

AMERICAN BAR ASSOCIATION

ADOPTED BY THE HOUSE OF DELEGATES

AUGUST 6-7, 2012

RESOLUTION

RESOLVED, That the American Bar Association urges federal agencies to pursue regulatory cooperation with relevant foreign authorities where appropriate and consistent with their legal authority, statutory mandates, and regulatory missions.

FURTHER RESOLVED, That the American Bar Association urges federal agencies to:

- 1) Work with their foreign counterparts to develop common regulatory agendas, harmonized regulatory standards, information exchanges, and mutual recognition of tests and inspections;
- 2) Strengthen relationships with foreign counterparts by providing training and technical assistance where such assistance is requested;
- 3) Promote in these cooperative efforts the core principles of sound administrative and regulatory process;
- 4) Seek early input from representatives of affected interests when engaged in discussions with foreign regulators, and, where appropriate, publicly disclose the substance of the international discussions;
- 5) Recommend corrective legislation to Congress where there is insufficient legal authority to permit the regulatory cooperation contemplated; and
- 6) Coordinate and share information among sister federal agencies to facilitate regulatory cooperation with foreign counterparts, including through the Regulatory Working Group chaired by the Office of Information and Regulatory Affairs in the Office of Management and Budget.

REPORT

International regulatory cooperation is an increasingly important facet of the work that agencies do to develop their missions and effectuate their oversight and supervision in a globalized world, where regulatory problems cross borders. For these reasons the Administrative Conference at the United States (“ACUS”) has issued recommendations in 1991 and 2011 broadly designed to encourage federal agency cooperation with foreign government regulators.

The Administrative Conference’s 1991 Recommendation observed that “if 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 the world’s development suggest that that era has come to a close.”¹

In December 2011 ACUS revisited this issue and, in a new recommendation, encouraged agencies to continue and strengthen their consideration of “strategies for regulatory cooperation with relevant foreign authorities where appropriate to further the agency’s mission or to promote trade or competitiveness when doing so does not detract from their missions.”² The 2011 Recommendation also promoted best practices in transparency, information sharing, and coordination between American and foreign agencies.

On May 1, 2012, President Obama issued a new Executive Order on Promoting International Regulatory Cooperation.³ The Order endorses much of the contents of ACUS’s 2011 recommendation, and specifically tasks the Regulatory Working Group (chaired by the Administrator of the Office of Information and Regulatory Affairs) with fostering greater coordination of U.S. Government strategies and approaches towards foreign regulators.

For reasons like those that animated the new ACUS Recommendation and the President’s Executive Order, the American Bar Association should adopt a resolution encouraging international regulatory cooperation where appropriate and consistent with the rule of law values that the ABA has consistently upheld.

This report hereafter draws from the 2011 ACUS report,⁴ permission to use which is gratefully acknowledged:

International regulatory cooperation has two basic benefits. First, it helps U.S. regulatory agencies accomplish their statutory regulatory missions domestically. Indeed, in areas such as regulating the safety of food and drugs, a large proportion of which are imported to the U.S.,

¹ Administrative Conference of the United States, Recommendation 91-1, “Federal Agency Cooperation with Foreign Government Regulators” (June 13, 1991), *available at* <http://www.acus.gov/acus-recommendations/federal-agency-cooperation-with-foreign-government-regulators/>.

² Administrative Conference of the United States, Recommendation 2011-6, “International Regulatory Cooperation” ¶ 1 (Dec. 8, 2011), *available at* <http://www.acus.gov/acus-recommendations/international-regulatorycooperation/>.

³ E.O. 13609, Promoting International Regulatory Cooperation, 77 Fed. Reg. 26413 (2012).

⁴ Michael T. McCarthy, *International Regulatory Cooperation, 20 Years Later: Updating ACUS Recommendation 91-1* (Draft of Oct. 19, 2011), *available at* <http://www.acus.gov/wp-content/uploads/downloads/2011/11/International-Reg-Cooperation-Report.pdf>.

