



ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

## **International Regulatory Cooperation (Updating ACUS Recommendation 91-1)**

### **Committee on Regulation**

#### **Proposed Recommendation | December 8–9, 2011**

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

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15 Given these developments, the Administrative Conference commissioned a research  
16 project to review international regulatory cooperation at United States government agencies  
17 today, assess how the 1991 recommendation has been implemented (or not), identify new  
18 challenges that have emerged in the past 20 years, and advise how the 1991 recommendation  
19 might be updated to guide agencies in improving international coordination today, to benefit  
20 regulatory goals and competitiveness. This research shows that, since the 1991  
21 recommendation was adopted, the international coordination efforts of agencies have greatly  
22 expanded. Yet the need for international coordination has also greatly expanded due to

**Comment [R.B1]:** Manager’s Amendment



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23 increased trade in goods, services, and information. Incompatible regulatory requirements in  
24 different countries persist. Sometimes these regulations are different for non-substantive  
25 reasons – regulators share common goals and methods of regulation, but for historical or other  
26 reasons, regulations remain inconsistent. Sometimes regulations differ because regulators in  
27 different countries do not agree on important substantive issues, such as how to weigh  
28 scientific evidence or balance competing priorities. When differences are substantive, they can  
29 sometimes be ascribed to countries’ asserting **legitimate** national goals such as protecting  
30 health, safety, or the environment at the levels that they consider appropriate. Other  
31 substantive differences, however, **may** disrupt trade ~~and serve no legitimate objective,~~ or  
32 otherwise operate as de facto protectionist measures. Moreover, even when standards are  
33 aligned, different national requirements for conformity assessment, such as testing,  
34 certification, inspection, or accreditation, frequently impose their own costs and delays.

**Comment [R.B2]:** Manager’s Amendment

**Comment [R.B3]:** Manager’s Amendment

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36 The Administrative Conference finds that improved international regulatory cooperation  
37 is desirable because it **can** help United States agencies accomplish their statutory regulatory  
38 missions domestically. Indeed, in some areas like regulating the safety of food and drugs, a  
39 large proportion of which are imported to the United States, **an agency’s awareness of** and  
40 **participation in foreign regulatory processes** ~~may be essential~~**can help** to ensure the safety of  
41 products reaching United States markets. International regulatory cooperation can also remove  
42 non-tariff barriers to trade and exports ~~that do not further the agency’s regulatory mission and~~  
43 ~~promote legitimate goals,~~ promoting global commerce and United States competitiveness.  
44 Moreover, these benefits of international regulatory cooperation are not incompatible and can  
45 be pursued in unison.

**Comment [R.B4]:** Manager’s Amendment

**Comment [R.B5]:** Siciliano Amendment 1

**Comment [R.B6]:** Goldman Amendment 1

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47 Because of the global nature of the economy, the domestic regulatory mission of **many**  
48 agencies is affected by what happens overseas. For example, imports of food and  
49 pharmaceutical products to the United States have greatly increased over the past 20 years, so

**Comment [R.B7]:** Manager’s Amendment



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50 that the Food and Drug Administration's (FDA) mission of ensuring food, drug, and device safety  
51 in the United States is necessarily intertwined with how these products are regulated in their  
52 countries of origin. The Consumer Product Safety Commission faces a similar challenge.  
53 Pollutants do not respect political boundaries, so the Environmental Protection Agency's  
54 ~~missions of ensuring clean air and clean waters~~success in achieving its mission in the United  
55 ~~States are reliant on~~can be affected by environmental regulations in other countries. Financial  
56 institutions in the United States participate in the global banking system and are exposed to  
57 risks in economies all over the world, which requires financial regulators to coordinate globally  
58 ~~in their missions of ensuring safety and soundness of United States institutions.~~ And trade in  
59 data crosses national boundaries, requiring the Federal Trade Commission to cooperate with  
60 other global regulators in policing Internet fraud.

