/news/vol21no2/acus_rip.html (lamenting ACUS's de-funding on behalf of the ABA Section). In light of this history of support and cooperation between ACUS and the ABA, it is

the wake of the ALR's withdrawal, and we are very pleased that you will no longer be partnering with the Chamber on such a biased event. We hope you will continue to steer clear of similar events in the future, recognizing how detrimental they can be to ACUS's reputation and influence.

ACUS's one-sided projects and activities can no longer be excused as isolated incidents, or justified as legitimate efforts to engage a variety of stakeholders[6]—especially since they seem to engage the same narrow set of stakeholders time and again. We respectfully urge you to (1) monitor research reports for bias in their methods and perspectives, (2) revise the composition of ACUS decisionmaking bodies (the Committees, the Assembly, and the Council) to include a balanced range of viewpoints, and (3) ensure that industry groups and their allies do not enjoy an outsized influence over the process or outcome of ACUS projects. If left unaddressed, this pervasive bias threatens to compromise ACUS's legitimacy and marginalize its role.

History of ACUS Project

From the outset, the IRC project was built on a biased foundation. It had its origins in a program co-hosted by ACUS and the Chamber of Commerce on April 28, 2011—the first of several such collaborations on this subject—where government officials and industry representatives discussed the responsibility of agencies to engage in regulatory cooperation activities.[7] Noticeably absent from the event were any members of the public interest community who might have offered a different perspective. As a result of this joint forum with the Chamber, ACUS decided to revisit its 1991 recommendations on IRC and commissioned a research report to inform the process.[8]

As you know, the IRC report was prepared by Michael McCarthy, then Executive Director of ACUS. While a portion of his research focused on the views of "stakeholders," he devoted nearly all his attention to discovering the wishes and concerns of industry groups. He reviewed nearly 100 industry comments submitted to the International Trade Administration on ways to improve regulatory cooperation with the European Union, Canada, and Mexico. Beyond that, he personally interviewed representatives from six of the largest business groups, including the U.S. Chamber of Commerce and the American Chemistry Council.[9] By contrast, he spent one brief paragraph on the concerns of consumer groups, citing only two articles and reporting the opinion of several agency officials that harmonization will not lead to lower standards.[10] He did not conduct interviews with consumer groups active in this area, such as the Transatlantic Consumer Dialogue, Public Citizen, Food and Water Watch, or Center for Science in the Public Interest, nor did he consult other publicly available reports on the dangers of harmonization.[11]

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particularly unfortunate that ACUS's partnership with the Chamber of Commerce prevented the Section's official journal from participating in this event.

[6] *See* Letter from Paul Verkuil, Chairman, ACUS, to Tom McGarity and Rena Steinzor, Ctr. for Progressive Reform (Apr. 30, 2012) (responding that ACUS's partnership with the Chamber of Commerce in sponsoring the May 1, 2012 Implementation Summit merely "reflects our efforts to publicize the Conference's work in a variety of forums to ensure that we engage organizations and individuals with a wide range of policy perspectives.").

[7] *See* Michael T. McCarthy, Original Draft: International Regulatory Cooperation, 20 Years Later: Updating ACUS Recommendation 91-1, at 3 n.2 (Sep. 16, 2011), http://www.acus.gov/sites/default/files/COR-IRC-Draft-Report-9-16-11.pdf [hereinafter McCarthy Original Draft] (listing the participants in the April 28th forum).

[8] *Id.* at 1; Comments on the Proposed IRC Recommendation Submitted by R. Bruce Josten, Exec. Vice Pres. of Gov't Affairs, U.S. Chamber of Commerce, at 1 (Dec. 2, 2011), *available at* http://www.acus.gov/sites/default/files/documents/Chamber-Comments-on-ACUS-IRC-Proposed-Recommendation-12-1-11.pdf.

[9] *See* McCarthy Original Draft, *supra* note 7, at 19-21.

[10] *See id.* at 22.

