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Facilitating Earlier Information Sharing and Cooperation Between the U.S. Department of Transportation and the EU

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Abstract

This study examines existing practices for communication and cooperation between regulators in the European Union (EU) and the United States (U.S.) responsible for transportation safety and other matters regulated by the U.S. Department of Transportation (DOT). The study describes current procedures, identifies successes and challenges to effective regulator-to-regulator cooperation, and offers suggestions for improving regulatory outcomes through cooperation. These observations may be useful for informing the Transatlantic Trade and Investment Partnership (TTIP) negotiations and providing support for policy recommendations.

¹ The contents of this working paper are the sole responsibility of author(s) and can in no way be taken to reflect the views of the European Union. This working paper does not represent an official position of the GW Regulatory Studies Center or the George Washington University. The Center's policy on research integrity is available at <http://regulatorystudies.columbian.gwu.edu/policy-research-integrity>.

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Facilitating Earlier Information Sharing and Cooperation Between the U.S. Department of Transportation and the EU

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The Department of Transportation consists of nine operating administrations and the Office of the Secretary (OST), each of which has statutory responsibility for a wide range of regulations. DOT regulates safety in the aviation, motor carrier, railroad, motor vehicle, commercial space, public transportation, and pipeline transportation areas. DOT also regulates aviation consumer and economic issues and provides financial assistance for programs involving highways, airports, public transportation, the maritime industry, railroads, and motor vehicle safety. In addition, the Department issues regulations to carry out a variety of statutes ranging from the Americans With Disabilities Act to the Uniform Time Act. Finally, DOT develops and implements a wide range of regulations that govern internal DOT programs such as acquisitions and grants, access for the disabled, environmental protection, energy conservation, information technology, occupational safety and health, property asset management, seismic safety, and the use of aircraft and vehicles.

One of the reasons DOT was created was to bring the various operating administrations together under one Department to allow better coordination of the interrelated responsibilities. For example, the Federal Aviation Administration and the National Highway Traffic Safety Administration coordinate on the development of rules for child safety seats so that the seats used in cars can also be used in aircraft; and all of the operating administrations regulating safety-sensitive employees coordinated on the development of drug and alcohol rules to share data, cover the same types of employees, and use the same testing procedures.

OST's and DOT Operating Administrations' Substantive Regulatory Responsibilities

- Federal Aviation Administration (FAA)
 - Aviation safety and operations
 - Certification of airmen, aircraft, and airports
 - Commercial space transportation
 - Airport and airway fees and charges
 - Foreign air carriers operating in the U.S. and U.S.-owned aircraft outside the U.S.
- Federal Highway Administration (FHWA)

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- Highways and roads
- Federal Motor Carrier Safety Administration (FMCSA)
 - Motor carrier safety, operations, and equipment
 - Bus safety
 - Commercial drivers' licenses
 - Hours of service
- Federal Railroad Administration (FRA)
 - Railroad equipment, operations, and workplace safety
 - Engineer qualifications and certification
- Federal Transit Administration (FTA)
 - Mass transit safety
- Maritime Administration (MARAD)
 - Cargo preference
- National Highway Traffic Safety Administration (NHTSA)
 - Motor vehicle safety and fuel economy
 - Highway safety programs
 - Consumer information
- Pipeline and Hazardous Material Safety Administration (PHMSA)
 - Hazardous materials
 - Pipeline safety
- Saint Lawrence Seaway Development Corporation (SLSDC)
 - Tolls
 - Seaway operations
- Office of the Secretary (OST)
 - Transportation of Americans with disabilities
 - Aviation consumer protection and civil rights
 - Aviation passenger manifests

Coverage of this Paper

This paper primarily covers FAA, NHTSA, and PHMSA hazardous materials responsibilities. Their responsibilities appear to have the greatest impact on the EU. They are also agencies that have been heavily involved in international regulatory cooperation efforts with other countries, particularly the EU, and international organizations. As a result, one can gain significant information about what is being done, what works well, what does not, and what problems to anticipate. This, in turn, will help identify policy recommendations. The paper also offers some excellent examples of international regulatory cooperation by other DOT agencies that help provide insight and support for the recommendations.

DOT and the Regulatory Process

Authority to Act

In the U.S. federal government, executive branch agencies can only act when they are given authority to do so by the Constitution or the Congress through a statute. The statutes can range from requiring specific action (e.g., require air bags in all motor vehicles) to providing very broad discretion (e.g., establish minimum standards for motor vehicle safety).

The Administrative Procedure Act

The basic statute governing the rulemaking process in the U.S. is the Administrative Procedure Act (APA).⁴ The APA requires that decisions be made through informal or formal rulemaking or informal or formal adjudicatory orders. The authorizing statute may provide the agency discretion to choose the approach or mandate a particular process.

Generally, DOT and other U.S. agencies use informal rulemaking to adopt standards. This process requires the agency to issue a notice of proposed rulemaking (NPRM) that explains the need and authority for the rule and the subjects and issues involved and asks for public comment. (This process is often simply referred to as the “notice-and-comment” process.) The APA does not require a public hearing, but agencies have the discretion to hold them. After the comment period closes, the agency may adopt a final rule, which must respond to public comment and provide a statement of basis and purpose for the rule. There are some exceptions or exemptions from these requirements (e.g., if there is “good cause” the agency can issue a final rule without following the “notice-and-comment” process).

Other Rulemaking Processes

DOT and other agencies may also be subject to statutes that impose “hybrid rulemaking” standards; i.e., additional or different standards required in particular situations. For example, they may require that the agency hold a public hearing on a rulemaking proposal if one person requests it or they may require that the agency issue an interim final rule (IFR) to address a particular matter and ask for comment on the IFR rather than a proposed rule. In addition, DOT and other agencies also generally have the discretion to take extra steps when they think they would be helpful. For example, they may issue an advance notice of proposed rulemaking (ANPRM) before an NPRM to help gather data or to get suggestions for alternatives to address a problem.

⁴ 5 U. S. C. §§ 551 – 559 and §§ 701- 706.

Additional Procedural Requirements =

DOT and other agencies are also subject to numerous statutes and executive orders primarily requiring multiple analytical requirements and directing the consideration of specific effects on their rulemakings. For example, agencies must assess the costs and benefits of their rules and must submit significant rulemakings to the Office of Management and Budget (OMB) Office of Information and Regulatory Affairs (OIRA) for interagency review.⁵ They must also consider the effects of those rules on small businesses.⁶

Of particular importance to the EU and other countries are statutes and an executive order imposing: (1) a prohibition on setting standards that create “unnecessary obstacles to the foreign commerce” of the U.S.; a requirement to use performance standards, where appropriate; and a requirement to consider international standards and, where appropriate, use them as the basis for U.S. standards;⁷ (2) a requirement to “use technical standards that are developed or adopted by voluntary consensus standards bodies” unless they are “inconsistent with applicable law or otherwise impractical;”⁸ (3) requirements to encourage and support international regulatory cooperation and to consider reforming existing significant rules to address “unnecessary differences in regulatory requirements between the United States and its major trading partners.”⁹

Types of Rules

There are four types of rules that are issued under the APA. It is important to understand the difference in their effects.

Legislative/substantive rules

These may only be issued following the notice-and-comment procedures, unless they meet one of the exceptions. They impose binding requirements on those to whom they apply; they have the same force and effect of a statute.

Interpretive rules

These interpret existing statutes or rules; they tell the public what the agency thinks a statute or rule means. Although agencies may ask for public comment on them, the APA does not require

⁵ Executive Order (EO) 12866 (Regulatory Planning and Review).

⁶ Regulatory Flexibility Act, 5 U.S.C. §§ 601 – 612.

⁷ Trade Agreements Act, 19 U.S.C. §§ 2531 – 2533.

⁸ National Technology Transfer and Advancement Act, 15 U.S.C. § 272, Note.

⁹ EO 13609 (Promoting International Regulatory Cooperation).

the agency to do so.¹⁰ Interpretive rules are not binding, but the courts may give some deference to an agency's interpretation. Moreover, although not legally binding, an interpretation may have a "practical" binding effect.¹¹

Policy Statements

These tell the public how the agency intends to exercise a discretionary power; for example, because of a reduction in appropriations, an agency may state that it will not enforce a speed limit until it is exceeded by at least 10 mph. As with interpretive rules, agencies are not required to seek public comment before issuing policy statements, but they may do so.¹² The agency is not bound by the statement.

Management, personnel, organization, procedure, and practice rules

These involve agency business and either do not affect the public or only provide information on the agency's structures, functions, and processes.

Public Rulemaking Record

The U.S. has a government-wide database for rulemaking files on each agency's rulemaking actions; it is referred to as regulations.gov.¹³ The files are commonly called "dockets." The public dockets for DOT include all of the agency-issued rulemaking documents (e.g., a notice of proposed rulemaking or a notice of a public hearing), rulemaking supporting documents (e.g., an economic or environmental analysis), public comments, and other related material. Interested persons can sign up on the website for an email notification when particular documents are placed in that docket.