**Comment [R.B8]:** Manager's Amendment

**Comment [R.B9]:** Manager's Amendment

61  
62 In addition to the impact on regulatory goals such as health, safety, environmental and  
63 consumer protection in the United States, inconsistent regulatory regimes can act as barriers to  
64 trade. For example, different food labeling requirements between the United States and  
65 Europe require producers who distribute food in both markets to produce the same goods in  
66 different packaging, depending on the market, which hinders economies of scale and adds cost  
67 and delay. Another example is that the United States and Europe have different approaches to  
68 regulating the length of tractor-trailers. Though the American design has better fuel economy,  
69 American manufacturers cannot export ~~their trucks which~~that comply with United States  
70 requirements into European markets without significant redesign, thereby creating an  
71 unnecessary barrier to trade.

**Comment [R.B10]:** Manager's Amendment

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73 Many agencies ~~are effectively~~successfully ~~engaginge~~ in international cooperation  
74 through a variety of different methods, such as coordination in regulatory promulgation,  
75 mutual recognition of inspection and certification regimes, and coordination and information  
76 sharing in enforcement. Some agencies have long coordinated effectively, both with respect to

**Comment [R.B11]:** Manager's Amendment



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77 domestic and international issues, even when not mandated to do so. Notably, there is  
78 evidence that better international cooperation can help agencies more proficiently accomplish  
79 their regulatory missions with fewer resources by dividing work, where appropriate, with  
80 foreign counterparts and mutually recognizing each others' inspection regimes and laboratory  
81 or test results. The FDA believes there is great potential for cost savings and improved health  
82 and safety in mutual reliance on the data from clinical trials and manufacturing quality  
83 inspection regimes in other countries. For example, the FDA recently concluded a pilot project  
84 with European and Australian regulators to inspect manufacturing plants in China and other  
85 countries that manufacture active pharmaceutical ingredients. The agencies compared their  
86 lists of plants subject to inspection and the resources that each country had available, and  
87 where two or more agencies were scheduled to visit the same plant, the agencies agreed on  
88 one agency to inspect that plant or to do a joint inspection, and reallocated resources so that  
89 they could cover more plants. Building on the success of that pilot, the FDA is now pursuing a  
90 similar project with European regulators for site inspections of clinical trials. These cooperative  
91 approaches, which show potential for cost savings without diminishing regulatory effectiveness,  
92 might be expanded to other agency settings for further cost-saving effects.

Comment [R.B12]: Manager's Amendment

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94 As regulatory frameworks continue to evolve, many countries' systems are converging  
95 towards core common precepts of effective governance, including effective laws, information  
96 disclosure and transparency, public participation, accountability (including robust compliance  
97 assurance systems), clearly defined roles and lines of authority, fair and responsive dispute  
98 resolution procedures, and public integrity. Convergence towards these precepts levels the  
99 playing field and improves regulatory coherence.

Comment [R.B13]: Siciliano Amendment 2

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101 However, global regulatory cooperation can be difficult to accomplish. Some agencies  
102 claim that they lack statutory authority to account for international effects when making  
103 regulatory decisions. Several agency officials, as well as high-level leaders, indicated that



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104 international regulatory cooperation was a low priority for certain agency leaders, as it is an  
105 issue with little visibility when accomplished successfully. Some agencies indicated that legal  
106 restrictions on information sharing can hinder international cooperation. Finally, coordination  
107 among some agencies within the United States government is a challenge, and agencies  
108 focused on trade and competitiveness, such as the Office of the United States Trade  
109 Representative (USTR), are not always aware of the activities of federal regulators.

Comment [R.B14]: Manager's Amendment

110  
111 Twenty years after the adoption of ACUS Recommendation 91-1, agencies increasingly  
112 recognize that international regulatory cooperation is an necessaryimportant component of  
113 their regulatory missions in today's globally integrated economy. While progress has been  
114 made, the scope of the problem leaves more work to be done to eliminate systemic barriers to  
115 coordination. The following recommendation restates the parts of the 1991 recommendation  
116 that remain valid and relevant and also addresses new considerations, to include promotion of  
117 best practices in transparency, mutual reliance, information sharing, and coordination within  
118 the United States. Accordingly, the recommendation supersedes Recommendation 91-1.