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awareness and participation in foreign regulatory processes may be essential to ensure the safety of products reaching U.S. markets. Second, international regulatory cooperation can remove non-tariff barriers to trade and exports, promoting global commerce and U.S. competitiveness. These benefits of international regulatory cooperation are not inconsistent; they often can be pursued in unison.

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 U.S. government is a challenge, particularly for independent regulatory agencies, so that agencies focused on trade and competitiveness are not always aware of the activities of other federal regulators.

Despite these challenges, many agencies do effectively engage in international cooperation. Notably, there is evidence that improved international cooperation has helped agencies better accomplish their regulatory missions with fewer resources by dividing work with foreign counterparts and, where appropriate, recognizing each others' inspections and other tests. These approaches, which show potential for cost savings without diminishing regulatory effectiveness, might be expanded for further cost-saving.

The United States has entered into a number of trade agreements intended to remove barriers to trade, such as tariffs, subsidies, and inconsistent technical standards or regulations. The Uruguay Round of the General Agreement of Trade and Tariffs was conducted from 1986 to 1994 and resulted in the creation of the World Trade Organization.⁵ This round also addressed the concern that, as free-trade agreements reduced measures such as tariffs, non-tariff barriers such as mandatory product standards and conformity assessment procedures could also disrupt trade.⁶ The Agreement on Technical Barriers to Trade (TBT Agreement), an outcome of the Uruguay Round and an elaboration of the Tokyo Round Standards Code, sets out procedures that countries must follow in developing, adopting and implementing mandatory product standards and conformity assessment procedures to protect the countries' legitimate regulatory interests such as protecting health, safety, and the environment, while avoiding the creation of unnecessary obstacles to trade in goods.⁷

The TBT Agreement acts as an analogue to the Administrative Procedure Act in the United States by setting out principles and procedures for countries to develop their regulatory standards to comply with WTO rules. Among the key obligations of the TBT Agreement are non-discrimination; ensuring that mandatory product standards are no more trade restrictive than

⁵ Marrakesh Agreement Establishing the World Trade Organization, 1867 U.N.T.S. 31874 (1994).

⁶ See David Lifshiz, *Updating American Administrative Law: WTO, International Standards, Domestic Implementation and Public Participation*, 24 WIS. INT'L L.J. 961, 961 (2007).

⁷ Agreement on Technical Barriers to Trade, Annex to the Marrakesh Agreement Establishing the World Trade Organization, 1868 U.N.T.S. 120 (1994). Another agreement, the Sanitary and Phytosanitary Measures Agreement (SPS Agreement), specifically addressed the alignment of international and domestic standards in food and agricultural products.

necessary to fulfill a legitimate objective; enhanced transparency in the development of mandatory product standards and conformity assessment procedures; the use of relevant international standards as a basis for mandatory product standards and conformity assessment procedures (unless ineffective or inappropriate to fulfill a legitimate objective); and, where appropriate, basing product requirements on performance or outcomes instead of specific designs or descriptions. The Agreement also strongly encourages the acceptance of foreign regulations as equivalents, mutual recognition of tests and certifications, permitting foreign conformity assessment bodies to participate in domestic conformity assessment procedures on no less favorable terms as those accorded to domestic conformity assessment bodies, and use of international systems of conformity assessment.⁸

Because access to information is important in coordinating regulation, the TBT agreement requires that each member publish certain proposed measures at an early stage so that other members may have an opportunity to comment and have comments considered, and to promptly publish final measures.⁹ Each country is required to establish a National Inquiry Point to facilitate access to this information. The National Institute of Science and Technology (NIST) within the Department of Commerce plays this role for the United States. NIST operates a database, Notify U.S., containing proposed mandatory product standards and conformity assessment procedures from other countries that may significantly affect trade.¹⁰ The Notify U.S. database compiles summary information on foreign measures, allows users to request complete texts, guides U.S. entities in preparing comments, and forwards these comments to foreign regulators. NIST is also responsible for notifying foreign countries of proposed U.S. federal and state measures that may have significant trade effects.¹¹

As one route to greater alignment, the TBT agreement encourages the adoption of voluntary international standards as national technical regulations.¹² The agreement requires Members to use relevant international standards as a basis for their mandatory product standards and conformity assessment procedures, provided that such standards are not ineffective or inappropriate to achieve the legitimate policy objective pursued.¹³ Such measures can be afforded a rebuttable presumption that they are not unnecessary technical barriers to trade.