"Ex Parte" Comments

In accordance with DOT policy,¹⁴ the agencies discourage oral communications from the public from the time an NPRM is issued until the end of the comment period and strongly discourage them between that time and the time a final decision is issued. If such comments occur, they must be summarized in writing and placed in the public dockets. If contacts occur after the close

¹⁰ Pursuant to OMB Bulletin M-07-07, all executive branch agencies must seek public comment on drafts of "economically significant" interpretive rules.

<https://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2007/m07-07.pdf>.

¹¹ Robert A. Anthony, "Interpretive Rules, Policy Statements, Guidances, Manuals, and the Like – Should Federal Agencies Use Them To Bind the Public?" 41 Duke Law Journal 1311, 1329 (1992). See, also, later section on "Guidance Material."

¹² Pursuant to OMB Bulletin M-07-07, all executive branch agencies seek public comment on drafts of "economically significant" policy statements.

<https://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2007/m07-07.pdf>.

¹³ <http://www.regulations.gov/#!home>.

¹⁴ DOT Order 2100.2, "Public Contacts in Rulemaking" (1970).

of the comment period, they must be closely scrutinized to determine whether it will be necessary to re-open the comment period. If oral communications occur before the NPRM is issued and contain information the agency wants to rely on, the information should be placed in the docket. This DOT policy is neither required nor prohibited by the APA. Some other agencies have similar policies. However, a 1995 Presidential Memorandum directed all agencies to “eliminate any [administrative ex parte rules] that restrict communication prior to the publication of a proposed rule.”¹⁵

It is important to note that oral communications with foreign governments may be permissible, if they are government-to-government. If the foreign government is presenting information concerning issues about such things as a potential conflict between a proposal a DOT agency is considering (e.g., a requirement to test pilots operating in the U.S. for certain drugs) and the other country’s privacy law, the informal contacts should be permissible (and the U.S. agency may want to consider adding the information about the conflict to its public docket). If, however, the foreign government wants to advocate on behalf of its citizens (e.g., the drug testing requirements will be too costly for its airlines), it would not be permissible. The foreign government and its citizens can still submit written comments to the docket or speak at any public hearings.

DOT Regulatory Website

DOT provides a significant amount of information about the regulatory proceedings of the Department and its operating administrations on its regulatory website¹⁶ and references will be made to it throughout this paper. However, there are two “pages” concerning the rulemaking process in general that might be especially valuable for EU officials and others in the EU affected by the Department’s rulemakings who are not familiar with the process. First, DOT provides a simple, question-and-answer description of the rulemaking process and how to effectively participate in it.¹⁷ In addition, the Department provides a summary description of the requirements imposed on the rulemaking process by statutes, executive orders, and other documents, such as those noted in the preceding paragraphs.¹⁸

Guidance Material

Interpretive rules and policy statements are often referred to as guidance. Many agencies provide substantial amounts of guidance. Some of it may be oral (in response to telephone calls, in meetings, etc.); much of it is in writing (letters responding to written requests, web sites with

¹⁵ Memorandum for Heads of Departments and Agencies, “Regulatory Reinvention Initiative” (March 4, 1995). <http://govinfo.library.unt.edu/npr/library/direct/memos/reinvent.html>.

¹⁶ <http://www.transportation.gov/regulations/>.

¹⁷ <http://www.transportation.gov/regulations/rulemaking-process>.

¹⁸ <http://www.transportation.gov/regulations/rulemaking-requirement>. This report has not been updated to include EO 13609.

answers to frequently asked questions, agency published documents, etc.). While much of it is in response to requests for guidance from affected interests, some guidance is initiated by the agencies, because they see a need for general guidance or clarification or to address particular problems.

There are three significant problems the public can have with guidance.¹⁹ First, some agencies treat guidance as if it were binding. It is easier and quicker to issue than a binding legislative rule, so they use it to address problems where a legislative rule should be used. Second, even when used to provide help, such as identifying a “safe harbor” (if you do X, you will be in compliance with the rule), some see that as equivalent to having a “practical” binding effect (because, if you cannot or do not want to do X and you need agency approval, you must find another alternative acceptable to the agency, and that may take time you cannot afford).²⁰ The third problem is that some affected by the guidance have trouble finding agency guidance or do not know how to get help that they need. To address some of the problems with guidance, DOT agencies seek public comment on some draft guidance, establish easy methods for getting help, and provide information on how their process works and how to find existing guidance.

DOT’s regulatory website has a section devoted to guidance.²¹ That section explains the types of guidance DOT issues and states that guidance is not binding on the public but explains the extent to which the public can rely on it. The site provides links to agency/OST lists of significant guidance documents, although it is not clear if these lists are being kept up-to-date. DOT also notes on this website that it has created a subcategory for “Guidance” in regulations.gov that the public may use to provide feedback or comments on any DOT guidance that is currently in effect and provides instructions on how to do that. Finally, the website also provides information on how to submit complaints about DOT’s compliance with OMB Bulletin on guidance, M-07-07, or whether the Department is treating a significant guidance document as binding.

The individual agencies may also maintain lists with links to all of their guidance documents, including training materials. For example, the FAA has a very well-organized and thorough webpage broken into categories;²² NHTSA has a webpage that contains its responses to public requests for interpretations based on specific factual circumstances;²³ and PHMSA has a webpage for its hazardous material guidance and related documents, including letters responding to specific factual circumstances.²⁴

¹⁹ See, e.g., Administrative Conference of the United States (ACUS) “Guidance in the Rulemaking Process,” Recommendation 2014-3 (2014). <https://www.acus.gov/recommendation/guidance-rulemaking-process>.

²⁰ See fn. 12.

²¹ <http://www.transportation.gov/regulations/guidance>.

²² http://www.faa.gov/regulations_policies/.

²³ <http://isearch.nhtsa.gov/>.

²⁴ <http://www.phmsa.dot.gov/hazmat/guidance>.

U.S.–EU Regulatory Cooperation Benefits and Concerns

For U.S.–EU regulatory cooperation to be most effective, the agencies must be willing participants in the process; they should not participate solely because they are directed to do so by what, in the U.S., are referred to as agency “political appointees” in senior leadership positions. This is especially important because effective initiatives may have to stretch over successive appointees and Presidential Administrations. It is also important for effective cooperation to understand the perspectives of the interests affected by the agencies’ regulations. Those interests could include such groups as consumers, manufacturers, transportation companies, and employees who are directly regulated or affected by DOT regulations. It could also include State, local, and foreign government officials. Finally, the perspectives of Members of the U.S. Congress, especially members of the agencies’ authorization and appropriations committees (those developing and overseeing the authority of, and budgetary resources for, the agencies) may be important. Without their support, the agencies may have problems effectively participating in regulatory cooperation efforts. The perspectives of these interests and recommendations for addressing their concerns will be noted as appropriate. In general, the best approach for gaining support from the agencies and those who are affected by or interested in their regulations is to stress the benefits of U.S.–EU regulatory cooperation.

It is also noteworthy that many of those interested in DOT rulemaking efforts are also members of organizations that very effectively represent their interests. Many employees are members of unions; companies have formed organizations; State or local governments have organizations representing state legislatures, city mayors, governors of States, State agencies, police, etc.; and the general public may be members of groups that are concerned about the safety of motor vehicles, drunken drivers, aviation accidents, etc. There are also organizations representing insurance company interests in the manufacture and operation of transportation vehicles. DOT agencies receive relatively small numbers of public comments on their rulemaking proposals. That may be because the groups can speak very well for large numbers of members. It also may indicate the ease with which the agency can communicate with the organizations.

Benefits of International Regulatory Cooperation

To the extent agencies or their affected interests do not fully appreciate the benefits of international regulatory cooperation described below, the respective governments should share examples of the good results of the steps taken.

Data Sharing

Under the U.S. rulemaking processes, agencies are required to have a reasonable basis for the actions they take. It is important that they have data identifying the problem that warrants the issuance of a rule and to help determine effective solutions, evaluate their costs and benefits, and

periodically conduct retrospective reviews of the rules that agencies issue to determine how effective the rules are.

There are situations where U.S. agencies need to turn to other countries for such data, especially when they are dealing with new issues or equipment. For example, NHTSA lacked data on the effectiveness of mandatory motor vehicle seat belt usage programs and needed to obtain data from other countries in the late 1970's and early 1980's. The agency also has worked with its European counterparts for decades on the effectiveness of different types of dummies used for crash testing.

FAA and PHMSA and other transportation agencies have been continuously engaged with their counterparts around the world to gather data on the safe transportation of lithium batteries. Moreover, the agencies recognize the importance of sharing data. In a May 23, 2011 speech to the Association for Safer International Road Travel, then NHTSA Administrator David Strickland noted the work of researchers around the world studying electronic stability control (ESC) used by their different populations in their different driving environments and noted that they “all came to remarkably similar conclusions about the effectiveness of ESC in real world driving conditions.”²⁵ It can be especially valuable to have access to this type of information when considering requirements for very expensive equipment. Those who seek to increase opportunities for regulatory cooperation need to stress the significant benefits to be gained by sharing data.

