Table of Contents

From: Susan E. Dudley (Public Member)
To: Assembly of the Administrative Conference
Re: Comments on Proposed International Regulatory Cooperation Recommendation
Date: November 23, 2011

I am concerned that some of the changes made to the draft recommendations at the Committee on Regulation meeting on October 25, 2011 dilute the value of the proposed recommendation to an extent that it will contribute little to the discussion on international regulatory cooperation. If these recommendations go no further than the 1991 recommendations to encourage agencies to consider international effects in developing and enforcing regulation, I question the value of issuing them at all.

Overarching concern with changes. ACUS should support international regulatory cooperation and competitiveness because open markets make US citizens better off, and should not limit its endorsement exclusively to situations where cooperation would further (as opposed to not conflict with) narrow agency missions (the implication of clauses added to recommendations 1, 2, 3 and 7).

Comments on Individual Recommendations

Recommendation 1. Page 5, Line 112: I would delete the phrase "where consistent with advancing that mission." The previous phrase, "when appropriate to further the agencies' regulatory missions," is sufficient.

Recommendation 2.
Page 5, Line 116: I would replace "could also consider" with "should consider." These are international agreements and Presidential guidance, and ACUS adds nothing by saying agencies "could" consider them.
Page 5, Line 120: I would add "and United States competitiveness" after "agency missions." This language was included in the recommendation considered at the October 25 committee meeting, and is important. ACUS should support competitiveness as well as furthering agency missions.
Page 6, Lines 121–22: I would replace "where in furtherance of" with "absent clear conflict with," in line with the language used in the recommendation considered at the October 25 committee meeting.

Recommendation 3. Page 6, Line 125: Delete inserted phrase, "and that cooperation would further their mission." This phrase changes the meaning of the recommendation to suggest that agencies should only cooperate if cooperation furthers their narrow mission, even if cooperation could bring large benefits to US citizens without detracting from an agency's mission. While I

prefer the language of the draft recommendation considered at the October 25 committee meeting, which simply recommended that agencies cooperate with foreign authorities when they have legal authority and an interest in doing so, I could accept "would not detract from" in lieu of "would further" their mission.

Recommendation 4.
Page 6, Lines 144–45: For the same reason stated above, I would drop any reference to maintaining standards and practices "that are no less effective that United States equivalents" and instead refer to maintaining "high quality and appropriate" standards and practices, as in the recommendation considered at the October 25 committee meeting. That language provides agencies sufficient discretion.
Page 6, Line 146: Delete "consider." The addition of "and practicable" already provides agencies discretion, and adding "consider" makes the recommendation meaningless.

Recommendation 5. Page 7, Line 162: I would delete the phrase "that are no less effective than United States equivalents" and instead refer to "high quality and appropriate" standards and practices, in accordance with the language used in the draft recommendation considered at the October 25 committee meeting.

Recommendation 6. Page 7, Line 169: The recommendation considered at the October 25 committee meeting contained the phrase "data-driven" prior to the word "decisionmaking." I would reinstate that language. ACUS should not encourage US regulators to engage with foreign authorities to promote decision-making that is not data-driven. Should ACUS promote decisions that are politically-driven, culturally-driven, emotionally-driven?

Recommendation 7.
Page 8, Line 175: The draft recommendation considered at the October 25 committee meeting contained the following sentence at the beginning of the seventh recommendation: "Agency interactions with their foreign counterparts should generally be transparent, subject to appropriate exceptions to protect law enforcement, trade secret, or similar sensitive information." I would re-insert that sentence at the beginning of this recommendation.
Page 8, Lines 178–79: I would delete the phrase "where it would further" and replace it with "consistent with," returning to the language contained in the recommendation considered at the October 25 committee meeting. Alternatively, I could support replacing "where it would further" with "where it would not impede."

To: Assembly of the Administrative Conference
From: Patti Goldman (Public Member)
Re: Comments on the Proposed International Regulatory Cooperation Recommendation
Date: December 2, 2011

During the Committee deliberations on an earlier version of this proposal, we discussed how far the Committee felt the recommendation should go. The original language recognized that an agency could pursue an option mandated by its authorizing statute without regard to different international approaches or a desire to promote international trade or cooperation. The Committee discussion focused on the situation in which an agency has the authority to regulate to protect, for example, public health, safety or the environment, but can, within that authority, choose from an array of options. The question was posed whether the Committee intended this proposal to suggest that an agency should, for the sake of promoting trade or international cooperation, pursue an option that would afford the public weaker protections from health, safety or environmental threats. An agreement seemed to emerge in the discussion that an agency should not weaken health, safety or environmental protections for the sake of promoting international cooperation, trade, or other economic goals. The Committee then edited the draft by inserting qualifying language to make it clear that agencies should pursue international regulatory cooperation only "when appropriate to further the agencies' regulatory missions and, where consistent with advancing that mission" and when "that cooperation would further their mission." See, e.g., Recommendation 1, page 5, lines 111-112; Recommendation 3, page 6, line 125. We softened other mandates in order to make it clear that the proposal would not elevate trade promotion goals over the agencies' primary missions and delegated authority to take actions to promote non-economic goals like public health and environmental protection.

I recommend one additional edit in keeping with the revisions made by the drafters. The change would be in the penultimate sentence of the third paragraph of the preamble where there is a suggestion that removing nontariff barriers is a goal. Page 2, line 42. In the Committee discussion, there seemed to an emerging sense that the recommendation should endorse removing nontariff barriers only where the barrier does not promote a legitimate objective. In keeping with this principle, I suggest that, after "nontariff barriers to trade and exports" on page 2, line 41, the following be added: "that do not further the agency's regulatory mission and promote legitimate goals."

I would also like to offer an amendment to delete Recommendation 10. The 1991 ACUS recommendation contained a similar provision. Compared to 1991, there are more trade promotion coordinating bodies throughout the federal agencies, including in the Executive Office of the President. No assessment has been presented the Committee of where those coordinating bodies have fallen short of meeting any assumed needs for coordination or of what type of role a new body would play. Moreover, the operations and impact of some coordinating bodies in the Executive Office of the President that review regulatory measures for their economic impacts have spurred much controversy. It would be prudent to have a full assessment of what bodies currently exist, the roles they play, and what types of unmet coordinating functions would warrant establishment of a new body. For this reason, I propose that Recommendation 10 be deleted.