[11] *See, e.g.*, TRANSATLANTIC CONSUMER DIALOGUE, PRINCIPLES OF HARMONIZATION (2000), *available at* http://tacd.org/index2.php?option=com_docman&task=doc_view&gid=127; Public Citizen, Archive of Harmonization Alerts

Many agencies have authorizing statutes that would permit international cooperation only to the extent it would further the agency's mission of health, safety, or consumer protection; several officials suggested that it would be improper for their agencies to promote U.S. business interests by pursuing a separate mission of harmonization.[12] The report regards these statutes and attitudes as "barriers" to IRC instead of considering that they might be necessary, legitimate constraints on harmonization activities.[13]

The report's imbalance went unnoticed during the process of review and revision; in fact, ACUS staff inserted a page-worth of additional material straight out of a report by the Chamber of Commerce.[14] One part of this material cites unquestioningly the conclusion of notoriously conservative economists that U.S.-EU regulatory cooperation would result in economic growth of $150 billion per year in GDP, which would in turn save 6,000 lives per year—an extrapolation based on very tenuous associations between GDP, average income levels, and statistics from 1990 about the average 35-year-old's tendency to engage in risky behaviors (smoking, excessive drinking, and lack of exercise).[15] This "richer is safer" thesis, a longstanding feature of reactionary attacks on protective regulations, has been exposed as illogical and absurd on a number of occasions.[16] ACUS staff made no effort to consider any additional *risks* to life, health, and safety that might result from downward harmonization of standards and increases in unsafe imports. (See the enclosed attachment for examples of the kinds of threats posed by harmonization that have gone unacknowledged throughout ACUS's project.)

The rest of the added material reproduces a series of ten questions suggested by the Chamber for agencies to use in deciding whether to pursue a particular harmonization effort. The questions are framed in such a way to favor harmonization as the default preference, requiring agencies to satisfy a heavy burden ("market failure" or "compelling national need") in order to justify "divergent regulations," and focusing almost exclusively on the trade increases, private sector benefits, and budgetary savings that would result from harmonization.[17]

After the first committee meeting on ACUS's report, public member Susan Dudley, who directs an industry-friendly think tank at George Washington University, sought to remove language from the minutes that even suggested IRC could lead to a "race to the bottom," and the Committee approved the

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1998 to 2003, http://www.citizen.org/trade/harmonization/alerts; CTR. FOR SCI. IN THE PUB. INTEREST, INTERNATIONAL HARMONIZATION OF FOOD SAFETY AND LABELING STANDARDS: THREATS AND OPPORTUNITIES FOR THE U.S. FOOD AND DRUG ADMINISTRATION AND THE U.S. DEPARTMENT OF AGRICULTURE (1997), *available at* http://www.cspinet.org/reports/codex.htm.

[12] *See* McCarthy Original Draft, *supra* note 7, at 22-23, 34-39 (describing statutory missions of agencies like the Consumer Product Safety Commission (CPSC), the National Highway Traffic Safety Administration (NHTSA), and the Federal Trade Commission (FTC), and recounting the attitudes of officials from the CPSC and FTC about the need to further their missions).

[13] *See id.* at 22-23 ("[E]ven if minor compromises on a safety regulation would allow regulatory harmonization that would greatly facilitate business and trade, these agencies do not believe that they have the statutory authority to make such a compromise").

[14] *See* Michael T. McCarthy, Redlined Draft: International Regulatory Cooperation, 20 Years Later: Updating ACUS Recommendation 91-1, at 26 (Oct. 19, 2011), http://www.acus.gov/sites/default/files/COR-IRC-report-10-19-11-redline.pdf [hereinafter McCarthy Redlined Draft].

[15] *Id.* at 12-13 n.30 (citing JOHN MORRALL III, DETERMINING COMPATIBLE REGULATORY REGIMES BETWEEN THE U.S. AND THE EU 2 n.6 (U.S. Chamber of Commerce White Paper) (2011), *available at* http://www.uschamber.com/sites/default/files/grc/Determining%20Compatible%20Regulatory%20Regimes%20-%20Final_0.pdf (citing Randall Lutter, John F. Morrall III & W. Kip Viscusi, *The Cost-Per-Life-Saved Cutoff for Safety-Enhancing Regulations*, 37 ECON. INQUIRY 599 (1999))).