The United States has undertaken other efforts to align its regulations with those of other nations, adopting a law encouraging the use of voluntary consensus standards instead of government-unique standards. The National Technology Transfer and Advancement Act of 1995 (NTTAA)¹⁴ directs U.S. regulatory agencies to adopt voluntary consensus standards,

⁸ Office of the United States Trade Representative, 2011 Report on Technical Barriers to Trade 9 (2011), *available at* <http://www.ustr.gov/sites/default/files/TBT%20Report%20Mar%2025%20Master%20Draft%20Final%20pdf%20Adobe%20Acrobat%20Pro.pdf>.

⁹ *Id.*

¹⁰ See Notify U.S. Web site, <https://tsapps.nist.gov/notifyus/data/index/index.cfm>.

¹¹ U.S. Dep't of Commerce, U.S. TBT Inquiry Point: What We Do, <http://gsi.nist.gov/global/index.cfm/L1-4/L2-12/A219>.

¹² Office of the U.S. Trade Representative, 2011 Report on Technical Barriers to Trade 21 (2011), *available at* <http://www.ustr.gov/sites/default/files/TBT%20Report%20Mar%2025%20Master%20Draft%20Final%20pdf%20Adobe%20Acrobat%20Pro.pdf>.

¹³ *Id.*

¹⁴ Pub. L. No. 104-113, 110 Stat. 775 (1996).

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instead of creating standards unique to the government, whenever possible. OMB Circular A-119, Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities, provides guidance to agencies on implementing the NTTAA. “This Circular instructs agencies to use voluntary consensus standards in lieu of government-unique standards except where inconsistent with law or otherwise impractical. It also provides guidance for agencies participating in voluntary consensus standards bodies and describes procedures for satisfying the reporting requirements in the NTTAA. The aim of the Circular is to reduce to a minimum the reliance by agencies on government-unique standards.”¹⁵

In addition to participation in the WTO, including the TBT agreement, the United States has also entered into free trade agreements with a number of countries that include obligations for regulatory cooperation beyond the framework of the TBT Agreement. For example, these free trade agreements require trade partners to recognize U.S. conformity assessment bodies, including testing and certification bodies, on no less favorable terms than they accord to their own testing and certification bodies, and vice versa.¹⁶

To facilitate greater levels of international regulatory cooperation, the United States created high-level, bilateral regulatory cooperation forums with the European Union, Mexico, and Canada.¹⁷ In addition, the United States has offered proposals in various fora, such as the WTO’s Doha Round, Asia-Pacific Economic Cooperation, and the Trans-Pacific Partnership negotiations to promote transparency and the use of good regulatory practices, as well as to better align regulatory approaches (including labeling and packaging requirements) in specific product areas such as textiles, apparel, footwear, and travel goods; electronic goods; goods with cryptographic capabilities; automotive goods; wine and distilled spirits; medical devices, pharmaceuticals, and cosmetics.¹⁸

Many agencies successfully engage in international cooperation through a variety of different methods, such as coordination in regulatory promulgation, mutual recognition of inspection and certification regimes, and coordination and information sharing in enforcement. Some agencies have long coordinated effectively, both with respect to domestic and international issues, even when not mandated to do so. 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 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

¹⁵ EU-US High-Level Regulatory Cooperation Forum, Report to the Transatlantic Economic Council, Oct. 15, 2008, at 4, available at http://www.whitehouse.gov/sites/default/files/omb/oir/irc/hlrcf_summary_report_october_2008.pdf.