CHAMBER OF COMMERCE
OF THE
UNITED STATES OF AMERICA

R. BRUCE JOSTEN
EXECUTIVE VICE PRESIDENT
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December 2, 2011

Paul Verkuil
Chairman
Administrative Conference of the United States
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Dear Mr. Verkuil:

The U.S. Chamber of Commerce, the world's largest business federation representing the interests of more than three million businesses and organizations of every size, sector, and region, is deeply committed to promoting and advancing international regulatory cooperation to the benefit of regulators, consumers, and businesses. On April 28, 2011, the Chamber was pleased to partner with ACUS to host a program on the role and responsibility of regulatory agencies to engage in international regulatory cooperation, and, partly as a result of that collaboration, the Chamber is pleased ACUS agreed to update its 1991 recommendations regarding international regulatory cooperation. The Chamber was actively involved throughout the process leading to the Proposed Recommendation for Consideration at the Plenary Session and appreciates the opportunity to offer comments to achieve the optimal international regulatory cooperation recommendation.

The Chamber urges the Assembly to pass an updated recommendation to international regulatory cooperation at the December 8 Plenary session, preferably a final version incorporating the comments below, which would represent a robust, forward-thinking, and practical nudge toward increasing the breadth and efficiency of U.S. regulators' international regulatory cooperation activities. We thank the Assembly for their consideration.

GENERAL COMMENTS ON PROPOSED RECOMMENDATIONS

The Chamber would like to direct the Assembly to the excellent background report by ACUS Executive Director Michael McCarthy – drafted after extensive research and interviews with consumer groups, regulators, and business – detailing specific international regulatory cooperation activities and benefits.[1] The background report served as a foundation for both the Proposed Recommendation, and, as clearly and expertly articulated throughout both the background report and the Proposed Recommendation, ACUS's findings that international regulatory cooperation results in benefits for consumers, business, and regulators alike.

Updates to the 1991 ACUS recommendation and closer adherence by regulators to any new recommendation are fundamental to fulfilling regulatory missions related to health, safety, the environment, etc. Additionally, U.S. regulators engaged in international regulatory

[1] International Regulatory Cooperation, 20 Years Later: Updating ACUS Recommendation 91-1 (available at http://www.acus.gov/wp-content/uploads/downloads/2011/10/COR-IRC-report-10-19-11.pdf).

cooperation are in a position to aid in boosting U.S. trade and competitiveness. The Obama Administration has consistently indicated that international regulatory cooperation is beneficial because it helps U.S. agencies more efficiently accomplish their statutory missions domestically and because it promotes U.S. competitiveness, promoting trade and exports, and creating jobs.[2] The Proposed Recommendation states that "the benefits of international regulatory cooperation are not incompatible and can be pursued in unison." One benefit should not be accomplished at the expense of the other, and the results are often inseparable.

Therefore, the Chamber was disheartened by the amendments to the Proposed Recommendation resulting from the October 25 Committee on Regulation meeting. In nearly every aspect, the amendments from October 25 would greatly weaken the effect of the Proposed Recommendation to an affirmation of the actions already undertaken by U.S. agencies, and provides reduced guidance to spur innovation and increase benefits to U.S. consumers, business, and regulators.

The Chamber shares many of the concerns expressed by Public Member Susan Dudley on November 23, 2011.[3] While several of our comments may overlap with those of Ms. Dudley, the Chamber believes the following changes are necessary to achieve a final recommendation that provides the greatest benefit to consumers, business, and regulators.

SPECIFIC CHANGES TO PROPOSED RECOMMENDATION

Recommendation 1 (page 5, line 112): The Chamber suggests deleting the phrase "where consistent with advancing that mission." This addition is confusing and weakens the previous version, as "when appropriate to further the agencies' regulatory mission *and*" (emphasis added) clearly indicates agencies should consider strategies that achieve both goals.

Recommendation 2: The Chamber strongly supports removing all changes from the October 25 meeting and restoring recommendation 2 to the previous version. The earlier version of recommendation 2 provided the foundation necessary to nudge U.S. regulators in the direction of increased, varied, and innovative international regulatory cooperation activities. In greater detail, the Chamber suggests the following changes:

- Page 5, line 116: Remove "could" and reinsert "should." When conducting the requested review of legal authority, U.S. regulators should seek to assure their authorities allow full compliance with all international agreements. The suggested change of "could" to "should" is necessary to provide a consistent review by all U.S. regulators.

- Page 5, line 120: After "agency missions" reinsert "and U.S. competitiveness," which was present in the previous recommendation and is essential to properly achieve the goals

[2] OMB's *2011 Report to Congress on the Costs and Benefits of Federal Regulations* recommended that "in order to promote trade and exports, and thus increase job creation, agencies should promote regulatory cooperation initiatives with key trading partners." (See http://www.whitehouse.gov/sites/default/files/omb/inforeg/2011_cb/2011_cba_report.pdf.) Further, at the November 28, 2011 U.S. – EU High Level Regulatory Cooperation Forum, high-level Administrative officials stated international regulatory cooperation should occur with an aim of promoting growth and job creation – or at least aim to remove factors preventing these goals.

[3] Available at http://www.acus.gov/wp-content/uploads/downloads/2011/11/Dudley-Comments-IRC.pdf.

of ACUS and this Administration, as well as maximize potential benefits of international regulatory cooperation.

- Page 6, lines 121-122: Remove the amended text of "where in furtherance of their legal authority" and reinsert the original "absent clear conflict." This change would enable U.S. regulators to participate in all possible regulatory and enforcement international regulatory cooperation activities while examining their authorities to determine if the scope of that authority should be increased.

Recommendation 3 (page 6, line 125): The Chamber suggests removing the phrase "and that cooperation would further their mission." We believe the earlier text on line 124 "legal authority and the interest" should be sufficient to provide guidance to agencies to act in a manner that will best increase the well-being of U.S. citizens without detracting from the agency's regulatory mission.

Recommendation 4 (page 6, line 146): We suggest removing "consider" as "where appropriate and practical" already would allow for U.S. regulators to exercise proper judgment while providing for stronger guidance.

Recommendation 6 (page 7, line 169): The Chamber suggests adding "evidence-based" or reinserting the previous descriptor "data-driven" to instruct the type of decision-making that should be required. Agency decisions should be made based on evidence, readily presentable and explainable, when appropriate.