[16] *See* Lisa Heinzerling & Frank Ackerman, *The Humbugs of the Anti-Regulatory Movement*, 87 CORNELL L. REV. 648, 666-70 (2002), *available at* http://www.law.georgetown.edu/faculty/Heinzerling/Articles/Heinzerling_Humbugs.pdf (criticizing, among other studies, the one whose conclusion is cited in the revised McCarthy report); Thomas O. McGarity, *A Cost-Benefit State*, 50 ADMIN. L. REV. 7, 40-49 (1998) (debunking the assumptions underlying this group of studies).

[17] *See* McCarthy Redlined Draft, *supra* note 14, at 26-27.

revision.[18] However, at the second committee meeting, public member Patti Goldman suggested that the draft preamble and recommendations improperly placed the reduction of trade barriers on par with agencies' statutory missions. She proposed additional language to correct these distorted priorities, which the Committee ultimately approved. The revisions clarified that agencies should pursue IRC only where doing so would advance their missions, and added that agencies should recognize the results of another country's inspections or certifications only if that country's standards and practices are "no less effective than United States equivalents."[19]

Between the second meeting and the plenary session where the recommendations would be debated and adopted, ACUS received written comments from Ms. Goldman, Ms. Dudley, and the Chamber of Commerce. Ms. Goldman reinforced the importance of the changes made at the second meeting, so that health, safety, and environmental protection would not take a backseat to trade objectives.[20] On the other hand, Ms. Dudley expressed concern that the changes would "dilute" the recommendations, suggesting that IRC should be pursued even when it does not further agencies' "narrow" missions because it promotes open markets.[21] The Chamber of Commerce was similarly "disheartened" by the changes, which it said would "greatly weaken" the recommendation "in nearly every aspect," and shared the concerns expressed by Ms. Dudley.[22]

While the Committee meetings were open to the public and made available by webcast, some of the project's most influential decisions were made outside of the transparent Committee process, when the ACUS Council reconsidered the recommendations without informing Ms. Goldman.[23] All but one of the Council's five public members represent the interests of industry groups hostile to government regulation: two high-profile lawyers active in the Federalist Society[24] and two senior officials at multinational banking corporations.[25]

According to remarks you made at the plenary session, the Council decided to endorse an additional set of amendments proposed by Council Member Ronald Cass, who is president of a consulting firm that assists industry clients and chairman of a think tank that seeks to eliminate regulatory barriers to

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[18] ACUS, Minutes from October 25, 2011 Meeting of the Committee on Regulation, at 1, *available at* http://www.acus.gov/sites/default/files/documents/COR-10-25-11-Meeting-Minutes.pdf (suggestion of Public Member Susan Dudley, founding director of the George Washington University Regulatory Studies Center).

[19] *Id.* at 2-4.

[20] Comments on the Proposed IRC Recommendation Submitted by ACUS Public Member Patti Goldman (Dec. 2, 2011), *available at* http://www.acus.gov/sites/default/files/documents/Goldman-Amendments-IRC.pdf.

[21] Comments on the Proposed IRC Recommendation Submitted by ACUS Public Member Susan Dudley (Nov. 23, 2011), *available at* http://www.acus.gov/sites/default/files/documents/Dudley-Comments-IRC.pdf.

[22] Comments on the Proposed IRC Recommendation Submitted by R. Bruce Josten, *supra* note 8, at 2.