¹⁶ Office of the U.S. Trade Representative, *2011 Report on Technical Barriers to Trade* 15 (2011), available at <http://www.ustr.gov/sites/default/files/TBT%20Report%20Mar%2025%20Master%20Draft%20Final%20pdf%20Adobe%20Acrobat%20Pro.pdf>.

¹⁷ *Id.* at 40.

¹⁸ *Id.* at 44.

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.

The U.S. government and business groups such as the U.S. Chamber of Commerce agree that, even as international regulatory cooperation has improved over the past 20 years, there are still shortcomings in cooperation that hinder regulatory effectiveness and commerce. While U.S. agencies have greatly expanded their international efforts, 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 regulations are different for non-substantive reasons – regulators share common goals and approaches, 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. Substantive differences can sometimes be ascribed to countries asserting legitimate national goals such as protecting health, safety or the environment at levels 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 regulations themselves are aligned, different national requirements for conformity assessment, such as testing, certification, inspection, or accreditation, frequently impose their own costs and delays.

Disparities between regulatory regimes hinder the regulatory effectiveness of the U.S. government and have costs to the U.S. economy. Regulatory differences between the U.S. and foreign governments can require U.S. agencies to “devote scarce enforcement resources to policing high volume but low-risk transatlantic trade, reducing their ability to adequately enforce regulatory requirements on imports from less well-regulated economies.”¹⁹ A 2009 European Commission study found that the elimination of 50 percent of non-tariff barriers between the U.S. and the EU would result in a \$150 billion increase in gross domestic product (GDP), yielding 0.7-percent and 0.3-percent in permanent increases to the EU’s and the U.S.’s GDP, respectively.²⁰ In addition to the financial savings, an increase in GDP could also result in lives saved²¹ and would yield other non-market benefits to public health, safety and the environment.²²

Because of the global nature of the economy, the domestic regulatory mission of U.S. agencies is affected by what happens overseas. For example, imports of food and pharmaceutical products to the U.S. have greatly increased over the past 20 years, so that the FDA’s mission of ensuring food, drug, and device safety in the United States is necessarily

¹⁹ John F. Morrall III, *Determining Compatible Regulatory Regimes between the U.S. and the EU* (U.S. Chamber of Commerce White Paper) (2011), at 23, available at http://www.uschamber.com/sites/default/files/grc/Determining%20Compatible%20Regulatory%20Regimes%20-%20Final_0.pdf.

²⁰ Judith M. Dean et al., *Estimating the Price Effects of Non-Tariff Barriers* (U.S. Int’l Trade Commission Working Paper) (2009), at 2, available at http://www.usitc.gov/publications/332/working_papers/EC200606Ar.pdf.

²¹ Morrall, *supra* note 19, at 2 n.6 (a \$150 billion increase in GDP would result in 6,000 lives saved).

²² *Id.* at 32.

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intertwined with how these products are regulated in their country of origin. Similarly, pollutants do not respect political boundaries and carbon emissions have global effects, so that 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.²³ And trade in data flows across national boundaries, requiring the Federal Trade Commission to cooperate with other global regulators in policing Internet fraud.

A CPSC report outlined reasons that disparate safety standards could have negative consequences, including:

- A potential for production errors due to periodic changes of components or procedures to meet different regulations. Such mistakes may result in an otherwise safe product meeting the “wrong regulation” or, worse, the accidental absence of, or even the intentional deletion of, a required safety element.
- Higher costs for consumers where production must be modified to meet different safety requirements.
- Confusion and concern by consumers who do not understand why a foreign safety requirement is not applied to the same products sold in their own market.
- Purchase abroad of an otherwise identical product that does not meet safety requirements in the consumer's own market.
- Unavailability of a useful and safe product in a given market because the manufacturer finds it cost-prohibitive to meet different safety standards in multiple markets.²⁴