CONCLUSION

The Chamber sincerely thanks ACUS for their exemplary professionalism and cooperation in the drafting of the updated recommendation on international regulatory cooperation. Again, we urge the Assembly to pass a recommendation during the December 8 Plenary session, and strongly prefer a robust version incorporating the above comments that would fully unlock the full potential benefits for regulators, consumers, and businesses alike.

Sincerely,

R. Bruce Josten

ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

Committee on Regulation Draft Recommendation

International Regulatory Cooperation
(Updating ACUS Recommendation 91-1)

NOTE: The U.S. Chamber of Commerce once again thanks the Administrative Conference for the opportunity to submit comments. We are pleased with the direction of the ACUS recommendations and look forward to their completion and to supporting and promoting their use.

In June 1991, the Administrative Conference issued Recommendation 91-1, "Federal Agency Cooperation with Foreign Government Regulators," finding that "[i]f American administrative agencies could ever afford to engage in regulatory activities without regard to the policies and practices of administrative agencies abroad, the character and pace of world developments suggest that that era has come to a close," and recommending practices such as information exchanges and establishment of common regulatory agendas to facilitate regulatory cooperation. While many of the issues identified in that recommendation remain relevant today, the pace of globalization in the past two decades has created new challenges and dynamics since then. Not only have institutions promoting international cooperation become more robust, with relevant developments including the founding of the World Trade Organization and increasing integration amongst the member states of the European Union, but the volume of trade in goods, services, and information across borders has increased dramatically.

Given these developments, the Administrative Conference commissioned a research project to review international regulatory cooperation at United States government agencies today, assess how the 1991 recommendation has been implemented (or not), identify new challenges that have emerged in the past 20 years, and advise how the 1991 recommendation might be updated to guide agencies in improving international coordination today, to benefit regulatory goals and competitiveness. This research shows that, since the 1991 recommendation was adopted, the international coordination efforts of agencies have greatly expanded. Yet the need for international coordination has also greatly expanded due to increased trade in goods, services, and information. Incompatible regulatory requirements in different countries persist. Sometimes these regulations are different for non-substantive reasons – regulators share common goals and methods of regulation, but for historical or other reasons, regulations remain inconsistent. Sometimes regulations differ because regulators in different countries do not agree on important substantive issues, such as how to weigh scientific evidence or balance competing priorities. When differences are substantive, they can

sometimes be ascribed to countries' asserting legitimate national goals such as protecting health, safety, or the environment at the levels that they consider appropriate. Other substantive differences, however, disrupt trade and serve no legitimate objective, or otherwise operate as de facto protectionist measures. Moreover, even when standards are aligned, different national requirements for conformity assessment, such as testing, certification, inspection, or accreditation, frequently impose their own costs and delays.

The Administrative Conference finds that improved international regulatory cooperation is desirable for two major reasons. First, it helps United States agencies accomplish their statutory regulatory missions domestically. Indeed, in some areas like regulating the safety of food and drugs, a large proportion of which are imported to the United States, awareness and participation in foreign regulatory processes may be essential to ensure the safety of products reaching United States markets. Second, international regulatory cooperation can remove non-tariff barriers to trade and exports, promoting global commerce and United States competitiveness. Moreover, these benefits of international regulatory cooperation are not incompatible and can be pursued in unison.

Because of the global nature of the economy, the domestic regulatory mission of agencies is affected by what happens overseas. For example, imports of food and pharmaceutical products to the United States have greatly increased over the past 20 years, so that the Food and Drug Administration's (FDA) mission of ensuring food, drug, and device safety in the United States is necessarily intertwined with how these products are regulated in their countries of origin. The Consumer Product Safety Commission faces a similar challenge. Pollutants do not respect political boundaries, so the Environmental Protection Agency's missions of ensuring clean air and clean water in the United States are reliant on environmental regulations in other countries. Financial institutions in the United States participate in the global banking system and are exposed to risks in economies all over the world, which requires financial regulators to coordinate globally in their missions of ensuring safety and soundness of United States institutions. And trade in data crosses national boundaries, requiring the Federal Trade Commission to cooperate with other global regulators in policing Internet fraud.

In addition to the impact on regulatory goals such as health, safety, environmental and consumer protection in the United States, inconsistent regulatory regimes can act as barriers to trade. For example, different food labeling requirements between the United States and Europe require producers who distribute food in both markets to produce the same goods in different packaging, depending on the market, which hinders economies of scale and adds cost and delay. Another example is that the United States and Europe have different approaches to

regulating the length of tractor-trailers. Though the American design has better fuel economy, American manufacturers cannot export their trucks which comply with United States requirements into European markets without significant redesign, thereby creating an unnecessary barrier to trade.

Although desirable, global regulatory cooperation can be difficult to accomplish. Some agencies claim that they lack statutory authority to account for international effects when making regulatory decisions. Several agency officials, as well as high-level leaders, indicated that international regulatory cooperation was a low priority for agency leaders, as it is an issue with little visibility when accomplished successfully. Agencies indicated that legal restrictions on information sharing can hinder international cooperation. Finally, coordination among agencies within the United States government is a challenge, particularly for independent regulatory agencies, and agencies focused on trade and competitiveness are not always aware of the activities of other federal regulators.

Despite these challenges, many agencies are effectively engaging in international cooperation ~~.~~ through a variety of different methods.[1] Notably, there is evidence that better international cooperation can help agencies more proficiently accomplish their regulatory missions with fewer resources by dividing work, where appropriate, with foreign counterparts and mutually recognizing each others' inspection regimes and laboratory or test results. The

Comment [a1]: In conjunction with other comments made below to Recommendation 2. We would welcome additional suggestions to expand the definition as we think one of the most significant contributions ACUS can make is to define all the ways in which regulatory cooperation can occur.