[23] The Council's responsibilities include approving the appointment of public members and the conduct of research studies. About the Council | ACUS, http://www.acus.gov/about-council. For reasons that are unclear, unlike the Committees and the Assembly, the ACUS Council is not treated as an advisory committee under the Federal Advisory Committee Act (FACA), so its meetings and discussions are not made available to the public. *See* Paul Verkuil, *What the Return of the Administrative Conference of the United States Means for Administrative Law*, 1 MICH. J. ENVTL. & ADMIN. LAW 17, 22-23 (2012), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2018543 ("The discussions in committee and at the plenary session are conducted pursuant to [FACA]"); ACUS, FY 2012 CONGRESSIONAL BUDGET JUSTIFICATION 22 (2011), *available at* http://acus.gov/sites/default/files/ACUS-2012-Cong-Budget.pdf (FACA governs operations of ACUS Assembly and committees); Bylaws of the Admin. Conf. of the U.S., 1 C.F.R. § 302.6(a) (2012) ("All sessions of the Assembly and all committee meetings shall be open to the public").

[24] *See* Ronald A. Cass | ACUS, http://www.acus.gov/contacts/ronald-cass, *and* Theodore Olson | ACUS, http://www.acus.gov/contacts/theodore-b-olson.

[25] *See* Preeta D. Bansal | ACUS, http://www.acus.gov/contacts/preeta-d-bansal, *and* Jane C. Sherburne | ACUS, http://www.acus.gov/contacts/jane-c-sherburne.

international trade.[26] Ms. Dudley signed onto the Council's amendments before the plenary session, recognizing that they were very similar to the ones she had suggested, and they were presented to the Assembly as the "Cass-Dudley amendments."[27] The Council's amendments reversed Ms. Goldman's changes, suggesting that agencies should pursue IRC not only to further their missions, but also to promote trade and competitiveness as an independent goal. The conditions placed on these trade-motivated IRC activities were considerably weaker than before—requiring only that they not "detract" from or "conflict" with the agencies' missions instead of requiring that they "further" those missions.[28] In other words, the conditions leave ample room for IRC activities that may not present a clear, demonstrated conflict at the time they are pursued but will ultimately jeopardize health, safety, or the environment. As the Transatlantic Consumer Dialogue has written, "[I]f there is not a clearly defined public benefit, there is no reason for governments to spend public resources to accomplish harmonization. The cost of harmonization which only benefits industry should be shifted back to the private sector to execute voluntary standards,"[29] a view echoed by the U.S. Consumer Product Safety Commission.[30]

The Council's amendments also suggested that agencies should recognize the results of another country's inspections or certifications provided they are "high quality and appropriate" (later changed to "high quality and effective" during the plenary session) instead of requiring that they be "no less effective than United States equivalents."[31] This condition would appear to permit reliance on foreign systems even if they were less effective than those in the United States as long as they could be vaguely described as "high quality"—an entirely subjective, manipulable standard that in reality is no constraint at all.

Ms. Goldman has resigned from ACUS and, given her extensive experience as one of the nation's foremost environmental attorneys, her contribution should be sorely missed.

Instead of voting on the version of the recommendations that emerged from the Committee's careful consideration, the Assembly was directed to vote up or down on the amendments inserted afterward by the Council and Ms. Dudley. Three public members spoke against the Council's amendments, while nine individuals defended them, assuring the first group that their concerns were unjustified.[32] The other roughly 88 members in attendance did not participate, and even among those who did speak, few seemed to have a clear idea of the specific meaning and implications of the language in question. You called for a voice vote on "the Cass-Council amendment[s]," and the "Ayes" had it.[33]