Easier and Less Costly Development

Regulatory cooperation can also ease the process and decrease the costs of developing a rule and the necessary supporting documents. Cooperating countries may be able to share the costs of research on alternative approaches, whether it is through gathering focus groups, performing technical analyses, or identifying research that has already been done. Furthermore, the exchange of ideas with experts in other countries may help refine approaches. All of these steps may help agencies develop solutions to safety or environmental issues more quickly.

More Effective Rules

If agencies in the EU and the U.S. cooperate in the development of their rules or take it further and harmonize or jointly develop them, the resulting rules may be more effective because they should be easier to comply with or enforce and less costly for regulated entities. As the world becomes one marketplace, a manufacturer or operator will find it easier to meet one standard or a harmonized standard; assembly lines will not have to be changed, and training courses will be simpler. Emergency responders will only have to learn one standard; e.g., one label for

²⁵ <http://search.usa.gov/search?utf8=%E2%9C%93&affiliate=dot-nhtsa&query=international+regulatory+cooperation&commit=Search>.

hazardous materials. Some fear that harmonization or joint development leads to less effective public participation and an increased likelihood of the adoption of a lower standard to get agreement. That is not necessarily true. Moreover, even if it results in a “lower” standard, that standard could be more effective, because a common standard may achieve better compliance.

More Acceptable Rules

Cooperation, harmonization, or joint development should lessen or eliminate overlapping or conflicting standards and, as noted above, lower costs of compliance. This should make the resulting rules more acceptable to the regulated entities, and they should be less likely to sue or otherwise challenge the agency and more likely to comply fully, easing the agency’s litigation and enforcement burdens.

Concerns

Regardless of whether the following concerns expressed by some of the staff interviewed in the U.S. DOT, its agencies, other involved agencies, and the affected interests are fair or legitimate, the U.S. and the EU need either to refute them or address them.

Loss of Control

Some agencies²⁶ may fear they will lose control over the rulemaking process if they engage in international regulatory cooperation. This could be the case if they were to be pressured to work with their EU counterparts when they do not believe it will be worthwhile, especially when it involves harmonization or joint development. Where they are willing to work on a project, they may think they will be pressured to accept compromises that will not be effective; some are very concerned that there will be too much emphasis on agreeing to “a” rule rather than “a good” rule.

They also may be concerned about the need to clear their documents and decisions with multiple other U.S. agencies, in addition to OIRA; these may include the United States Trade Representative (USTR), the Department of Commerce (DOC), the Department of State (DOS), and some third agency or office that may be designated to resolve disputes. Even though other agencies may review another agency’s rulemaking documents under existing requirements, an agency may avoid engaging in a regulatory cooperation activity if it believes that agencies that did not normally have an interest in its rules would want to review any resulting rulemaking documents.

²⁶The generic term “agencies” is used throughout the “Concerns” section of this paper. In some instances it may be a position of senior agency political appointees, senior agency career staff, or lower-level career staff. Whether it is the position of one, two, or all three of those, it can be an impediment to progress. Where it is necessary to distinguish for a clearer understanding of the concern, the paper will be more specific.

Negotiation Balancing

Related to the concern about loss of control is a concern about the proper balance between developing rules to achieve agency statutory responsibilities for such things as safety or environmental protection and free trade objectives. There is some concern inside and outside the government that trade objectives—where they dominate—may lead to lower levels of protection than are appropriate. In this regard, it is important to note that taking into account trade-related objectives of regulatory cooperation can also lead to more effective regulations. Moreover, some have noted that the TTIP negotiations are leading to changes that are addressing regulators’ concerns about protecting their statutory responsibilities. In addition, to address its concerns, one U.S. agency took a positive approach: the Food and Drug Administration (FDA) hired a person with trade experience as well as regulatory expertise to head an Office of Public Health and Trade. The agency believes he is a very effective negotiator and has helped significantly improve perspectives within FDA, as agency staff observed how well he represented their safety interests in the negotiations.

Necessary Data

Although U.S. agencies have received some very helpful data from their counterparts in other countries, there is significant concern in the U.S. about the lack of sufficient, quality data in many instances—data that the U.S. needs to meet its analytical or justification requirements. The concern appears to vary by agency and by country. Moreover, other countries, and also supranational organizations such as the EU, due to the specific features of their regulatory systems and instruments used, apply a different approach when it comes to data than the U.S. It is particularly problematic when the U.S. and the other countries are trying to agree on mutual recognition of each other’s certifications or equivalency of standards.

From the U.S. perspective, its problem is compounded in the EU by both the lack of data and the difficulty in obtaining what data there are, in some cases where a lot of the data are held by individual Member States, there is no focal point for gathering the data at the EU level. Despite these concerns, there was some thought that the EU is trying to do a better job. Interestingly, when they cannot get data from their counterparts, some U.S. agencies can get the data from companies that have an incentive to provide it.

Inability to Protect Confidential and Related Information

When the U.S. cooperates with other countries and there is a need to share data, drafts of rulemaking documents, supporting analyses, and other documents that should be protected from public release during the pre-decisional stage, there is some concern on the U.S. side that the other country will “leak” the document to affected interests. Because this has happened, it is already hampering closer coordination through the sharing of such documents. For example, some agencies will not share drafts of their rulemaking documents with EU agencies that have

provided them to non-governmental entities (e.g., a manufacturer). Again, the problems vary by country.

There is also a related concern in the U.S. that not all U.S. agencies can protect confidential data that other countries may be willing to share with them from release under the Freedom of Information Act.²⁷ The FDA does have authority to protect such documents as law enforcement investigatory records, trade secrets, and confidential business information received from other countries as part of cooperative law enforcement and regulatory activities; it also has authority to provide such documents that it has gathered as part of its domestic activities to countries with whom it has such cooperative activities.²⁸

FDA's program might serve as a model for similar grants of statutory authority for other agencies that could benefit from being able to receive and share more information with other governments as part of international regulatory cooperation efforts. This is not a problem for all agencies in all their programs, because they do not need confidential data to support their decisions; for example, PHMSA may only need to know the chemical in a product, not the specific percent used under the company's formula for its specific products.

Differences in Supporting Analyses

Some agencies also believe that differences in the analytical support necessary to inform/justify a rule in the EU and the U.S. hamper effective cooperation, particularly harmonization efforts. Agency staff who were interviewed for this paper raised the following concerns:

- The U.S. has a higher analytical burden.
- EU analyses are not as thoroughly prepared and objectively reviewed as the U.S. agencies' analyses.
- The EU only provides a basis for the action it wants to take.
- Scientific analysis and risk assessment is conducted separately by some decentralized agencies while risk management decisions are left to the EU Commission.
- Some U.S. agencies may try to avoid thorough analyses by contending that an international or multi-lateral agreement obviates the need for one. They will contend that, for example, harmonized standards decrease costs and are, therefore, cost-beneficial. In some cases, they may encourage an international or multi-lateral standard that they could not otherwise justify under U.S. requirements and then contend they "must" adopt that standard.

Although some believe that the EU is taking steps to improve the quality of its analyses, it may take some time to overcome some of these concerns. Moreover, on the U.S. side, despite the

²⁷ 5 U.S.C. § 552.

²⁸ 21 CFR 20.89.

recent issuance of guidance on Executive Order 13609, there does not appear to be a good understanding of what is required for a well-done assessment of the international impacts of a rule.

Inconsistent Implementation

The desire to increase U.S.–EU regulatory cooperation does not clearly or specifically address the concerns that implementation can be different. For example, as pointed out by Dudley and Wegrich in their article = comparing U.S. and EU regulatory systems, “the EU in its capacity as a regulatory state has to rely on its member states for implementation and enforcement.”²⁹ By contrast, in the U.S. enforcement is generally assumed by the same agencies who draft and issue the rule. In addition, there are differences in the role of judicial review and the approach to ex-post evaluation/restrospective review.

There are concerns in the U.S. that EU agencies do not enforce their rules as effectively as U.S. agencies do and they have different ways of using voluntary consensus standards to support regulation. Some commenters fear that different levels of stringency may exist between EU Member States' bodies; but any of them can certify products for the whole EU market, and companies may abuse this situation.

U.S. agencies also have to respond to recommendations from independent investigative agencies, such as the National Transportation Safety Board (NTSB), the Government Accountability Office (GAO), and Offices of Inspector General (OIG), which may recommend changes to regulations.³⁰ The EU may have similar entities examining their agencies. These responsibilities need to be addressed for any coordination to be effective, but the EU and the U.S. also need to consider the significant resources that would be required to coordinate these activities.

Reliance on Consensus Standards Bodies

U.S. agencies are subject to a statutory requirement to “use technical standards that are developed or adopted by voluntary consensus standards bodies” unless they are “inconsistent with applicable law or otherwise impractical.”³¹ DOT is one of many U.S. agencies that significantly relies on such standards in its regulations. In any cooperation between the U.S. and the EU that relies on consensus standards bodies, the U.S. agency must meet the U.S. requirements for use of consensus standards bodies; among other things, the voluntary consensus

²⁹ Susan E. Dudley and Kai Wegrich. “The role of transparency in regulatory governance: comparing U.S. and EU regulatory systems.” *Journal of Risk Research*, Vol. 18, 2015.