[1] International cooperation is not limited to a set definition, as efforts come in many forms, including numerous activities already routinely performed by many agencies. Many of these various methods are covered in the recommendations and often intermingle so as to be indistinguishable as distinct categories. However, in the interest of defining international regulatory cooperation that can better inform agencies and aid in ~~the~~the development of their own international engagement strategies, international regulatory cooperation can be defined as:

1. Coordination of enforcement and implementation activities.
2. Domestic regulatory promulgation consisting of regulators working directly with their foreign counterparts in coordination;
3. Giving consideration, as part of the cost benefit analysis during the domestic rulemaking process, for the potential impact regulation may have on U.S exports, global competitiveness, and trade;
4. Removing regulatory divergence by advocating the advantages of U.S regulatory best practices, the body of U.S. administrative law, and the transparency of the U.S. regulatory system as a whole;
5. Encouraging foreign regulators to adopt or mutually recognize U.S. regulations; and

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FDA believes there is great potential for cost savings and improved health and safety in mutual reliance on the data from clinical trials and manufacturing quality inspection regimes in other countries. For example, the FDA recently concluded a pilot project with European and Australian regulators to inspect manufacturing plants in China and other countries that manufacture active pharmaceutical ingredients. The agencies compared their lists of plants subject to inspection and the resources that each country had available, and where two or more agencies were scheduled to visit the same plant, the agencies agreed on one agency to inspect that plant or to do a joint inspection, and reallocated resources so that they could cover more plants. Building on the success of that pilot, the FDA is now pursuing a similar project with European regulators for site inspections of clinical trials. These cooperative approaches, which show potential for cost savings without diminishing regulatory effectiveness, might be expanded to other agency settings for further cost-saving effects.

Twenty years after the adoption of ACUS Recommendation 91-1, agencies increasingly recognize that international regulatory cooperation is a necessary component of their regulatory missions in today's globally integrated economy. While progress has been made, the scope of the problem leaves more work to be done to eliminate systemic barriers to coordination. The following recommendation restates the parts of the 1991 recommendation that remain valid and relevant and also addresses new considerations, to include promotion of best practices in transparency, mutual reliance, information sharing, and coordination within the United States.

RECOMMENDATION

1. Agencies should inform themselves of the existence of foreign (including regional and international) authorities whose activities may relate to their missions. Agencies should consider strategies for regulatory cooperation with relevant foreign authorities when appropriate to further the agencies' regulatory missions and/or remove unjustified barriers to international trade. When appropriate, if two or more domestic agencies' missions are interrelated, agencies should jointly consider strategies for domestic agency cooperation that maximize efficient use of resources and prevent potential redundant or conflicting actions.

Comment [a2]: For example, USDA and FDA have similar regulatory missions and their work internationally should be coordinated.

2. Agencies should review their legal authorities to cooperate with foreign authorities and international organizations under their authorizing statutes, the World Trade Organization Agreement on Technical Barriers to Trade and other relevant treaties adopted by the U.S., and Office of Management and Budget (OMB) guidance. Where legal authorities do

not sufficiently permit the opportunity for a full range of regulatory and enforcement methods of international cooperation that would benefit regulatory missions and United States competitiveness, agencies should recommend corrective legislation to OMB and Congress. As a general matter, absent clear conflict with their legal authority, agencies should evaluate the international implications of regulatory activities.

3. When agencies conclude that they have legal authority and the interest in cooperation from foreign authorities, they should consider various modes of cooperation with those authorities, including but not limited to:

a. establishment of common regulatory agendas;

b. exchange of information about present and proposed foreign regulation;

c. concerted efforts to reduce differences between the agency's rules and those adopted by foreign government regulators where those differences are not justified;

d. holding periodic bilateral or multilateral meetings to assess the effectiveness of past cooperative efforts and to chart future ones; and

e. mutual recognition of tests, inspections, clinical trials, and certifications of foreign agencies.

4. To deploy limited resources more effectively, agencies should identify foreign regulatory agencies that maintain high quality and appropriate standards and practices and identify areas in which the tests, inspections, or certifications by agencies and such foreign agencies overlap. Where appropriate, agencies should divide responsibility for necessary tests, inspections, and certifications and mutually recognize their results. When practicable, agencies should also create joint technical or working groups to conduct joint research and development and to identify common solutions to regulatory problems (for example, through parallel notices of proposed rulemaking) and establish joint administrative teams to draft common procedures and enforcement policies. Agencies should document cost savings and regulatory benefits from such mutual arrangements and periodically communicate these findings to interested stakeholders.

5. To assess accurately whether foreign authorities maintain high quality and appropriate standards and practices, agencies should develop and maintain relationships with foreign counterparts by providing training and technical assistance to foreign agencies and

Comment [a3]: The goal here is to make sure an agency doesn't review their authority too narrowly and consider only certain aspects of international cooperation. It is important that each agency be consistent in its examination and consider a full range of regulatory cooperation activities that it may or may not be able to engage in. To aid in the evaluation of the various forms regulatory cooperation can take we added in footnote 1 a non-exhaustive definition of international regulatory cooperation. We would welcome further contributions to building a definition that is as comprehensive as possible.

Comment [a4]: Not entirely clear if the communication component is intended to be read into this sentence.

Adding a clarifying point to ensure that all the success and good work is effectively communicated so interested parties can effectively learn about activities and success in a timely manner. The more success that can be demonstrated the easier future activities will be.

developing employee exchange programs, as resources permit. Agencies should also review whether foreign or international practices would be appropriate for adoption in the United States.

6. Agencies should engage in exchanges of information with their foreign counterparts to promote better data-driven decisionmaking. Types of information exchanges can range from formal agreements to share data to informal dialogues among agency staff. To the extent practicable, information exchange should be mutually beneficial and reciprocal. Prior to exchanging information, agencies must reach arrangements with foreign counterparts that will protect confidential information, trade secrets, or other sensitive information.

7. Agency interactions with their foreign counterparts should generally be transparent, subject to appropriate exceptions to protect law enforcement, trade secret, or similar sensitive information. When engaging in regulatory dialogues with foreign counterparts, agencies should seek input and participation from interested parties as appropriate, through either formal means such as Federal Register notices and requests for comments or informal means such as outreach to regulated industries, consumers, and other stakeholders. Agencies should, consistent with their statutory mandate and the public interest, consider petitions by private and public interest groups for proposed rulemakings that contemplate the reduction of differences between agency rules and the rules adopted by foreign government regulators, where those differences are not justified. While international consultations of the sort described in this recommendation do not usually depart from an agency's standard practices in compliance with applicable procedural statutes, an agency engaged in such consultations should describe those consultations in its notices of proposed rulemaking, rulemaking records, and statements of basis and purpose under the Administrative Procedure Act. Where the objective of aligning American and foreign agency rules has had a significant influence on the shape of the rule, that fact also should be clearly acknowledged.