In addition to the impact on regulatory goals such as health, safety, and environmental and consumer protection in the United States, inconsistent regulatory regimes can act as barriers to trade. Past and current informal regulatory barriers include (i) uncertainty about foreign regulations, which could force U.S. manufacturers to “make practical design, production, and commercial decisions without adequate information”;²⁵ (ii) uncertainty caused by excessive time to process appeals from regulatory decisions;²⁶ (iii) ineffective, inconsistent or overly lengthy

²³ Coordination with foreign financial regulators often occurs through a variety of means, which affords flexibility in addressing cross-border issues. Examples include membership in international standard setting bodies, such as the International Organization of Securities Commissions (IOSCO); bilateral and multilateral engagements; and the Financial Stability Board.

²⁴ CPSC Office of International Programs and Intergovernmental Affairs, *Toy Safety Regulatory and Standards Coordination and Alignment: A Roadmap*, April 25, 2011, at 5.

²⁵ *Id.* at 14 n. 10. The U.S. has entered into Free Trade Agreements with regulatory cooperation provisions with Australia, Bahrain, Central America and the Dominican Republic, Chile, Morocco, Oman, and Peru.

²⁶ *Id.* at 193.

enforcement efforts;²⁷ and (iv) reimbursable advances (loans) and direct subsidies for companies;²⁸ and (v) lack of regulatory transparency of foreign markets.

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. While the U.S. regulations address the length of the trailers, the European regulations address the combined length of the tractor and trailer.²⁹ The result of this disparity is that European trucks typically place the driver's cab over the engine compartment so that the truck is shorter, while American trucks place the driver's cab behind the engine compartment, resulting in a longer truck with a more aerodynamic profile. This disparity has both regulatory and trade effects: the American design has better fuel economy, and American manufacturers cannot export their trucks which comply with U.S. requirements into European markets without significant redesign.

International regulatory cooperation is one route – partial, but important – to ameliorating these problems. It also offers one other secondary benefit. The resolution urges agencies to promote in these efforts the sound principles of administrative and regulatory process. Such principles include transparency, openness, and public participation; evidence-based and risk-informed regulation; cost-benefit analysis; consensus-based standard setting; accountability under the law; clearly defined roles and lines of authority; fair and responsive dispute resolution procedures; and impartiality. While U.S. agencies are not, of course, in a position to dictate to their foreign counterparts, international dialogue and cooperation offers an opportunity for promoting these principles.

Agencies have increasingly recognized that international regulatory cooperation is an important 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.

Respectfully submitted,

Michael Herz
Chair, Section of Administrative Law and Regulatory Practice
August 2012

²⁷ *Id.* at 191-92.

²⁸ *Id.* at 206-08.

²⁹ Comment of Navistar, Inc. in response to Request for Public Comments Concerning Regulatory Cooperation Between the United States and the European Union That Would Help Eliminate or Reduce Unnecessary Divergences in Regulation and in Standards Used in Regulation That Impede U.S. Exports, 76 Fed. Reg. 24860 (May 3, 2011), *available at* <http://www.regulations.gov>, Docket No. ITA-2011-0006-0046.

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GENERAL INFORMATION FORM

Submitting Entity: Section of Administrative Law and Regulatory Practice

Submitted By: Michael Herz, Chair

1. Briefly summarize the resolution.

The resolution urges federal agencies to cooperate with their foreign counterparts – for example by harmonizing regulatory standards, exchanging information, and recognizing each other’s tests and inspections -- when doing so would further their missions and be consistent with their legal authority.

2. Indicate when the resolution was approved or will be considered by the governing body of the submitting entity. If the vote was taken other than at a regularly scheduled meeting of the governing body, describe the procedure.

The Council of the Section of Administrative Law and Regulatory Practice approved the resolution at its spring meeting on April 21, 2012.

3. If this or a similar resolution has been submitted previously to the House of Delegates or the Board of Governors, please include all relevant information – a summary of the resolution, when and before what group the resolution was considered, and what action or position was taken on the matter.

No.

4. Are there any existing Association policies which are relevant to this resolution, and if so, how would they be affected by the adoption of this resolution?