³⁰ See p. 16, under “NTSB, DOT IG, or GAO Recommendations,” for more information about those entities affecting DOT.

³¹ National Technology Transfer and Advancement Act, 15 U.S.C. § 272, Note.

standards body must have openness, a balance of interests, due process, and an appeals process.³² These issues are currently being discussed in the TTIP negotiations.

Inadequate Resources

Agencies are concerned that regulatory cooperation may increase costs, such as for travel to meetings, technology for on-line meetings or to provide early notice of regulatory actions, or sharing data. It also may take extra time, which may cause problems for a short-handed agency or one facing a short-term statutory or judicial deadline to complete a rulemaking.

Limits on Transparency and Public Participation

U.S. agencies and, to a greater extent, those outside the government—especially individuals and small businesses—express concern that international regulatory cooperation decreases the opportunity for effective public participation in the rulemaking process as required under the APA. They fear that decisions between EU and U.S. agencies would be made in non-public meetings, often before the public has an opportunity to express its views or provide important data. Moreover, even though the agreements the U.S. reaches in negotiations may be subject to the APA requirements before they can be implemented through rules, the public may fear that it will be difficult to convince the agency to change the proposal after the time and effort the agency put into the international negotiations. However, there are some excellent examples of steps that agencies have taken to alleviate these concerns.

While increasing opportunities for public participation may address U.S. concerns, the EU may be frustrated when the U.S. notice-and-comment process leads to a need for the U.S. to make a change to what it agreed to do. This may be exacerbated if the U.S. takes extra time to obtain public comments before and during the negotiations with the EU.

“Lowest Common Denominator” Syndrome

Some agencies and some public interest groups are concerned that international regulatory cooperation, especially efforts to attain harmonized or jointly developed standards, results in the lowest standard being considered by those in the negotiations group. Whether or not this is a legitimate concern, it needs to be addressed. Especially with respect to the public interest groups, it compounds their concerns about the potential lack of transparency and limited opportunities for effective public participation.

Limitations on Likelihood of Success

There are two separate concerns here. First, there is some strong concern that the differences between the U.S. and the EU systems of government make it very difficult to adopt equivalent or

³² OMB Circular A-119 Revised, *Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities* (1998). https://www.whitehouse.gov/omb/circulars_a119/#4.

common standards. These differences are significant from a rulemaking perspective. The important role of the Member States in implementing EU directives and enforcing EU regulations also exacerbates the concern in the U.S. about whether there can be actual equivalence. The second concern is that U.S. Presidents change every four to eight years and political leadership within an agency generally changes more frequently. Those changes can lead to loss of support for international cooperation efforts. There could also be changes in either House of Congress that could lessen support. For these reasons, especially when close to an election, agency staff may be reluctant to enter into cooperation agreements, as they may believe it would be a waste of time and resources.

Existing U.S. DOT International Regulatory Cooperation Activities

Although the U.S. has required certain actions by executive branch agencies to enhance practices for communicating and cooperating on regulatory matters with other countries and international bodies, DOT took many initiatives on its own many years before they were required. This is noteworthy, because it indicates that the Department and its agencies, on their own, identified the benefits of doing so. The actions range from efforts to provide detailed information on the status of DOT rulemakings that may affect other countries, to engaging in harmonization or joint development of rules. They do not need to be convinced of the benefits, but they will need help in addressing the concerns they and those affected by their rules have.

This section is divided into two parts. The first covers steps that DOT and others take that provide early notice and information about actions that may lead to rulemaking that could affect other countries. The second section discusses cooperation activities in which DOT already engages; they may provide “lessons learned” or models to further enhance regulatory cooperation between the EU and the U.S.

Early Notice

In general, there are two stages to early communication about U.S. rulemaking. The first is information about actions that could lead an agency to initiate rulemaking; the second is information about rulemakings that have been initiated. The first could be actions by the agency or other entities, such as the Congress, the courts, investigatory agencies or offices, or even public petitioners. The second would be by the agency, and the first step would usually be when the agency publicly announces it has initiated action via the semi-annual Regulatory Agenda or some other agency public status report on its rulemaking activity. Sometimes the agency will first announce a new rulemaking through such steps as speeches or Congressional testimony and then add it to the Regulatory Agenda or status report. Some of these reports or other actions will provide information about potential rulemakings many months or even years before the agency issues a proposed rule. This early notice can provide opportunities for earlier and more enhanced regulatory cooperation before alternative approaches to the problem are even identified.

Regulatory Agenda

Agencies are required by statute, executive order, and, in some agencies, by internal agency orders to prepare agendas of their pending and recently completed regulatory actions. In response to these requirements, OIRA has established a uniform report, the Unified Agenda of Federal Regulatory and Deregulatory Actions, and publishes all of the agencies' Regulatory Agenda's semi-annually; they are supposed to be published in October and April of each year, but are often late. The Agenda provides an abstract and timetable for each rulemaking along with other helpful information. Pursuant to E.O. 13609, the agency is required to designate those rulemakings in the Agenda that may have significant international impacts.

The public can find the government-wide Agenda, including DOT's portion, on the OIRA regulatory website.³³ It also can be accessed from other sites, such as DOT's Regulatory site. When a docket has been opened for a rulemaking, its number is included in the Agenda and other DOT reports; by using that number, the public can locate the docket for that rulemaking in regulations.gov. Once entered into the Agenda data base, rulemakings are assigned a Regulation Identifier Number (RIN); that number may be used to help find a docket when it is created. The RIN can also be used to identify a specific rulemaking in other reports.

Regulatory Plan

Pursuant to E.O. 12866, a Regulatory Plan is published annually with the Fall Regulatory Agenda. The Plan describes the Department's regulatory priorities for the next year, its retrospective reviews of existing regulations; and expanded Agenda entries (providing more details on such matters as costs and benefits) for those pending rulemakings "that the Department believes will merit special attention in the upcoming year." E.O. 13609 added a requirement that agencies summarize their international regulatory cooperation activities, including a list of their significant rulemakings that are expected to have international effects. The Plans can be accessed at the same internet site as the Agenda.

Status Reports

At the beginning of each month, DOT provides an updated status report on each of its pending or recently issued significant rulemakings.³⁴ The reports contain abstracts of the rulemakings, the effects (such as effects on the EU) of the rulemaking, current schedules, and other information about the rulemakings. Because they are updated monthly, new rulemakings or actions on existing rulemakings may appear in this report before appearing in the Agenda.

³³ <http://www.reginfo.gov/public/>.

³⁴ <http://www.transportation.gov/regulations/report-on-significant-rulemakings>.

Effects Reports

DOT also provides a separate, monthly-updated report on each of 21 different effects of all of its rulemakings.³⁵ The different effects include such categories as information collection, privacy, economically significant, EU, NAFTA, and foreign. A glossary defines the terms. For example, an EU effect means: “A rulemaking that would have an effect on the European Union or one of its member countries or the countries’ business entities, citizens, etc.” The report for each effect lists all of the rules with that effect, their current stage, and their RIN and docket number (if available).

Legislation

One of the earliest signs that an agency may undertake a new rulemaking is legislative action that may require or authorize the agency to issue new rules or take other action to explore the need for new rules. Congress may also require an agency to report to it on the need for new rules or hold hearings to gather information on whether rulemaking action is warranted. Agency websites may contain information on pending legislation or a Congressional hearing, but the best way to find this information is through the Congressional website.³⁶ At this website, for example, typing “Federal Aviation Administration” in the search box will pull up a list of pending legislation (called “bills”) Congress is considering concerning the FAA, including the current status of the bills. A link to lists of pending committee hearings in each House can also be found on the home page.

NTSB, DOT IG, or GAO Recommendations

These entities have the authority to conduct investigations or studies that could result in recommendations to an agency to issue new rules or amend existing rules. For example, the NTSB issued a recommendation on January 15, 2015, that the FAA

require that all newly manufactured aircraft used in extended overwater operations and operating under Title 14 Code of Federal Regulations (1) Part 121 or (2) Part 135 that are required to have a cockpit voice recorder and a flight data recorder, be equipped with a means to recover, at a minimum, mandatory flight data parameters; the means of recovery should not require underwater retrieval. Data should be captured from a triggering event until the end of the flight and for as long a time period before the triggering event as possible.³⁷

Although not binding on the agency, the recommendations of these entities carry substantial weight, and the agency must respond to each recommendation.

³⁵ <http://www.transportation.gov/regulations/reports-on-effects-DOT-rulemakings>.

³⁶ www.Congress.gov.

³⁷ <http://www.nts.gov/safety/safety-recs/recletters/A-15-001-008.pdf>. Recommendation A-15-3.