8. Agencies should promote to their foreign counterparts and to other standards-setting bodies the principles of transparency, openness and participation, evidence-based and risk-based regulation, cost-benefit analysis, consensus-based decisionmaking, and impartiality that undergird the United States administrative and regulatory process. When appropriate, an agency should also promote similar and compatible regulatory outcomes with their foreign counterparts. An agency engaging in international regulatory cooperation should also be alert to the possibility that foreign regulatory bodies may have different regulatory objectives, particularly where a government-owned or controlled enterprise is involved.

Comment [a5]: An agency should where appropriate go beyond promoting the U.S. regulatory framework and process but also, whenever it is consistent with our enforcement interests or in the interest of taking a least trade restrictive approach promote a similar and compatible regulatory outcome from regulation abroad.

9. When engaging with foreign authorities, agencies should consult with other government agencies with interests that may be affected by the engagement, including but not limited to OMB's Office of Information and Regulatory Affairs (OIRA); the Office of the United States Trade Representative (USTR); and the Departments of Commerce, State, and Defense. In particular, agencies should adhere to the requirements of 22 C.F.R. § 181.4, requiring agencies to consult with OIRA before entering into international agreements that require significant regulatory action, and 19 U.S.C. § 2541, giving USTR responsibility for establishing mutual arrangements for standards-related activities.

10. To provide high-level, government-wide leadership on international regulatory issues, the Executive Office of the President should ~~consider~~ creat~~ing~~e a high-level interagency working group of agency heads and other senior officials. This group should meet regularly, and consider, amongst other topics, creation of a list of best practices to effectively implement these recommendations, methods to foster an agency-wide environment that promotes and emphasizes regulatory cooperation, the continued development of efforts at interagency coordination, and opportunities for communication to stakeholders, and outreach and technical assistance methods towards foreign authorities. The Chairman of the Administrative Conference should convene a meeting of the heads of interested agencies to consider the best form of organization for such a working group, including funding and staffing of such a mechanism; the incorporation of existing efforts at interagency coordination; and differences among agencies with respect to existing international cooperation agreements. One goal of this meeting would be to recommend whether an Office of International Affairs should be established within OIRA or some other executive branch agency to coordinate international regulatory cooperation.

Comment [a6]: We are in favor of using this language from the revised report as it indicates a stronger level of commitment.

Comment [a7]: The Chamber believes that it is important to enumerate some of the topics that this high-level group should consider to maximize the value of, and political commitment to, the group. While we believe that all of the activities listed are important, please see the comment below on the key component.

Comment [a8]: We believe this is the most important activity the high-level group can undertake. This idea is the key bridge towards moving from recommendations to concrete actions.

Comment [a9]: We suggest moving this consideration to be a topic to be regularly considered during the meetings of this high-level group, and suggest removal if the committee finds inclusion here redundant, however, we do not object to also providing consideration at the initial meeting of heads of agencies.

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September 28, 2011

Administrative Conference of the United States
Committee on Regulation
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Washington, DC 20036

RE: Comments on "International Regulatory Cooperation, 20 Years Later: Updating ACUS Recommendation 91-1," Committee of Regulation

To Whom It May Concern:

ASTM International (ASTM) is pleased to submit these comments to the Committee of Regulation in response to the report entitled, ñInternational Regulatory Cooperation, 20 Years Later: Updating ACUS Recommendation 91-1ò.

ASTM is a leading non-profit organization devoted to the development of voluntary consensus standards that are utilized by ninety industrial sectors in the U.S. and in most geographic regions of the world. For more than 100 years, ASTM has served society as a leading venue for consumers, industry and regulators to work together in the development of voluntary consensus standards that promote health, safety, the environment, and that improve the overall quality of life. ASTM is accredited by the American National Standards Institute and meets World Trade Organization principles for the development of international standards.

The U.S. Standards System

The Office of Management and Budget (OMB) Circular A-119 and the National Technology Transfer and Advancement Act (NTTAA) of 1995 establishes existing federal policy and guidance on the development and use of private sector technical standards. The policies foster public-private collaboration and a decentralized system of standardization driven by the diverse and evolving needs of stakeholders from every sector of the economy. The OMB Circular A-119 and the NTTAA continue to be extremely effective by benefiting the federal government and the regulated community alike and making government regulation and procurement more efficient and globally relevant.

The flexibility of the U.S. standards process empowers the U.S. government and private sector to participate in international standards activities in a variety of ways, including: through organizations such as ISO and IEC where the United States is represented by a single ñnational bodyò organization; through treaty organizations where governments are members; through consortia, whose membership is typically technology based; and through professional and technical organizations and U.S.-domiciled standards development organizations (SDOs) whose membership is on an individual or organizational basis. For example, as the largest and most prolific SDO domiciled in the U.S., ASTM International is a globally recognized venue for technical experts, consumer advocates and regulators from over 125 WTO member countries to engage directly under an open, transparent and balanced process in the

development of international voluntary consensus standards that can be utilized to meet regulatory objectives, promote safety and the environment, or to improve the overall quality of life.

WTO Technical Barriers to Trade (TBT) Agreement and International Standards

As a signatory to the World Trade Organization (WTO) Technical Barriers to Trade (TBT) Agreement, the U.S. government pledged to use international standards as the basis for technical regulations whenever possible, with a view towards eliminating the use of standards as barriers to trade. The U.S. governmentôs commitment to base technical regulations on international standards that meet the principles embodied in the WTO TBT Agreement has led to an increased use of voluntary standards in the U.S. and elsewhere. While the U.S. standards system is rooted in the principles of consensus, openness and assistance to others, unfortunately, the standards policies of other countries and regions are more restrictive and often result in U.S. companies (including SMEs) having to comply with unfamiliar technical standards that were developed with limited U.S. input.

In some instances, foreign governments dictate that international standards can only emanate from organizations such as ISO and IEC where countries are represented by a single ñnational bodyò organization. In Europe, the absence of a legal mechanism that exists in the European regulatory infrastructure to allow standards from U.S. domiciled organizations to achieve the same acceptability as European standards presents a barrier to trade and international regulatory cooperation. U.S government agencies have the flexibility to choose from a broad portfolio of standards based on important factors such as technical quality and relevance. In some cases, U.S. agencies utilize European standards for U.S. government purposes. The flexibility to choose standards based on important considerations such as technical quality, market relevance, and global coherence often results in the utilization of standards that best match the emerging regulatory need. It is a model regulatory policy for other nations and should be promoted as the U.S. government pursues regional or international harmonization of technical regulations. It also creates a mode of effective, enforceable, and transparent, and coherent regulations based on sound science.