None are directly relevant.

5. Explain what urgency exists which requires that action on this matter be taken at this meeting. If deferral is acceptable, note the time by which action is necessary.

International regulatory cooperation is an increasingly important facet of the work that agencies do to develop their missions and make their oversight and supervision possible in a globalized world where regulatory problems cross borders. For these reasons the Administrative Conference at the United States (ACUS) issued recommendations in 1991 and now 2011 broadly designed to encourage federal agency cooperation with foreign government regulators. The American Bar Association should also adopt a recommendation encouraging international regulatory cooperation where appropriate and consistent with the rule of law values that the ABA has consistently upheld.

6. If the resolution is a legislative resolve, indicate the current status in the Congress.

No bills containing the specific measures proposed in the resolution are known to exist.

7. Briefly explain plans for implementation of the policy, if adopted by the House of Delegates.

The Section would plan to publicize the resolution among federal officials to promote the undertakings urged by the resolution; it would be appropriate to consult and coordinate with ACUS in doing so.

8. If adoption of the resolution would result in expenditures, estimate the funds necessary, suggest the anticipated source for funding, and list proposed direct and indirect costs. Indirect costs include those such as staff time or administrative overhead.

N/A

9. Review the background of the proponents of the resolution to determine if there are potential conflicts of interest. If such potential is found, list by name those proponents who have a material interest in the subject matter of the resolution due to specific employment or representation of clients. Note all individuals who abstained from voting on the resolution due to a conflict of interest.

None.

10. List the sections, committees, bar associations, or affiliated entities to which the resolution has been referred, the date of the referral, and the response of each group, if known.

An earlier version was referred to the Section of International Law (5/7/12) and the Section of Business Law (5/7/12). This version is being referred to those Sections as well as the Sections of Antitrust Law, Intellectual Property Law and Science and Technology Law.

11. Indicate the name, address, and telephone number of the person who should be contacted prior to the meeting concerning questions about the report.

David Zaring
662 Jon M. Huntsman Hall
3730 Walnut Street
Philadelphia, PA 19104
Phone: (215) 573-7154
zaring@wharton.upenn.edu

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Neysun A. Mahboubi
University of Connecticut School of Law
65 Elizabeth Street, Hartford, CT 06105
Tel.: 860.570.5107 (o), 610.952.2921 (m)
Email: neysun.mahboubi@law.uconn.edu

12. Indicate the name of the person who will present the resolution to the House and who should be contacted at the meeting when questions arise concerning its presentation and debate. Please be sure to include email addresses and cell phone numbers for your on-site contacts.

Randolph J. May
The Free State Foundation
P. O. Box 60680
Potomac, MD 20859
(301) 984-8253 (tel)
(202) 285-9926 (cell)
rmay@freestatefoundation.org

John M. Vittone
2017 Lanier Drive
Silver Spring, Md. 20910
(301) 585-0592 (tel)
(301) 580-8164 (cell)
vittone.john@gmail.com

EXECUTIVE SUMMARY

1. Summary of the resolution

The resolution urges federal agencies to cooperate with their foreign counterparts – for example by harmonizing regulatory standards, exchanging information, and recognizing each other’s tests and inspections -- when doing so would further their missions and be consistent with their legal authority.

2. Summary of the issue that the resolution addresses

As the world has globalized and international trade increased, different countries’ inconsistent regulatory requirements have become an increasing burden for firms operating internationally. In addition, in a global economy, the activities of regulators abroad affect the ability of agencies in the U.S. to accomplish their domestic missions.

3. Please explain how the proposed policy position will address the issue

The resolution urges agencies to cooperate with their foreign counterparts, as appropriate and consistent with U.S. and international law, to harmonize regulatory requirements, share information, accept the results of each other’s tests and inspections, and undertake related efforts in order to minimize burdens on trade, increase U.S. competitiveness, enhance their regulatory missions, and operate more efficiently.

4. Summary of minority views

No minority views are known to exist.