Comment [R.B15]: Manager's Amendment

Comment [R.B16]: Manager's Amendment

### RECOMMENDATION

119 1. Agencies should inform themselves of the existence of foreign authorities<sup>1</sup>  
120 whose activities may relate to their missions. Agencies should consider strategies for  
121 regulatory cooperation with relevant foreign authorities when appropriate to further the  
122 agencies' regulatory missions or to promote trade and competitiveness when doing so does not  
123 detract from their missions and, where consistent with advancing that mission, remove  
124 unjustified barriers to international trade.

Comment [R.B17]: Cass, Dudley Amendments

<sup>1</sup> Throughout this recommendation, the term "foreign authorities" includes a range of foreign and international counterparts, including but not limited to foreign government agencies, regional and international bodies, and, where appropriate, standard-setting organizations.



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126 2. Agencies should review their legal ~~authorities~~ authorization to cooperate with  
127 foreign authorities under their authorizing statutes, ~~bearing in mind obligations under-~~  
128 ~~Agencies could also consider~~ the World Trade Organization Agreement on Technical Barriers to  
129 Trade and other relevant treaties adopted by the United States ~~and as well as~~ Office of  
130 Management and Budget (OMB) guidance. Where legal authorities do not sufficiently permit  
131 appropriate international cooperation in regulation and enforcement that would benefit  
132 ~~agencyies'~~ missions ~~or promote trade and competitiveness without detracting from their~~  
133 ~~missions~~, agencies should recommend corrective legislation to OMB and Congress. As a general  
134 matter, ~~absent conflict with where in furtherance of~~ their legal authority ~~or missions~~, agencies  
135 should evaluate the international implications of regulatory activities.

Comment [R.B18]: Cass Amendment

Comment [R.B19]: Cass, Dudley Amendments

Comment [R.B20]: Manager's Amendment

Comment [R.B21]: Cass, Dudley Amendments

Comment [R.B22]: Cass, Dudley Amendments

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137 3. When agencies conclude that they have legal authority and the interest in  
138 cooperation from foreign authorities, and that cooperation would further ~~their agencies'~~  
139 ~~missions~~ ~~or promote trade and competitiveness without detracting from their missions~~, they  
140 should consider various modes of cooperation with those authorities, including but not limited  
141 to:

Comment [R.B23]: Cass, Dudley Amendments

- 142  
143 (a) establishment of common regulatory agendas;  
144  
145 (b) exchange of information about present and proposed foreign regulation;  
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147 (c) concerted efforts to reduce differences between the agency's rules and those  
148 adopted by foreign government regulators where those differences are not  
149 justified;

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151 (d) holding periodic bilateral or multilateral meetings either in person or by  
152 teleconference or video conference to assess the effectiveness of past  
153 cooperative efforts and to chart future ones; and

**Comment [R.B24]:** Manager's Amendment

155 (e) mutual recognition of tests, inspections, clinical trials, and certifications of  
156 foreign agencies.

158 4. To deploy limited resources more effectively, agencies should where  
159 appropriate and practicable, identify foreign authorities that maintain high quality and  
160 appropriate standards and practices ~~that are no less effective than United States equivalents~~  
161 and identify areas in which the tests, inspections, or certifications by agencies and such foreign  
162 agencies overlap. Where appropriate and practicable, agencies should consider:

**Comment [R.B25]:** Manager's Amendment

**Comment [R.B26]:** Cass, Dudley Amendments

**Comment [R.B27]:** Manager's Amendment

164 (a) dividing responsibility for necessary tests, inspections, and certifications and  
165 mutually recognizing their results;

**Comment [R.B28]:** Manager's Amendment

167 (b) creating joint technical or working groups to conduct joint research and  
168 development and to identify common solutions to regulatory problems (for  
169 example, through parallel notices of proposed rulemaking);

**Comment [R.B29]:** Manager's Amendment

171 (c) establishing joint administrative teams to draft common procedures and  
172 enforcement policies; and or

**Comment [R.B30]:** Manager's Amendment

**Comment [R.B31]:** Manager's Amendment

174 (d) documenting and publishing cost savings and regulatory benefits from such  
175 mutual arrangements.