Accordingly, ASTM recommends that the U.S. government collaborate with other U.S. stakeholders to do more to help foreign stakeholders understand the benefits of the approach embodied in the U.S. Standards System. To advance the diverse international standards objectives and interests of U.S. stakeholders, the U.S. government should continue to seek full implementation of the WTO TBT Agreement and annexes as well as decisions taken in the WTO TBT Committee. ASTM encourages the U.S. government to engage their international counterparts and recommend that they incorporate the international standards principles outlined in the Decision of the WTO TBT Committee [1] into its legal framework. Lastly, the U.S. government should continue to foster and support the unique character and strengths of the public-private partnership in standards development as it pursues trade and other international agreements, regulatory cooperation, and legislative and regulatory approaches. Currently, the U.S. government is engaged in numerous bi-lateral and multi-lateral fora where international regulatory cooperation and standards are being discussed, including the Transatlantic Economic Council (TEC), Trans Pacific Partnership (TPP), Regulatory Cooperation Council (RCC), Asia Pacific Economic Council (APEC), and others.

Value and Significance of Standards for Business Productivity and Profitability

[1] See the USTR TBT Agreement web page for a review of the Agreement, Decisions and Annexes at: http://www.ustr.gov/trade-agreements/wto-multilateral-affairs/wto-issues/technical-barriers-trade

The U.S. standards process offers enormous benefits to businesses, consumers, and society, facilitating innovation and strengthening economic competitiveness. Realizing such benefits, U.S. companies of all sizes invest their technical resources in the development of standards that match their interest and business objectives. When international barriers to the acceptance of such standards impair the companiesô ability to utilize them, it is these companies who are most affected through the need for additional product testing or possibly the need for product redesign to achieve the desired international market access.

An internationally agreed-upon approach on adopting and implementing the principles embodied in the WTO TBT Agreement into law would have far-reaching and significant effects, including: increase in harmony, efficiency, choice, flexibility, and much needed relief from expensive, duplicative procedures for companies that trade internationally. Fast moving areas involving advanced technologies stand to benefit the most from the ability to utilize a broader array of international standards through lower costs and time spent in developing standards.

Coherence and Convergence

ASTM International embraces the WTO TBT principle of coherence which us defined as follows ñIn order to avoid the development of conflicting international standards, it is important that international standardizing bodies avoid duplication of, or overlap with, the work of other international standardizing bodies. In this respect, cooperation and coordination with other relevant international bodies is essential[2]ò. ASTM International encourages its technical committees and the industries they represent to carefully and strategically develop a standards strategy that meets their needs: minimize the duplication of international standards, utilize the standards that exist, normatively reference existing standards instead of duplicating standards, harmonize if possible and necessary, respect the intellectual property of developers and allocate the resources to support the standardization strategy. While differing regulatory approaches and other factors often makes harmonization of international standards unable to achieve, ASTM International promotes technical and commercial collaboration with other SDOs to achieve greater compatibility. Recent examples include technical cooperation with other bodies to achieve greater standards compatibility in emerging areas such as toy safety, biofuels, and additive manufacturing.

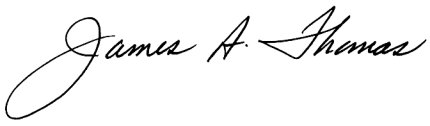
Conclusion

In summary, existing U.S. standards policies promote public-private sector standards development efforts that reduce the cost and improve the management and effectiveness of government, while reducing global technical barriers to trade. It is vital to the competitiveness of U.S. industry and the safety of the public that U.S. government agencies continue to engage strategically with SDOs in the development of standards, and to promote the global implementation of technical regulations based on international standards that meet WTO TBT Agreement principles. This will not only promote the use of regulatory best practices around the world but serve as a mechanism to reduce divergent regulations, and eliminate the regulatory complexity all companies, especially small and medium size enterprises face when moving goods across borders.

[2] See the USTR TBT Agreement web page for a review of the Agreement, Decisions and Annexes at: http://www.ustr.gov/trade-agreements/wto-multilateral-affairs/wto-issues/technical-barriers-trade

ASTM International is pleased for the opportunity to provide comments on this important review conducted by the ACUS Committee on Regulation. Please contact Jeff Grove in the ASTM Washington Office at 202-223-8505 for any additional information.

Sincerely,



James A. Thomas

CHAMBER OF COMMERCE
OF THE
UNITED STATES OF AMERICA

SEAN HEATHER
EXECUTIVE DIRECTOR
GLOBAL REGULATORY COOPERATION

1615 H STREET, N.W.
WASHINGTON, D.C. 20062-2000
202/463-5368

September 29, 2011

Michael McCarthy
Executive Director
Adminstriave Conference of the United States
1120 20th Street NW Ste. 706 South
Washington, DC 20036

Dear Mr. McCarthy:

The U.S. Chamber of Commerce, the world's largest business federation representing the interests of more than three million businesses and organizations of every size, sector, and region, is deeply committed to promoting and advancing international regulatory cooperation to the benefit of regulators, consumers, and businesses. On April 28, 2011, the Chamber was pleased to partner with ACUS to host a program on the role and responsibility of regulatory agencies to engage in international regulatory cooperation. In part, as a result of that collaboration the Chamber is pleased ACUS has agreed to review its 1991 recommendations regarding international regulatory cooperation with an eye to revising and updating it.

The original ACUS recommendations on international regulatory cooperation were prescient in recognizing the needs for U.S. regulators to engage with their foreign counterparts in order to satisfy their statutory mandates in a globalized economy. Twenty years later, the world is becoming increasingly inextricably intertwined, and regulators must engage in some form of international regulatory cooperation in order to meet their regulatory obligations. Updates to the 1991 ACUS recommendation and closer adherence by regulators to any new recommendations are fundamental to fulfilling their regulatory objective related to health, safety, the environment, etc. However, regulators engaged in international regulatory cooperation are increasingly in a position to also aid in boosting U.S. trade and competitiveness.