National Transportation Safety Board

The National Transportation Safety Board has the authority to investigate transportation accidents or perform safety studies and make recommendations to improve safety. NTSB recommendations can be found on its website.³⁸ An interested user may search the data base in a variety of ways, including by the mode of transportation or a specific accident. Agency responses may also be available on the internet.³⁹

Department of Transportation Inspector General

The DOT Office of the Inspector General has the autonomy to do its work without interference. The OIG has the general responsibility to stop fraud, waste, and abuse in departmental programs through audits and investigations. The OIG may act on its own initiative or be asked to conduct an audit at the request of a Member of Congress or the Secretary of Transportation. The DOT OIG lists its audits on its website.⁴⁰

Government Accountability Office

The Government Accountability Office is an independent, nonpartisan agency that works for Congress. GAO is headed by the Comptroller General, who is appointed by the President from a list of candidates proposed by Congress and confirmed by the Senate. It investigates how the Federal government spends its money. GAO performs its work at the request of Congressional committees or subcommittees, as mandated by Congressional legislation or committee reports, or pursuant to the general authority of the Comptroller General. Its reports can be found on its website.⁴¹

Petitions for Rulemaking

Under the informal rulemaking procedures in the APA, the public has the right to petition an agency for the issuance, amendment, or repeal of a rule.⁴² DOT agencies generally post these petitions in their public rulemaking docket at regulations.gov and may publish the petitions in the *Federal Register* and/or post them on the internet. They may also seek public comment on the petitions before making a decision. The decision on a petition is usually a response to the requestor, but if the agency places the petition in the docket, it should also place the response in the docket. A full or partial grant of the petition would only be a commitment to initiate a rulemaking and seek public comment.

³⁸ <http://www.nts.gov/layouts/nts.recsearch/RecTabs.aspx>

³⁹ See, e.g., <http://www.phmsa.dot.gov/nts>.

⁴⁰ <http://www.oig.dot.gov/audits>.

⁴¹ <http://www.gao.gov/browse/date/week>.

⁴² 5 U.S.C. §553 (c).

DOT agencies generally note in the DOT Regulatory Agenda and monthly status reports which rulemakings were initiated in response to a petition. Some agencies have publicly available lists of pending petitions for rulemaking.⁴³ For others, it may be necessary to search the agency website for “petitions for rulemaking” to obtain information.⁴⁴

Retrospective Reviews of Existing Rules

Agencies are required by statute, executive order, and, for some, their own internal requirements to periodically review their existing rules to determine whether they need to be revised or revoked. These reviews, obviously, could result in new rulemaking initiatives. DOT has performed such reviews for decades, and in 1998, the Department began a more organized approach by creating a formal plan for the review of all of its rules over a 10-year period, with a new plan created every 10 years; the plans may have to be modified if others, such as the President, require specific reviews and deadlines for action.

DOT’s regulatory website has a section on its retrospective review plan that describes its 10-year plan and also provides information about any special reviews it is required to conduct.⁴⁵ The Department also provides information and brief status reports on each of its reviews in the Regulatory Agenda. The public may submit comments or information about the plan and the specific, individual reviews. This information can provide a very early opportunity for getting a DOT agency to focus on unnecessary differences in the regulatory standards of the U.S. and the EU, and E.O. 13609 specifically directs agencies to consider such unnecessary differences when selecting rules for retrospective review.

Agency Studies or Reports

Agencies may identify the need to consider changing existing rules or issuing new ones through a wide variety of factors. For example, after an aviation accident, FAA may identify a problem with an existing rule that should have prevented the accident. As a result of a review of general data, NHTSA may note increasing deaths and injuries in side collisions. An excellent example of this is the June 2015 report on “Overview of NHTSA Priority Plan for Vehicle Safety and Fuel Economy, 2015 to 2017.”⁴⁶ Indeed, NHTSA notes in the report that it is “a means to communicate to the public and regulators in other countries NHTSA’s highest priorities.” NHTSA hopes the report will “encourag[e] regulatory cooperation.”⁴⁷ In the second part of the report, the agency describes its priority projects and includes milestone dates for activities such as completing research or participating “in automotive industry’s sharing forum to ensure timely

⁴³ See, e.g., <http://www.phmsa.dot.gov/hazmat/standards-rulemaking/petitions>.

⁴⁴ See, e.g., <http://search.usa.gov/search?utf8=%E2%9C%93&affiliate=dot-nhtsa&query=petitions+for+rulemaking&searchCommit=Search>.

⁴⁵ <http://www.transportation.gov/regulations/dot-retrospective-reviews-rules>.

⁴⁶ www.nhtsa.gov/staticfiles/nvs/pdf/NVS_priority-plan-June2015_final.pdf.

⁴⁷ Id. at p. 4.

exchange of information concerning cybersecurity threats.”⁴⁸ There does not appear to be a consistent manner for finding these kinds of reports other than periodic searches of agency websites.

Federal Register

Agencies subject to the APA are required to publish their proposed and final rules in the *Federal Register*, unless those subject to the rule are personally served or otherwise have actual notice. It is relatively rare for a rule not to be published. Even if the agency uses personal service, if the agency wants the rule to remain in effect for more than a short-term event or emergency, it needs to publish the rule in the *Federal Register* for it to be codified in the Code of Federal Regulations (CFR).

If interested persons want to receive notice about a particular rulemaking, a general category of rulemakings, or all of a particular agency’s rulemakings, the Office of the Federal Register (OFR) provides for email notification subscriptions or RSS feeds. OFR provides a number of options; for example, users can subscribe to a particular agency’s documents, a particular topic, or create a customized subscription. Users could also limit the rulemakings to those identified as “significant.” OFR provides instructions for this service on its website.⁴⁹

Litigation Reports

After a U.S. agency issues a final rule, it can be challenged in court. The court may uphold the rule, remand it to the agency for further review, or overturn it in whole or in part. Anyone who is interested in the progress of any litigation because of its potential impact on a rule can follow its status via a DOT-wide, semi-annual “Litigation News” report and a list of, and links to, court decisions in a DOT-wide report on “Recent Judicial Decisions.” Both reports can be accessed at a DOT website.⁵⁰

Notices of Opportunities for Public Participation in International Regulatory Cooperation

DOT agencies generally advise the public of their international regulatory cooperation activities and opportunities to comment on any issues. Below are some examples of this.

PHMSA issued a notice on November 19, 2013, that it was participating in a public meeting of the U.S. Interagency Globally Harmonized System (GHS) coordinating Group in preparation for a meeting with the United Nations (UN) Subcommittee of Experts on the GHS of Classification of Labelling of Chemicals. The notice said the Group would provide the public “an update on

⁴⁸ Id. at p. 11.

⁴⁹ www.federalregister.gov/learn/user-information/.

⁵⁰ <http://www.transportation.gov/administrations/office-general-counsel/office-litigation>.

GHS-related issues and an opportunity to express their views orally and in writing for consideration in developing U.S. Government positions for the upcoming UNSCEGHS [United Nations Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals] meeting.”⁵¹

NHTSA issued a similar notice in 1998 to announce that it was seeking public comment and holding a public workshop on a draft statement of policy concerning its priorities in implementing the UN/Economic Commission for Europe 1998 Agreement on Global Technical Regulations for Wheeled Vehicles, Equipment and Parts and its activities and practices for facilitating public participation in the implementation of that agreement. It also announced it was exploring other means of effective public participation, such as “the possibility of including members of the public as advisers in the NHTSA delegation.”⁵²

The FAA has a Regulatory Cooperation Council Work Plan with Canada covering their collaboration on unmanned aircraft systems that includes combined “efforts on bilateral webinar discussions with stake holders” during 2015–2020. It lists possible topics and notes events for stakeholder engagements. The Work Plan is available on a Department of Commerce website.⁵³

Cooperation Activities

DOT has engaged in regulatory cooperation activities that run the full gamut of possibilities from exchanging information to jointly developed standards. They have used negotiated rulemakings and joint public meetings; they have provided opportunities for public participation before and during negotiations on international or bilateral agreements; they have done joint research and investigations; and they have agreed to mutual recognition/acceptance and common standards. Many of these activities have been with the EU or its members states, but this paper also notes actions with other countries, particularly Canada, or international bodies; there is no apparent reason those approaches could not be used with the EU also. Moreover, the extent to which the DOT agencies have engaged, and the variety of the methods they have used, in regulatory cooperation activities clearly illustrates their willingness to participate, their appreciation of the benefits, and importantly, the wide range of very effective approaches available.

International Organizations

DOT agencies work with a number of international organizations. FAA primarily deals with the International Civil Aviation Organization (ICAO); NHTSA works with the United Nations/Economic Commission for Europe (UN/ECE) and the World Forum For Harmonization

⁵¹<http://www.phmsa.dot.gov/portal/site/PHMSA/menuitem.6f23687cf7b00b0f22e4c6962d9c8789/?vgnextoid=1e12894e08c12410VgnVCM100000d2c97898RCRD&vgnnextchannel=597583b287227110VgnVCM1000009ed07898RCRD>.