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[26] *See* Honorable Ronald A. Cass, http://cassassociates.net (list of his roles and affiliations); Center for the Rule of Law, http://rule-of-law.us (message from the think tank's chairman, Mr. Cass).
[27] *See* Proposed Amendments to ACUS Recommendation on IRC, at 5-8 (Dec. 8-9, 2011), *available at* http://www.acus.gov/sites/default/files/Proposed-IRC-Recommendation-with-Amdendments-12-6-20111.pdf; December 8, 2011 Plenary Session of ACUS Assembly (Video Webcast), *available at* http://www.acus.gov/webcast/december-8-2011-plenary-session [hereinafter Plenary Session Webcast].
[28] *See* Proposed Amendments to ACUS Recommendation on IRC, *supra* note 27, at 5-6.
[29] TRANSATLANTIC CONSUMER DIALOGUE, *supra* note 11, at 3.
[30] *See* McCarthy Original Draft, *supra* note 7, at 34 ("CPSC staff expressed the view that it is the responsibility of industry to work through voluntary standards organizations toward harmonization, not the job of national governments to make everything magically line up").
[31] Proposed Amendments to ACUS Recommendation on IRC, *supra* note 27, at 7-8.
[32] The individuals defending the amendments included yourself, Mr. Cass, Ms. Dudley, Michael Fitzpatrick (Deputy Administrator of the White House Office of Information and Regulatory Affairs (OIRA), now at General Electric), Jeff Weiss (an official from the Office of the U.S. Trade Representative, now at OIRA), Don Elliott (a law professor and practitioner well-known for representing companies and trade associations in regulatory matters), Randolph May (president of the anti-regulatory Free State Foundation), Jim Chen (law professor and vocal conservative), and Carol Ann Siciliano (Associate General Counsel from the U.S. Environmental Protection Agency).
[33] *See* Plenary Session Webcast, *supra* note 27.

All the foregoing factors—the biased research report that set the terms of the debate, the complexity and unfamiliarity of the topic, the weighty opinion of the Council, and the largely industry-biased composition of the Assembly itself—culminated in a vote to approve the Council's amendments, reversing the changes made at the committee stage. In the aftermath, President Obama issued Executive Order 13609, hailed by the Chamber of Commerce because it continued to reflect their priorities,[34] and ACUS co-sponsored a second event with the Chamber to discuss ways to implement the IRC recommendations and the new Executive Order.

Conclusion

In its previous incarnation, ACUS gained a reputation for achieving a number of laudable improvements in the administrative process—from administrative penalty authority and alternative dispute resolution to the elimination of a jurisdictional amount in suits under the Administrative Procedure Act (APA). Its process and its accomplishments garnered broad, bipartisan support from a wide range of organizations.[35] We urge you to closely examine the composition, practices, and alliances of the "new" ACUS, and take the necessary steps to restore the organization to the neutral and independent agency it was intended to be, instead of the industry-dominated forum it has become.

Thank you for considering these views.

Sincerely,

Thomas O. McGarity
CPR Board Member
Joe R. and Teresa Lozano Long Endowed
Chair in Administrative Law,
University of Texas School of Law

Rena Steinzor
President, Center for Progressive Reform
Professor of Law,
University of Maryland School of Law

Michael Patoka
Policy Analyst, Center for Progressive Reform

Enclosure

cc: Members of the ACUS Council and Members of the ACUS Committee on Regulation

[34] Press Release, U.S. Chamber of Commerce, U.S. Chamber Welcomes Executive Order on International Regulatory Cooperation (May 1, 2012), *available at* http://www.uschamber.com/press/releases/2012/may/us-chamber-welcomes-executive-order-international-regulatory-cooperation (considering the Executive Order to be a "landmark" achievement).
[35] Funk, *supra* note 5.

ATTACHMENT

IRC activities pose very real threats to health, safety, and the environment that have gone unacknowledged and unaddressed throughout ACUS's work on this project.

Harmonization activities come in many different forms. U.S. agencies may adopt new domestic standards that conform to those of foreign or international authorities. Somewhat less directly, U.S. agencies may declare that a foreign country's regulatory standards and systems are "equivalent" to those of the United States, thereby allowing goods produced in those countries to freely enter U.S. markets as if they had been produced here. Alternatively, the United States might enter into more formal "mutual recognition agreements" (MRAs) that allow nations to rely on the results of each other's testing, inspection, or certification regimes, although such agreements can also be used to achieve broader equivalency or harmonization of standards. Because the standards, procedures, and enforcement practices of other countries may be significantly less protective than those of the United States, such reliance on foreign systems can expose the American public to unsafe imports produced under inferior conditions.[36]

The threats posed by harmonization activities are not merely theoretical. A number of current proposals and recent events in the area of food safety demonstrate how harmonization efforts can lead to lower levels of protection.