The Chamber appreciates the opportunity to offer comments designed to maximize the value of the ACUS report and shape updated ACUS recommendations.

General Comments on Summary and Background Information

Benefits to Regulatory Cooperation

First, the Chamber believes it is imperative that the report clearly underscore the benefits of international regulatory cooperation from a regulator and consumer perspective. As mentioned in the introductory section of the ACUS report the primary benefit of international cooperation is that it helps regulators accomplish their statutory obligation. The world is now an interconnected marketplace, and participation in various forms of international regulatory cooperation is essential to regulatory effectiveness over global supply chains. Further, undertaking international regulatory cooperation makes the job of regulators easier by efficiently allocating resources through cooperation with like-minded foreign counterparts. These actions also lead to enhanced consumer protections as competing regulatory frameworks become more aligned assuring higher levels of protection.

A secondary and supplemental benefit of international regulatory cooperation is the removal of non-tariff barriers to trade, resulting in an increase of U.S. trade, exports, and competitiveness. In his 2010 State of the Union Address, President Obama established the national goal of doubling U.S. exports in the next five years, and the Administration subsequently launched the National Export Initiative. International regulatory cooperation can make a meaningful contribution to boosting exports by facilitating the removal of non-tariff barriers to trade.

It is also important for the ACUS report and subsequent recommendations to endorse that these two benefits, enjoyed by regulators, consumers, and business alike – helping regulators better achieve their statutory mandates domestically and the removal of non-tariff barriers to trade – are not inconsistent with one another. A regulator's statutory obligation to meet its regulatory objective need not be compromised when a regulator engages in international regulatory cooperation to minimize the frictions regulations can have on trade at home or abroad. It is important that the final ACUS report and corresponding recommendations make this point clearly.[1]

[1] The Chamber commends the ACUS report's existing commentary in this regard, but would encourage an even stronger articulation of this point.

Defining International Regulatory Cooperation

As ACUS deliberates its recommendations, it is important that it have a common definition of the various forms in which international regulatory cooperation can take. The Chamber believes international regulatory cooperation can be divided into the following methods:

1. Domestic regulatory promulgation – this includes:

    a. Regulators working directly with their foreign counterparts in coordination regarding emerging regulatory policies to develop regulations that meet a legitimate regulatory objective in a manner that is no more trade restrictive than necessary.

    b. Consideration during the rulemaking process for the potential impact regulation may have on trade and U.S. global competitiveness as part of cost benefit analysis and impact assessments.[2]

2. Removing regulatory divergence – this includes:

    a. Advocating the advantages of U.S regulatory best practices, the body of U.S. administrative law, and the transparency of the U.S. regulatory system as a whole; and

    b. Encouraging foreign regulators to adopt or mutually recognize U.S. regulations.

Regulation as Trade or Investment Barriers

In section III, page 8, the ACUS report enumerates several ways in which regulatory barriers can become trade irritants or even an outright trade impediments including: "(i) uncertainty about foreign regulations, which could force U.S. manufacturers to "make practical design, production, and commercial decisions without adequate information";(ii) uncertainty caused by excessive time to process appeals from regulatory decisions; (iii) ineffective or overly lengthy enforcement efforts; and (iv) reimbursable advances (loans) and direct subsidies for EU companies."

[2] To this extent the Chamber applauds the ACUS report highlighting recent efforts by OIRA and USTR to note existing obligations of U.S. agencies and the importance of reducing unnecessary regulatory barriers to exports and trade as a means to promote economic growth and job creation. We also suggest ACUS consider adding a reference to OMB's 2011 Report to Congress on the Costs and Benefits of Federal Regulations, recommending that "in order to promote trade and exports, and thus increase job creation, agencies should promote regulatory cooperation initiatives with key trading partners." See http://www.whitehouse.gov/sites/default/files/omb/inforeg/2011_cb/2011_cba_report.pdf.

The Chamber believes ACUS lists most of the key concerns of businesses. However, in the interest of capturing the full scope of regulatory barriers to trade and investment, we would suggest adding uneven and inconsistent enforcement of regulation. We also suggest altering the reference to "EU companies" found in (iv) to just "companies" as U.S. businesses encounter subsidies in a broad range of countries beyond the European Union. Further, the Chamber also suggests the lack of regulatory transparency as well as inadequate notice and comment and stakeholder engagement by foreign regulators with foreign stakeholders be added as barrier separate and apart from what is captured in (i).

Using "Alignment" Instead of "Harmonization"

The Chamber notes that the term "harmonization" is used in several places in the report. We do not believe this is the best term to be used in relation to international regulatory cooperation as it carries various and often unhelpful meanings. Further, in most cases, harmonization is not what is being sought nor is it even desirable. Instead, we suggest the report use the words "alignment" or "coordination" of compatible regulatory regimes. We note that footnote 2 of the original 1991 ACUS recommendation recognized the limits of the term "harmonization" and suggest that for those very reasons, still in existence 20 years later, the report avoid, whenever practicable, the use of the term.

COMMENTS ON THE PROPOSED REVISED ACUS RECOMMENDATIONS

We would like to reiterate that the Chamber strongly supports the ACUS report's new set of recommendations. The recommendations reflect the thoughtful and thorough work that went into the report. The Chamber would make the following comments with regard to the recommendations.

Internal U.S. Agency Coordination and Development

ACUS Proposed Recommendation 1, on page 30 of the report, suggests agencies inform themselves of existing foreign regulatory bodies with similar missions and explore regulatory cooperation activities, when appropriate. The Chamber supports this recommendation, but suggests going beyond merely informing oneself.

It is important that this recommendation call for the development of a strategic plan for international regulatory cooperation. A coherent and synchronized internal vision is necessary to achieve a truly efficient and well-rounded international regulatory cooperation program. Further, the

recommendation should also speak to the need to form intra-agency efforts that allow the international office within a regulatory agency a greater seat at the domestic regulatory policy and promulgation table. This strategy should also cover interactions with other relevant agencies, domestic stakeholders, and foreign regulatory counterparts.