⁵²<http://www.nhtsa.gov/cars/rules/rulings/RIN2127-AH29/RIN2127-AH29.html>.

⁵³ <http://trade.gov/RCC/documents/f5-tc-dot-wp-aviation-regs.pdf>.

Of Vehicle Regulations, and the World Trade Organization (WTO). Because of the multi-modal aspects of hazardous material transportation regulations, PHMSA deals with a number of organizations, including the UN and its Committee on Transportation of Dangerous Goods, ICAO, and the International Maritime Organization (IMO). All three also work with international voluntary consensus standards organizations, such as the International Standards Organization (ISO) and the Society of Automotive Engineers. All three also engage in international regulatory cooperation efforts with other countries pursuant to bilateral or multi-lateral agreements such as the North American Free Trade Agreement.

EU Bodies

FAA

The most noteworthy agreement in the aviation area is “The Agreement between the United States and the European Union on Cooperation in the Regulation of Civil Aviation Safety” signed in 2008.⁵⁴ The broad scope of this agreement is significant. Its purpose is to enable reciprocal acceptance, promote a high degree of safety, and “ensure the continuation of the high level of regulatory cooperation and harmonization between the” U.S. and the European Community.

This agreement created an oversight board to ensure effective functioning; its responsibilities included discussions of common approaches to safety and environmental issues, sharing of information, consultation on proposals for new or changed safety measures; early warning of draft regulations and legislation. It requires acceptance of findings of compliance and approvals made by the other party and agreement that the other party’s standards, etc. are “sufficiently compatible to permit reciprocal acceptance of approvals and findings of compliance with agreed upon standards.” It also requires the parties to adopt procedures for regulatory cooperation in safety and environmental testing and approvals, including, where possible, an opportunity for experts from one party to consult and participate in the early drafting stages of “aviation regulatory materials” by the other party. It allows the participation of one party in the other’s “internal quality assurance and standardization inspection functions related to accreditation and monitoring.” The parties also agreed to provide “appropriate mutual cooperation and assistance in any investigation or enforcement proceeding of any alleged violation of any laws or regulations under the scope of this Agreement.” It provides for the exchange of safety information and notice of “all applicable requirements, procedures and guidance material.” Finally, it provides for the protection of proprietary data and requests for information.

⁵⁴ http://www.faa.gov/aircraft/air_cert/international/bilateral_agreements/baa_basa_listing/media/EU-US-agreement-ROA5.pdf.

The Agreement, in turn, resulted in another very important step. On June 13, 2013, FAA and the European Aviation Safety Agency (EASA) signed “Rulemaking Cooperation Guidelines.”⁵⁵ The Agreement documented what EASA and FAA had already been doing for a long time. They agreed “that harmonization can best be achieved through effective communication during the definition and early stages of implementation of the respective rulemaking programmes.” Their stated objectives include exchanging “intentions and priorities” to align their programs, identifying initiatives of common interest to “avoid unnecessary divergence and duplication,” and defining “working methods.”

Finally, they provided three different methods that could be used to execute rulemaking tasks they have identified as “tasks of common interest” and set out procedures for ensuring appropriate communication. The three methods were: (1) EASA takes the lead and gives the FAA “sufficient involvement in the EASA rulemaking project to understand the content of the draft rule and to be able to contribute to this process as necessary to allow it, where appropriate, to launch an equivalent” NPRM or take other equivalent action; (2) FAA takes the lead giving EASA the same sufficient involvement; and (3) the FAA and EASA “develop their rulemaking projects separately, but concurrently (to the extent practicable).”

EASA and FAA expect to develop work plans for each project. Among other things, these plans will include a description of technical documents, which may include “jointly developed issue papers, analyses, research results, and other technical documents;” participation in work groups that might include advisory committees; and other cooperative activities deemed mutually beneficial. The work plans for identified projects and the current status of the rulemakings are publicly available on an EASA website.⁵⁶

With respect to the provision above for participation in advisory committees, U.S. agencies have authority to establish advisory committees pursuant to the Federal Advisory Committee Act (FACA).⁵⁷ These committees can provide the agency with advice and recommendations on rulemaking activities, but they are subject to requirements such as representational balance and openness. In addition, foreign governmental agencies, businesses, or individuals can be appointed to membership in the committees but are not allowed to vote (with some special exceptions). Although they cannot vote, their views can be clearly heard and accommodated by the voting members. FAA has a large, standing committee for rulemaking issues referred to as the Aviation Rulemaking Advisory Committee (ARAC), and it has foreign members. FAA also has some committees that are created under different statutory authority that are not subject to

⁵⁵ http://easa.europa.eu/system/files/dfu/FAA-EASA%20Rulemaking%20Cooperation%20Guidelines_signed%20text_13%20June%202013_Paris.pdf.

⁵⁶ <http://easa.europa.eu/system/files/dfu/EASA-FAA%20pilot%20projects%20status%20report%20revision%20-%20V.6%202%202015.pdf>.

⁵⁷ 5 U. S. C. App. II.

FACA limitations.⁵⁸ Committees established under the latter authority are referred to as Aviation Rulemaking Committees (ARC).

Under FAA's Aviation Rulemaking Advisory Committee (ARAC) Order,⁵⁹ a committee charter can include the assignment of specific rulemaking actions for which the committee may be asked to develop a draft proposed rule. Section 12. d. specifically provides that civil aviation authority representatives from other governments can request non-voting status, and many have been made members. The FAA has also established ad hoc advisory committees under its non-FACA authority for specific rulemaking issues.⁶⁰ Foreign governments may participate but not vote in the ARCs.

NHTSA

Although NHTSA's cooperation efforts are primarily done through the UN, the EU or its Member States have traditionally been the key players in the UN process under what is referred to as the 1998 Global Agreement.⁶¹ The Agreement is administered by the UN Economic Commission for Europe's World Forum for the Harmonization of Vehicle Regulations (WP.29).

An example of the benefits of this Agreement is a final rule issued by NHTSA in 2007 on "Federal Motor Vehicle Safety Standards; Door Locks and Door Retention Components."⁶² NHTSA noted in the final rule that its efforts to improve its rules to better address door ejections coincided with the adoption of a work program under the 1998 Global Agreement. The agency "sought to work collaboratively on door ejections with other contracting parties," particularly Canada, the EU, and Japan. The four governments exchanged information on ongoing research and testing and leveraged resources for testing and evaluation, leading to the first global technical regulation (GTR) under the 1998 Agreement.⁶³ In the final rule, NHTSA noted that

This first GTR demonstrated that U.S./EU regulatory cooperation can achieve increased safety and harmonized standards that are science-based and free of unjustified requirements. If adopted into domestic law by the U.S. and EU, the GTR on door locks and door retention systems would essentially eliminate the differences between the U.S. and EU standards... Adopting the amendments based on the GTR will not only result in improvements to the U.S. standard, but also to the EU standard. This will also benefit other countries since the EU

⁵⁸ 49 U.S.C. § 106(p)(5).

⁵⁹ <http://www.faa.gov/documentLibrary/media/Order/1110.119P.pdf>.

⁶⁰ http://www.faa.gov/regulations_policies/rulemaking/committees/documents/index.cfm/committee/definitions.

⁶¹ <http://www.unece.org/trans/main/wp29/wp29wgs/wp29gen/wp29glob.html>.

⁶² 72 Fed. Reg. 5385 (2/6/07).

⁶³ Id at 5386.

standard is the United Nations' Economic Commission for Europe regulation (ECE R.11), which is used by the majority of the world community.⁶⁴

Unlike the earlier 1958 Global Agreement (to which the U.S. was not a signatory), the 1998 Agreement requires consensus and addresses many of the other problems the U.S. had with the earlier agreement. The U.S. may feel more comfortable with the 1998 Agreement, and it might provide a forum for a significant strengthening of cooperation under TTIP and work on developing consensus positions.

NHTSA also has a variety of programs for joint research. For example, they are involved in an Experimental Safety Vehicles (ESVs) Program originated four decades ago under the North Atlantic Treaty Organization (NATO) Committee on the Challenges of Modern Society. It was implemented through bilateral agreements between the Governments of the U.S., France, Germany, Italy, Great Britain, Japan, and Sweden. They agreed to develop ESVs to advance the state-of-the-art technology in automotive engineering and to meet periodically to exchange information. The group has grown to include a number of others, including the European Commission.⁶⁵ Another example is a study with France that covered a vehicle's compartment strength and occupant protection systems.⁶⁶

PHMSA

Although PHMSA primarily works through international bodies on its hazardous materials rulemaking, when it does this, it often will work with another country, such as the Netherlands,⁶⁷ Germany,⁶⁸ or Belgium⁶⁹ to develop a joint proposal for the international body to consider.

DOT Regulatory Cooperation with Other Countries

FAA

FAA has agreed to promote cooperation in the early stages of a rulemaking with its Canadian counterpart, Transport Canada (TC). This was intended to help the U.S. and Canada align their Unmanned Aircraft Systems (UAS) programs as they prepare new UAS regulations. The FAA provided and discussed with TC the release of its UAS Roadmap and a Comprehensive Plan on the UAS Path Forward. TC and FAA also have coordinated their efforts addressing illegal UAS operations.⁷⁰

⁶⁴ Id.