The FDA's Proposed Rule on Import Tolerances for Residues of Unapproved Drugs

The Food and Drug Administration (FDA) has proposed procedures for establishing "import tolerances" for residues of unapproved new animal drugs in food shipped to the United States.[37] As long as the drug in question can be lawfully used in another country, the FDA would bypass its normally extensive drug approval process—lasting 6 months to one year and incorporating input from a team of veterinarians and scientists—and instead conduct an abbreviated review, taking only about 100 hours of a mid-level FDA employee's time.[38] Where possible, the FDA would seek to harmonize its tolerances with the maximum residue limits in the Codex Alimentarius, an international standard-setting body that offers industry groups a formal role but lacks any meaningful participation from citizens or consumer groups.[39]

Imports account for 15 percent of all food consumed in the U.S., including 91 percent of our seafood, 61 percent of our honey, 8 percent of our red meat, and 2 percent of our dairy products.[40] As it

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[36] *See* PUBLIC CITIZEN, ACCOUNTABLE GOVERNANCE IN THE ERA OF GLOBALIZATION: THE WTO, NAFTA, AND INTERNATIONAL HARMONIZATION OF STANDARDS 5-6 (2000), *available at* http://www.citizen.org/documents/BCKGRNDforpdf.PDF (more detail on the various types of harmonization).

[37] Import Tolerances for Residues of Unapproved New Animal Drugs in Food, 77 FED. REG. 3653 (proposed Jan. 25, 2012), *available at* http://www.gpo.gov/fdsys/pkg/FR-2012-01-25/pdf/2012-1430.pdf.

[38] Comment Submitted by Ctr. for Sci. in the Pub. Interest on FDA Import Tolerance Proposed Rule, at 3-4, Apr. 20, 2012, *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2001-N-0075-0009.

[39] *See* Import Tolerance for Residues of Unapproved New Animal Drugs in Food, 77 FED. REG. at 3655; PUBLIC CITIZEN, *supra* note 36, at 5 (industry domination of Codex); David Livshiz, Updating American Administrative Law: WTO, International Standards, Domestic Implementation and Public Participation, 24 WIS. INT'L L.J. 961, 970 n.60 (2007), *available at* http://hosted.law.wisc.edu/wordpress/wilj/files/2012/02/livshiz.pdf ("The inclusion of NGO observers in the Codex, however, does not mean that the Codex is overly receptive to public interest organizations. To date, the overwhelming majority of NGOs that have received observer status are industry and professional organizations.").

[40] U.S. GOV'T ACCOUNTABILITY OFFICE, FDA COULD STRENGTHEN OVERSIGHT OF IMPORTED FOOD BY IMPROVING ENFORCEMENT AND SEEKING ADDITIONAL AUTHORITIES 1 (2010), *available at* http://www.gao.gov/assets/130/124619.pdf (15 percent of all food); FishWatch, U.S. Nat'l Oceanic & Atmospheric Admin., Outside the U.S., http://www.fishwatch.gov/farmed_seafood/outside_the_us.htm (91 percent of seafood imported); Stephen Haley, USDA Econ.

is, the FDA inspected less than 0.1 percent of imported seafood for drug residues in 2009,[41] and its inspections have found violations about 10 percent of the time.[42] Establishing more permissive drug tolerances for imported foods than for domestic foods could expose the American public to significantly greater risks of allergic reactions, cancer, and other serious health effects—considerations that are often ignored in the push to ease trade restrictions, as they were throughout ACUS's project.