U.S. Agency Review of Statutory Authority

ACUS Proposed Recommendation 2, on page 31 of the report, suggests agencies review their legal authorities. The Chamber strongly supports this recommendation as it represents an important step for regulators to properly establish a robust and interactive program of international regulatory cooperation and seek expanded statutory authority from Congress where and if needed. In order to further highlight the importance of this step, we suggest that ACUS bolster this recommendation by adding language stressing review be undertaken in as timely manner as practicable. In order to ensure uniformity of this review, we also recommend that ACUS make explicit that an agency's office of general counsel undertake this review and that any review consist of, at a minimum, examines whether the agency currently undertakes, and whether the legal authorities currently allow, the regulatory agency to engage in all four parts of the definition of international regulatory cooperation the Chamber recommends ACUS incorporate into its paper and recommendations. These steps will ensure each agency consistently conducts the due diligence necessary to request any statutory changes that may be needed by examining the same potential scope of regulatory cooperation.

Regulators should be encouraged to seek expanded scope where necessary and if after examining their legislative authority, regulators decide they need to request Congressional authority, it should still be permissible to undertake a limited number of methods of international regulatory cooperation. To this extent we suggest adding either a subparagraph or an additional recommendation to this section that indicates all agencies have sufficient regulatory authority to undertake some aspects of international regulatory cooperation.

For example, notwithstanding any clear, indisputable conflicts with their respective authorizing statutes, U.S. agencies should follow OMB guidance[3] and consider the impact of any regulatory changes on U.S. competitiveness and

[3] See Office of the U.S. Trade Representative and Office of Information and Regulatory Affairs, Export and Trade Promotion, Public Participation, and Rulemaking, M-11-23, May 19, 2011, *available at* http://www.whitehouse.gov/sites/default/files/omb/memoranda/2011/m11-23.pdf.

ensure that all regulations are drafted and implemented in a manner no more burdensome than necessary to achieve a legitimate objective.

Support for Mutual Recognition

ACUS proposed recommendation 3, on page 31 of the report, contains suggestions for various modes of cooperation. The Chamber strongly supports this section and suggests ACUS should indicate that the list is not exhaustive and U.S. agencies have the freedom to pursue other creative avenues of cooperation. The Chamber would recommend adding to ACUS's list that where statutory authority permits, regulatory agencies should consider how mutual recognition might be more robustly employed.

Interagency Coordination

ACUS proposed recommendation 9, on page 32 of the report, suggests consultations with the relevant government agencies, OIRA, USTR, Commerce, State, and Defense, when a U.S. agency engages with foreign regulators. We suggest adding an additional sentence stating that U.S. agencies also conduct the same level of U.S. governmental level cooperation with the relevant government agencies, OIRA, USTR, Commerce, and State as part of their domestic rulemaking process to better understand what impact such a rule might have on U.S. exports, trade, or investment. We support efforts that facilitate coordination with USTR on any regulatory changes that may have international impact to ensure that all actions are fully aligned internally between U.S. domestic and international policy pursuits. The Chamber would note that such coordination is not at odds with an agency's statutory authority.

SUGGESTED NEW RECOMMENDATIONS

Communication and Transparency

ACUS should explicitly add a recommendation that encourages regulators be more communicative and transparent with stakeholders on international regulatory cooperation efforts that an agency is pursuing. Too often, regulators do not seek informed stakeholder input as to the regulatory challenges that exist both from a compliance as well as trade perspective, when developing regulatory cooperation work plans and conducting bilateral meetings with regulatory agencies within foreign counterparts.

In addition, it is important for regulators to communicate their success in regulatory cooperation. Achievements are not touted in a manner that demonstrates the progress that has or is being made. A greater emphasis on communicating deliverables and explaining the valuable contribution regulatory

cooperation has achieved in a specific regulatory area will only serve to further endorse continued work. In short, success breeds success, especially where that success is well documented, well measured, and well communicated.

Advancing the U.S. Regulatory Approach and U.S. Least Trade Restrictive Regulation

The Chamber strongly believes that ACUS's updated recommendations need to speak to regulatory agency support for advancing the U.S regulatory approach embodied in U.S. administrative law as well as promoting specific U.S. regulations to the fullest extent possible. In doing so, regulators serve to export well established regulatory best practices. Further, in the case of advancing specific U.S. regulation, regulators should be empowered to share better regulatory alternatives with their foreign counterparts in order to achieve the same or better regulatory outcome in a least trade restrictive manner. Engaging in removing regulatory barriers in foreign markets is something the European Union does quite effectively as its regulators work much closer with its commercial and trade counterparts within the European Commission to advance EU commercial interests.

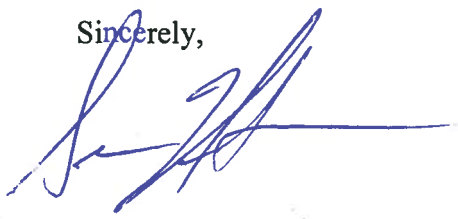
Making International Regulatory Cooperation a Political Priority

In order to address the concerns stated in the report regarding a lack of empowerment and attention given to international regulatory cooperation, the Chamber suggests adding an ACUS recommendation that international regulatory cooperation consistently be made a high political priority within any Administration and encourage agency heads and high-level senior political leadership foster an environment that promotes and emphasizes international trade and the continued enhancement of U.S. competitiveness within the regulatory agencies. ACUS's recommendation should go so far as to suggest an executive order be issues in support of ACUS's final recommendations.

CONCLUSION

The Chamber sincerely thanks ACUS, and particularly the efforts of Michael McCarthy in preparing the ACUS report and outline of potential updated recommendations. We appreciate the opportunity to submit these comments, and we look forward to future engagement to ensure the final recommendations on international regulatory cooperation unlock the full potential benefits for regulators, consumers, and businesses alike.

Sincerely,



Public Comment on International Regulatory Cooperation Project

From: bk1492@aol.com [mailto:bk1492@aol.com]
Sent: Friday, September 02, 2011 4:13 PM
Subject: public comment on federal register re

committee on regulations. the american public opposes any agreement that lets any other countrys regulations be in place of ours. who would want somalia's regulations or zimbabwe's regulations? we also need our agencies to critique each other. where are employees from cdc and nih, high priced medical alleged experts, not testifying when fda approves bad food, or when usda allows farm animals to be abused with regulations, or when epa approves every toxic chemical that comes before it. the highest priced experts we have on the govt payroll are notably absent, when they should be on the record on what happans to a human body or an animal body whenyou abuse it so that it is carrying 248 toxic chemicals in its body.

http://hygienemom.wordpress.com/2011/03/19/malformed-babys-parents-wait-on-tests/

jean public address if required