⁶⁵ See, <http://www-nrd.nhtsa.dot.gov/pdf/esv/esv22/introduction.pdf>.

⁶⁶ <http://www-nrd.nhtsa.dot.gov/pdf/esv/esv21/09-0329.pdf>.

⁶⁷ See, e.g., <http://www.unece.org/fileadmin/DAM/trans/doc/2008/ac10c3/ST-SG-AC10-C3-2008-87e.pdf>.

⁶⁸ See, e.g., <http://www.unece.org/fileadmin/DAM/trans/doc/2012/dgac10c3/ST-SG-AC10-C3-2012-56e-ST-SG-AC10-C4-2012-4e.pdf>.

⁶⁹ See, e.g., <http://www.unece.org/fileadmin/DAM/trans/doc/2014/dgac10c3/ST-SG-AC.10-C.3-2014-74e.pdf>.

⁷⁰ See, <https://www.whitehouse.gov/sites/default/files/omb/oira/irc/us-canada-rcc-joint-forward-plan.pdf>, p.37.

NHTSA

NHTSA has been involved in many regulatory cooperation efforts with Canada. For example, it has done several collaborative research projects with Transport Canada; these include one on quiet vehicles and child restraints and another on fuel vehicle safety and clean technologies (e.g., low rolling resistance tires). Finally, they are taking steps to ease collaboration on enhanced standards development.⁷¹

PHMSA

PHMSA also has taken various regulatory cooperation actions with other countries. For example, it may approve an application from a foreign-based company to perform cylinder inspections and verifications based on an approval by a competent authority of the country where the cylinder is manufactured.⁷² In addition, PHMSA and its Canadian counterpart, the National Energy Board, have agreed to improve their cooperation and coordination to improve the safety of their pipelines. There is a growing number of cross border pipelines being built, and they are jointly inspecting and sharing accident and enforcement data on these operations as well as conducting joint technical analyses. PHMSA is also working with its Canadian and Mexican counterparts to develop consistent guidelines for use by firefighters, police, and other emergency services personnel for hazardous material transportation incidents.⁷³ PHMSA and some of its bilateral partners jointly chair some public meetings.

In May of 2015, PHMSA also issued a final rule jointly developed with FRA partly in response to an accident in Canada involving a U.S. railroad.⁷⁴ Before the accident, PHMSA had also received petitions from the railroad industry to address problems that played a role in the accident. The rulemaking is important in the context of international regulatory cooperation because PHMSA and FRA worked with their Canadian counterpart in developing the rule as a result of common concerns. In addition, other countries also had an interest because their businesses manufacture railroad train cars, and there was close cooperation with them also. FRA and PHMSA used FRA's Railroad Safety Advisory Committee (RSAC), which is similar to the FAA ARAC described above, and Canada and the other interested governments participated in that process. The final rule notes the many steps taken to effectively cooperate and illustrates the importance placed on those steps. For example, the final rule notes that, in an effort to harmonize their rules, PHMSA and FRA met with their Canadian counterpart, Transport Canada, for informal staff discussions; they held formal discussions through a Regulatory Cooperation Council; the leadership of DOT and TC met frequently; and the DOT Secretary and Canadian Transport Minister held multiple meetings to specifically discuss the rulemaking issues.

⁷¹ See, *id.* at 35

⁷² 49 CFR 107.803(c)(8).

⁷³ <http://www.phmsa.dot.gov/international>.

⁷⁴ 80 Fed. Reg. 26643.

Multiple DOT Agencies

After a railroad accident in the 1980's involving a crash between two trains, where the crew of one had been using marijuana, the DOT Secretary decided it was necessary for the Department to impose drug testing on safety-sensitive employees working in six modes of transportation (at the time, the U.S. Coast Guard was part of DOT). Subsequent to the successful completion of those rulemakings, the Secretary decided to create alcohol testing requirements for the same employees.⁷⁵ Some of the rules had international effects, particularly the FAA's, which affected every airline that operated into the U.S. The most significant effects were on Canada. Canada's airlines, commercial motor vehicles, and maritime vessels operated into U.S. territory, its trains and pipelines crossed over U.S. borders in some locations.

When Transport Canada learned of DOT's decision to initiate the drug testing rulemaking, it informally asked to meet with DOT officials to discuss how this would impact their operators under their privacy laws. Recognizing the need to address these significant governmental concerns as well as DOT's concerns that any rules needed to be effectively implemented, the Department agreed to meet and continued to meet regularly throughout the drug and alcohol rulemakings, successfully addressing Canada's concerns and issuing effective rules.

FHWA

Another example involved the use of negotiated rulemaking. This is a process in which an agency is required to use, or identifies regulatory issues that it believes can be best addressed by, an advisory committee that has representatives of all interests potentially affected by the rulemaking. The committee attempts to develop a consensus proposal with the help of a neutral facilitator, and after notice and comment proceedings under the APA, a final rule. Although the rule has to be approved by the head of the agency and comply with APA requirements, the agency is represented on the committee and any negotiated rule would generally satisfy the agency head. The proposal should also result in shorter comment periods and less adverse comment. The Negotiated Rulemaking Act⁷⁶ establishes a "framework" for negotiating a rulemaking but makes it clear that agencies are permitted to innovate and experiment with the process.⁷⁷ Although not appropriate for many rulemakings, it can be valuable for some contentious ones.

⁷⁵ Final rules for both drug and alcohol testing were issued by each of the six DOT agencies regulating such things as who was covered. Separate rules covering the testing procedures to be used by each of the agencies were issued by OST. The rules have been amended many times. The current version of the testing procedures are in 49 CFR Part 40.

⁷⁶ 5 U. S. C. §§ 561 – 570a.

⁷⁷ *Id.* at § 561.

This FHWA rulemaking arose from the concern of the U.S. Congress that the States had diverse laws covering parking permits for people with disabilities and that the permit of one state was not always accepted by another state, causing problems for permit holders. So Congress passed legislation directing DOT (which did not otherwise regulate parking permits) to convene a negotiated rulemaking advisory committee to develop a uniform system for the States to use for such permits.

Again, Transport Canada asked to be involved. The Canadians thought that it would be better for both countries to have one uniform system since U.S. and Canadian citizens routinely drive through each other's country. DOT invited TC to be a member of the advisory committee that it was establishing. Although as a foreign entity it could not vote, it was heard, and a final standard was successfully adopted by FHWA, which represented DOT in the negotiations. The preamble to the 1991 final rule describes the rulemaking.⁷⁸

FMCSA

Another noteworthy program involves FMCSA's commercial drivers licenses (CDLs). The U.S. and Canada agreed in 1989 that the testing and issuance of CDLs in the two countries was similar and would be mutually recognized.⁷⁹

Recommendations

The Department of Transportation is generally at the forefront of international regulatory cooperation. It has effectively worked with international organizations, individual countries, and regional bodies through formal treaties or agreements and very informal decisions to work together to address common problems or just assist the other with information and data. Nevertheless, as noted earlier in the paper, cooperation efforts may face some obstacles. At some or all levels—career staff, career senior officials, and politically-appointed officials—DOT agencies may harbor concerns about international regulatory cooperation that could cause them to oppose or reluctantly and ineffectively participate, particularly with the steps necessary to develop harmonized or common standards or mutual recognition.

To make the process easier, there are a number of steps that could be taken—individually or in concert with other recommendations—to address the possible concerns. Generally, as noted earlier, to the extent agencies do not appreciate the benefits of cooperation, the EU and the U.S. need to present them with the data or examples illustrating the benefits. The concerns may be unfair or legitimate, but the EU and the U.S. should either refute them or address them; they should not ignore them.

⁷⁸ 56 FR 10329, March 11, 1991.

⁷⁹ <http://www.fmcsa.dot.gov/international-programs/reciprocity-and-recognition-united-states-and-canadian-commercial-drivers>

Encouraging Regulatory Agency Participation in Regulatory Cooperation

If the U.S. President and the Commission President want agencies to engage in regulatory cooperation, it is very likely to happen. In the long run, it may achieve significant benefits. However, in the short term, to get effective cooperation from reluctant agencies it is not sufficient to merely issue a mandate. Senior Executive Branch and Commission officials need to be involved in ensuring effective implementation by, and support from, the regulatory agencies.

Positive steps have already been taken during the TTIP negotiations, but more may be necessary to address agency concerns. The concerns may be more of a perceived than an actual problem, but efforts to ensure that all participants in the agency process are aware of what is being done could help either way. Informal roundtable discussions where staff can be asked for input or can ask what is being done or what they can do if they do not think there is a proper balance might help, especially if there are actual problems. Other alternatives would be to provide an anonymous process for concerns to be raised or for an independent ombudsman to be available to review the concerns. Additionally, U.S. agencies could consider following the FDA approach by hiring officials who have both a trade and a regulatory background.