The USDA's Harmonization of Import Rules to Prevent Bovine Spongiform Encephalopathy

The Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) has proposed harmonizing its rules on importing cattle and bovine products with guidelines from the Office of International Epizootics (OIE), an intergovernmental standard-setting organization.[43] The Center for Food Safety has criticized the proposal as a "race to the bottom," pointing out that the OIE guidelines are among the weakest available approaches for preventing bovine spongiform encephalopathy (BSE), commonly known as mad cow disease.[44]

Under the proposal, APHIS would assign each beef-exporting country to one of the OIE's "risk categories," with different import rules for each category. According to the Center for Food Safety, those categories are poorly designed, often grouping nations with wildly different standards into the same category. Moreover, in its rush to harmonize with these "international guidelines," APHIS has failed to justify why they are the most appropriate option for the United States, in light of more rigorous and effective approaches taken by countries like Japan and Australia. Finally, in an effort to minimize the rule's impact on trade, APHIS carved out numerous exceptions to the import prohibitions for all risk categories—exceptions that essentially swallow the rule and pose additional risks to food safety.[45] By encouraging the elimination of regulatory differences even where it fails to advance an agency's mission, ACUS's recommendations on IRC will promote more harmonization efforts like this, driven by trade interests with little regard for public health and safety.

The USDA's Equivalency Determinations: Serious Flaws and a Lack of Meaningful Oversight

The USDA's program of making and maintaining equivalency determinations for countries exporting meat and poultry to the United States highlights many of the flaws and dangers associated with this type of harmonization. The USDA's Food Safety Inspection Service (FSIS) determines a foreign country's regulatory system to be equivalent by conducting a "system audit"—reviewing documents and

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Research Serv., Sugar and Sweeteners Outlook 7 (Mar. 15, 2011), *available at* http://www.ers.usda.gov/media/574579/sssm271_1_.pdf (61 percent of honey); USDA Econ. Research Serv., Import Share of Consumption, http://www.ers.usda.gov/topics/international-markets-trade/us-agricultural-trade/import-share-of-consumption.aspx (8 percent of red meat and 2 percent of dairy).

[41] U.S. GOV'T ACCOUNTABILITY OFFICE, FDA NEEDS TO IMPROVE OVERSIGHT OF IMPORTED SEAFOOD AND BETTER LEVERAGE LIMITED RESOURCES 21 (2011), http://www.gao.gov/new.items/d11286.pdf [hereinafter GAO SEAFOOD IMPORTS].

[42] *See* David Love et al., *Veterinary Drug Residues in Seafood Inspected by the European Union, United States, Canada, and Japan from 2000 to 2009*, 45 ENVTL. SCI. & TECH. 7232, 7233 tbl.1 (2011), *available at* http://wisconsinaquaculture.com/Docs/457.PDF (from 2001 to 2006, an average of 24 violations per year, with an average of 229 inspections per year). *See also* FOOD & WATER WATCH, IMPORT ALERT: GOVERNMENT FAILS CONSUMERS, FALLS SHORT ON SEAFOOD INSPECTIONS 10-13 (2007), *available at* http://documents.foodandwaterwatch.org/doc/ImportAlertJuly2007-1.pdf (about the significant rise in animal drug residues in seafood imports).

[43] Bovine Spongiform Encephalopathy; Importation of Bovines and Bovine Products, 77 FED. REG. 15848 (proposed Mar. 16, 2012), *available at* http://www.gpo.gov/fdsys/pkg/FR-2012-03-16/pdf/2012-6151.pdf.

[44] Comment Submitted by the Center for Food Safety on USDA's Proposed Rule for BSE and the Importation of Bovines and Bovine Products, at 6-7, May 15, 2012, http://www.regulations.gov/#!documentDetail;D=APHIS-2008-0010-0050.

[45] *Id.* at 7-9, 11, 13.

data, meeting with inspection officials from the country, and inspecting a small sample of the country's facilities on-site.[46] The ultimate decisions as to which systems are "equivalent" are, as one might expect, very subjective and imprecise.[47]

FSIS auditors have deemed many countries equivalent despite significant safety deficiencies that would violate U.S. requirements, including: (1) company employees performing tasks that must be performed by government inspectors, (2) failure to conduct monthly government supervision reviews, (3) improper testing procedures and repeated sanitation violations, and (4) insufficient resources to carry out the required safety functions.[48] In declaring China "equivalent" for the purpose of exporting poultry products to the United States, the FSIS' process revealed even more serious problems: evidence suggested that the equivalency determination was made as part of a quid pro quo to resume U.S. beef exports to China, and moreover, the FSIS based its decision on incomplete, outdated audit information.[49]

