



ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

October 24, 2012

Mr. Daniel Mullaney
Assistant U.S. Trade Representative for Europe and the Middle East
Office of the United States Trade Representative
600 17th Street NW
Washington, DC 20508

Re: Request for Comments from the Public on Promoting U.S. EC Regulatory Compatibility, 77 Fed. Reg. 59702 (Sept. 28, 2012)

Dear Mr. Mullaney:

On behalf of the Office of the Chairman of the Administrative Conference of the United States, and pursuant to 5 U.S.C. § 595(c)(2), we submit these comments in response to your September 28, 2012 request for comments on promoting regulatory compatibility between the United States (US) and European Union (EU). As you may know, the Administrative Conference recently adopted Recommendation 2011-6, *International Regulatory Cooperation*,¹ which endorses coordination between US-government agencies and foreign authorities and urges US agencies to promote international regulatory cooperation to the extent that doing so advances their regulatory missions or removes non-tariff barriers to trade without undermining those regulatory missions. On May 1, 2012, at a workshop co-hosted by the Administrative Conference and the United States Chamber of Commerce, Cass Sunstein, then-Administrator of the Office of Information and Regulatory Affairs (OIRA), announced the issuance of Executive Order (EO) 13609, *Promoting International Regulatory Cooperation*,² which implements several of the proposals contained in the Administrative Conference Recommendation. The Office of the Chairman submits these comments to highlight the provisions of Recommendation 2011-6 (and corresponding provisions of EO 13609) that help guide agencies' international cooperation efforts. These recommendations provide a framework for international regulatory cooperation that can guide the Office of the United States Trade Representative (USTR) and individual agencies in their efforts to promote greater collaboration between the US and EU (as well as other key trading partners).

Recommendation 2011-6 is based largely on a report prepared by Michael T. McCarthy, who previously served as Executive Director of the Administrative Conference. Mr. McCarthy's report highlighted the significant benefits agencies can derive from coordination with foreign authorities. First, in many instances, international cooperation is critical to fulfilling an agency's regulatory mission. For instance, the Food and Drug Administration cannot effectively ensure

¹ 77 Fed. Reg. 2257, 2259 (Jan. 17, 2012) (hereafter "ACUS Recommendation 2011-6").

² 77 Fed. Reg. 26413, 26414 (May 4, 2012) (hereafter "EO 13609").



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the safety of imported food and drugs without closely cooperating with its counterpart agencies in those foreign jurisdictions from which such goods are imported.³ Second, though different nations may adopt disparate thresholds for determining when to act or apply differing levels of protection in the regulations they enact, many regulations differ simply for historical reasons unrelated to current regulatory goals; the requirement that regulated entities comply with disparate regimes can act as a non-tariff barrier to trade.⁴ The economic effect of such disparities can be substantial: a 2009 European Commission study found that eliminating 50% of non-tariff barriers between the US and EU would yield a 0.7% increase in EU Gross Domestic Product (GDP) and a 0.3% increase in US GDP.⁵

Recommendation 2011-6 provides a framework by which United States agencies can work with foreign authorities to enhance regulatory cooperation. As a general matter, the recommendation urges agencies to collaborate with foreign authorities in two sets of circumstances: (a) when cooperation would further the agency's mission and (b) when cooperation would promote trade and competitiveness and not otherwise detract from the agency's mission.⁶ When the agency deems that cooperation with foreign authorities would accomplish one or both of these objectives, it should consider engaging in the following activities: (a) establishing common regulatory agendas with foreign agencies; (b) exchanging information about present and proposed regulation; (c) pursuing concerted efforts to reduce unjustified differences between the agency's rules and those adopted by foreign governments; (d) holding periodic bilateral or multilateral meetings to discuss the effectiveness of past cooperation efforts and coordinate future efforts; and (e) mutually recognizing tests, inspections, clinical trials, and certifications of foreign agencies and/or dividing authority for undertaking such processes with trusted foreign entities.⁷ Agencies should also strive to maintain strong relationships with foreign authorities by providing training and technical assistance, exchanging relevant information (with appropriate protections for confidential, trade secret, and other sensitive information), and developing employee exchange programs, as resources permit.⁸ Further, agencies should promote the principles undergirding the United States regulatory system, such as evidence-based and risk-informed regulation, cost-benefit analysis, and transparency, when coordinating with foreign authorities.⁹

³ Michael T. McCarthy, *International Regulatory Cooperation, 20 Years Later: Updated ACUS Recommendation 1991-1*, at 8 (Oct. 19, 2011), *available at* <http://www.acus.gov/wp-content/uploads/downloads/2011/10/COR-IRC-report-10-19-11.pdf>.