**Comment [R.B32]:** Manager's Amendment

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177 | 5. To assess accurately whether foreign authorities maintain high quality and  
178 | appropriate standards and practices ~~that are no less effective than United States equivalents,~~  
179 | agencies should develop and maintain relationships with foreign counterparts by providing  
180 | training and technical assistance to foreign authorities and developing employee exchange  
181 | programs, as resources permit. Agencies should also as resources permit, review whether  
182 | foreign or international practices would be appropriate for adoption in the United States.

**Comment [R.B33]:** Manager's Amendment

**Comment [R.B34]:** Cass, Dudley Amendments

**Comment [R.B35]:** Manager's Amendment

183 |  
184 | 6. Agencies should engage in exchanges of information with foreign authorities to  
185 | promote better evidence-based decision-making. Types of information exchanges can range  
186 | from formal agreements to share data to informal dialogues among agency staff. To the extent  
187 | practicable, information exchange should be mutually beneficial and reciprocal. Prior to  
188 | exchanging information, agencies must reach arrangements with foreign counterparts that will  
189 | protect confidential information, trade secrets, or other sensitive information.

**Comment [R.B36]:** Cass, Dudley Amendments

**Comment [R.B37]:** Manager's Amendment

190 |  
191 | 7. Agency interactions with their foreign counterparts should generally be  
192 | transparent, subject to appropriate exceptions to protect law enforcement, trade secret, or  
193 | similar sensitive information. When engaging in regulatory dialogues with foreign authorities,  
194 | agencies should seek input and participation from interested parties as appropriate, through  
195 | either formal means such as Federal Register notices and requests for comments or informal  
196 | means such as outreach to regulated industries, consumers, and other stakeholders. Agencies  
197 | should, where ~~it would further~~ consistent with their statutory mandate, missions, and the public  
198 | interest, consider petitions by private and public interest groups for proposed rulemakings that  
199 | contemplate the reduction of differences between agency rules and the rules adopted by  
200 | foreign authorities, where those differences are not justified. While international consultations  
201 | of the sort described in this recommendation do not usually depart from an agency's standard  
202 | practices in compliance with applicable procedural statutes, an agency engaged in such  
203 | consultations should describe those consultations in its notices of proposed rulemaking,

**Comment [R.B38]:** Dudley Amendment

**Comment [R.B39]:** Cass, Dudley Amendments



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204 rulemaking records, and statements of basis and purpose under the Administrative Procedure  
205 Act. Where the objective of aligning American and foreign agency rules has had a significant  
206 influence on the shape of the rule, that fact also should be clearly acknowledged.

207

208 8. Agencies should promote to foreign authorities the principles that undergird the  
209 United States administrative and regulatory process, including, as appropriate, transparency,  
210 openness and public participation, evidence-based and risk-based regulation, cost-benefit  
211 analysis, consensus-based standard setting, accountability under the law, clearly defined roles  
212 and lines of authority, and impartiality. An agency engaging in international regulatory  
213 cooperation should also be alert to the possibility that foreign regulatory bodies may have  
214 different regulatory objectives, particularly where a government-owned or controlled  
215 enterprise is involved.

Comment [R.B40]: Siciliano Amendment 3

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217 9. When engaging with foreign authorities, agencies should, as appropriate, share  
218 information and consult with other government agencies with having interests that may be  
219 affected by the engagement, including but not limited to OMB's Office of Information and  
220 Regulatory Affairs (OIRA); the Office of the United States Trade Representative (USTR); and the  
221 Departments of Commerce, State, and Defense.<sup>2</sup>

Comment [R.B41]: Cass Amendment

Comment [R.B42]: Manager's Amendment

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223 ~~10. — The Executive Office of the President should consider creating a high-level~~  
224 ~~interagency working group of agency heads and other senior officials to provide government-~~  
225 ~~wide leadership on, and to evaluate and promote, international regulatory cooperation.~~

Comment [R.B43]: Goldman Amendment 2

<sup>2</sup> Agencies should comply with note-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. [Cass Amendment]