Finally, the FSIS fails to exercise any effective oversight of countries deemed equivalent. Once these determinations are made, they are extremely unlikely to be rescinded, no matter how bad the country's food safety record becomes. For example, every time the FSIS identifies systemic problems in Brazil's food safety system, they appear to be remedied shortly thereafter but then resurface 2-3 years later, a pattern that has repeated at least four times.[50] In fact, the FSIS has *never* revoked a country's equivalency determination.[51] To make matters worse, the number of countries annually audited by the FSIS has declined by 60 percent since 2008. Apparently, the FSIS changed its policy three years ago, auditing foreign countries once every three years instead of once a year, and made the change public only in the last several weeks. Former officials have attributed the reduction in oversight to budget constraints.[52] The ACUS recommendations endorse mutual recognition of inspections without attending to the flaws that undermine these programs in the real world, while introducing even greater subjectivity into assessments of foreign systems ("high quality and effective" instead of "no less effective").

The above examples (import tolerances for drug residues, import rules to prevent BSE, and USDA equivalency determinations) illustrate just a few of the hazards of policies that encourage harmonization of standards and widespread reliance on foreign regulatory systems without ensuring that health and safety are not compromised in the process. ACUS failed to address—or even acknowledge—these legitimate concerns in the course of its work on IRC.

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[46] *See* PUBLIC CITIZEN, THE WTO COMES TO DINNER: U.S. IMPLEMENTATION OF TRADE RULES BYPASSES FOOD SAFETY REQUIREMENTS 12-13 (2003), *available at* http://www.citizen.org/documents/PCfoodsafety.pdf [hereinafter WTO DINNER].
[47] *See* PUBLIC CITIZEN, TRADE DEFICIT IN FOOD SAFETY: PROPOSED NAFTA EXPANSIONS REPLICATE LIMITS ON U.S. FOOD SAFETY POLICY THAT ARE CONTRIBUTING TO UNSAFE FOOD IMPORTS 22 (2007), *available at* http://www.citizen.org/documents/FoodSafetyReportFINAL.pdf; TRANSATLANTIC CONSUMER DIALOGUE, *supra* note 11, at 3.
[48] *See* WTO DINNER, *supra* note 46, at vii-viii.
[49] Food & Water Watch, Citizen Petition for Rulemaking to Remove the People's Republic of China as Being Eligible to Export Poultry Products to the United States under 9 CFR 381.196 (b), at 4-6, 10-12, Jan. 19, 2011, *available at* http://www.fsis.usda.gov/PDF/Petition_Food&Water_Watch.pdf.
[50] *See* Letter from Wenonah Hauter, Exec. Dir. of Food & Water Watch, to Tom Vilsack, Sec'y of USDA, Aug. 9, 2010, at 2 n.7, *available at* http://documents.foodandwaterwatch.org/doc/brazil-vilsack-letter.pdf.
[51] FDA Public Hearing on Ensuring the Safety of Imported Foods and Animal Feed: Comparability of Food Safety Systems and Import Practices of Foreign Countries, Mar. 30, 2011 (transcript available at http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/ucm254816.htm) (statement of Mary Stanley, Dir., Int'l Policy Div., Office of Policy & Program Dev., USDA FSIS).
[52] *See* Helena Bottemiller, *Investigation: USDA Quietly Eliminated 60 Percent of Foreign Meat Inspections*, FOOD SAFETY NEWS, Nov. 1, 2012, http://www.foodsafetynews.com/2012/11/usda-quietly-eliminated-60-percent-of-foreign-meat-inspections/#.URwq6fI3mSo; Helena Bottemiller, *FSIS Makes Cut to Foreign Meat Safety Audits Public*, FOOD SAFETY NEWS, Jan. 28, 2013, http://www.foodsafetynews.com/2013/01/fsis-makes-cut-to-foreign-meat-safety-audits-public/#.URwq7vI3mSp.