⁴ *Id.*

⁵ *Id.* at 10 (citing Judith M. Dean et al., *Estimating the Price Effects of Non-Tariff Barriers 2* (U.S. International Trade Commission Working Paper, 2009), *available at* http://www.usitc.gov/publications/332/working_papers/EC200606Ar.pdf).

⁶ ACUS Recommendation 2011-6, *supra* note 1, ¶ 1.

⁷ *Id.* ¶¶ 3-4.

⁸ *Id.* ¶¶ 5-6.

⁹ *Id.* ¶ 8.



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Recommendation 2011-6 also urges agencies to coordinate their international cooperation efforts with other agencies and with the Executive Office of the President. Specifically, agencies should work with OIRA, USTR, the Department of Commerce, the Department of State, the Department of Defense, and any other agency whose work is implicated by the proposed international cooperation effort.¹⁰ Agencies also should seek public input from parties interested in their international cooperation efforts and notify the public of such efforts when they impact proposed rules.¹¹ Finally, the Executive Office of the President should consider creating a high-level working group to promote and to provide government-wide leadership on international regulatory cooperation.¹²

In this light, Recommendation 2011-6 provides important guidance to agencies as they coordinate with foreign authorities, sister agencies, and the Executive Office of the President in attempting to promote their statutory missions and remove unnecessary barriers to trade.¹³ The Conference intends to work with agencies to encourage implementation of the proposals contained in Recommendation 2011-6 and to serve as a forum wherein agencies can share “best practices” and exchange ideas related to international regulatory cooperation. Historical information concerning the recommendation and updates regarding the Administrative Conference’s ongoing efforts in the field of international regulatory cooperation are available on the Conference’s website at <http://www.acus.gov/research/research-and-recommendations/implementation/international-regulatory-cooperation/>. Any inquiries concerning the project may be directed to Attorney Advisor Reeve T. Bull (rbull@acus.gov), who leads the Conference’s efforts related to the International Regulatory Cooperation project. Thank you for providing an opportunity to comment on the question of promoting enhanced regulatory compatibility between the US and EU, and we look forward to working with you in encouraging increased cooperation between US agencies and foreign authorities.

¹⁰ *Id.* ¶ 9.

¹¹ *Id.* ¶ 7.

¹² *Id.* ¶ 10. EO 13609 also recognizes the importance of coordination amongst regulatory agencies and the Executive Office of the President, assigning the Regulatory Working Group headed by the Administrator of OIRA the task of “serv[ing] as a forum to discuss, coordinate, and develop a common understanding among agencies of U.S. Government positions and priorities with respect to” international cooperation efforts. EO 13609, *supra* note 2, § 2.

¹³ During the consideration of Recommendation 2011-6, several agencies took the position that they did not possess statutory authorization to consider international impacts when making regulatory decisions. McCarthy, *supra* note 3, at 19. Hence, Recommendation 2011-6 urged agencies to notify the Office of Management and Budget and Congress if they lacked such authority and to seek corrective legislation. ACUS Recommendation 2011-6, *supra* note 1, ¶ 2. To the extent that an agency is not statutorily foreclosed from considering international implications of its work, EO 13609 clearly directs agencies to do so, requiring all executive branch agencies to submit regulatory plans summarizing their international regulatory cooperation activities and explaining how those activities advance the purposes of EO 13563, and “encourage[ing]” independent regulatory agencies to do the same. EO 13609, *supra* note 2, §§ 3, 5.



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Sincerely,

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Chairman

Reeve T. Bull

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