For some, encouragement may have to include discussions about the benefits of regulatory cooperation. For example, that may mean illustrating for staff how uniformity may result in higher safety at lower cost than a more demanding U.S. standard that may conflict with an EU standard; the conflict may result in implementation problems causing confusion and raising costs. Alternatively, raising a U.S. standard to achieve consistency may be objectionable to a U.S. agency that thinks it may impose unnecessary costs. Extensive, good quality data and thorough analyses of the alternative approaches should help with the necessary balancing. Most importantly, it may be necessary to agree to support the agency if it has a clear case for not agreeing. Agreement for agreement's sake can be helpful to get a program going, but it may do more damage in the long run. It helps to have agency regulatory staff involved in the discussions.

It is also valuable to accent for the agency that its early participation in increased cooperation efforts can help it shape the process. For example, getting in on the “ground floor” by volunteering to work on initial cooperation projects might mean the agency will have opportunities to play a significant role in setting up effective procedures that address its concerns (e.g., clear procedures for when and how USTR or OIRA participate or standards for trade impact analyses). DOT has recognized the advantages of ground floor participation via its active participation in the development and use of digital technology to enhance its rulemaking work. Other steps could include informal meetings, such as those noted above, to hear and address staff concerns.

Resources

When considering cooperation projects, it is also necessary to consider alternatives for the extra resources that an agency may need to participate effectively. For example, increased cooperation should not have to result in fewer opportunities for public participation. The EU and the U.S. might need to focus on areas where additional resources may be available. As an example, it may be possible that an agency could get additional appropriations for some projects and not others, because of interest in those projects in Congress. Alternatively, an agency may be able to move funds from a lower-priority project to some cooperation projects. New technology may be able to decrease the costs of cooperation. For example, certain projects may be easier to work on together because necessary meetings could be held effectively with digital technology.

Rulemaking Processes

The EU and the U.S. need to help both agency staff and the public better understand their respective rulemaking processes and their differences. This is important because the agencies and the public need to be able to effectively participate in the cooperation process. More importantly, the agencies and the public may be able to identify better approaches that will address their concerns if they have a better understanding of the processes. The steps that the two governments could take include the following:

- **Guidance on cooperation:** The U.S. and the EU should include in TTIP or another document provisions enabling and guiding regulatory cooperation (including the commitment to offer to each other early opportunities for information and cooperation and to take into account each other's approaches).
- **Educational material:** The EU and the U.S. should provide information on, or easy access to, studies that have been done on the two processes, such as the American Bar Association study of "Administrative Law of the European Union" (2008) and the recent EU comparative studies of EU and U.S. law by Parker and Alemanno (2014) and Dudley and Wegrich (2015).
- **Joint training courses:** Although this may be difficult without extra resources, it might be possible to conduct joint training courses when officials from the EU or the U.S. are visiting the other on business. Joint training could be especially valuable since the "students" may be especially helpful to each other when questions arise or confusion reigns.
- **Employee exchange programs:** Again, resources may make this unlikely, but even if a small number of employees could work in their counterpart's offices for 3–6 months, the learning experience could be very valuable for both the visiting employee and the visited agency but also for what the employee brings back to her office to help others at home.

- **Agency rulemaking websites:** More agencies on both sides of the Atlantic should be encouraged to put more information on the web about their rulemaking processes—not just about how they develop and issue binding rules, but also other things such as how they grant waivers and exemptions, how they work on international regulatory cooperation, and how the public can participate in the process.
- **Best practices:** After training on how the respective rulemaking processes work, it is important for the EU and the U.S. to begin providing regular training opportunities on best practices for EU/U.S. regulatory cooperation.
- **Lessons learned:** Training in best practices should also include developing and continually updating joint guidance documents for regulatory cooperation drawing on input from the regulators, on their experiences with what works best, and what could be a model for other agencies facing similar problems.
- **Addressing particular problems:** The EU and the U.S. should also develop guidance on such cross-cutting issues as how to resolve issues relating to exchange and use of confidential information between agencies, bridging differences in regulatory processes, and how to fund joint cooperation initiatives.

In order to be effective in the educational steps as well as the work on individual rulemaking projects, it is important that the U.S. and the EU assess their own processes for appropriate consistency in implementation. For example, the EU and U.S. agencies should be able to have informal, oral communications any time before or after a proposed rule is issued as long as they are not doing so to raise concerns of their regulated entities or affected interests with the proposal. Although the APA and agency policies do not prohibit it, some think it is not permitted. Pre- and post-NPRM informal meetings can be very valuable for effective negotiations.

Another area for emphasis in any educational efforts is the practical effect of U.S. agency guidance, including potential judicial deference to the guidance.

Initial Projects

The EU and the U.S. should focus initially on identifying projects for which success should be relatively easy but that will allay concerns and clearly illustrate the advantages of cooperation. For example, on the process side, they might look for early, easily and automatically provided notifications to each other about studies, recommendations, or rulemaking status. For a substantive rulemaking, even if only one side is currently considering a rule, they might agree to jointly chair a public meeting on the issues held via the internet. Moreover, selecting easy-to-accomplish rulemakings may also quickly generate best practices or lessons learned that will help when the agencies move to more complex matters.

Another area to focus on for initial regulatory cooperation efforts is currently unregulated matters—areas where an agency is not yet “locked into” an approach or existing scheme. Essentially, for an emerging risk, the goal might be for the EU and the U.S. to jointly gather the data, analyze the risks, and develop alternative solutions. One subject might be driverless motor vehicles. Another could be unmanned aircraft systems; as noted above, the U.S. and Canada are working together on this issue. A third might be transportation of lithium batteries.

The agencies may already have moved too far on these matters, but if they have not developed a reasonable solution yet, a cooperative approach may be worth considering. A generic area might be where agencies are moving from rules that impose risk control (e.g., no driver may drive more than eight hours without a rest) to risk management (e.g., a driver must operate under a system, approved by the agency, that is tailored to the driver’s specific operations by assessing and managing risks by monitoring and evaluating performance; presumably, the use of technology in the vehicle that measures fatigue symptoms would suffice).⁸⁰ This approach to regulatory requirements might also lessen concerns about enforcement differences between the EU and the U.S.

Public Participation

Both governments must emphasize the value of public participation to their agencies and not allow the use of regulatory cooperation to avoid it. The EU has announced the extra steps it intends to take to ensure more effective participation in its “Better regulation for better results – An EU agenda.”⁸¹ The U.S. objective should be to provide as much opportunity for participation as possible before and during negotiations with the EU to try to lessen the likelihood that changes will be necessary after the NPRM is issued. The governments should encourage early planning to ensure time is available for the participation, help identify and encourage the use of effective technology to enhance it and perhaps lower its cost, help obtain necessary resources to support it, and encourage the use of joint efforts by the counterpart agencies, such as joint public hearings or meetings, to increase its effectiveness.

Joint Public Meetings

EU and U.S. agencies should consider jointly chairing public meetings with interest groups, regulated entities and others who wish to attend to (1) discuss the benefits of, and objections to, regulatory cooperation; (2) discuss EU and U.S. proposals for addressing concerns or objections; and (3) receive and respond to public questions and suggestions. In addition, after identifying initial projects on which the EU and the U.S. agree to proceed with cooperation, the first steps

⁸⁰ See, e.g., 14 CFR 117.7. See, also, the FAA’s “Risk Management Handbook” at

http://www.faa.gov/regulations_policies/handbooks_manuals/aviation/risk_management_handbook/.

⁸¹ “Better regulation for better results – An EU agenda,” Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions (2015).

should be to hold a public meeting to hear comments and discuss suggestions. Joint public meetings could also be held to obtain public comment during the comment period.

Early Notice

DOT and its EU counterparts should jointly explore whether they are taking sufficient steps to provide early notice of legislative and interpretative rules and policy statements. Both sides should discuss what they need and why they need it, rather than simply requesting or demanding specific action; that should enable them to identify the best and easiest way to provide it. The emphasis should be on getting notice of potential rulemakings early enough so that the agencies can lessen or eliminate possible conflicts or problems. Examples such as the DOT drug and alcohol and parking permits rulemakings illustrate the value to both sides of early notice.

Both sides should also discuss whether better access to U.S. information about petitions for rulemaking, exemptions, and waivers; litigation; draft legislation; NTSB, OIG, and GAO recommendations; retrospective reviews; agency reports or studies; and other similar information and the comparable EU information would be valuable. If so, the agencies should explore best practices for providing better access and take appropriate steps. For example, if helpful, U.S. agencies should be able to create separate files for petitions for rulemaking, waivers, or exemptions in regulations.gov and “code” them with effects such as “EU” to help searches or generate reports.

Regular Meetings

Regular meetings (or video-conferencing or phone-calls) between counterpart agencies can ensure momentum is established and maintained. DOT agencies hold regular meetings currently with some of their counterparts. They could require extra time and expenses, especially if the meetings require travel, but that could be mitigated by taking advantage of internet meeting tools. Among other things, the discussions could cover research priorities, identification of new safety or environmental problems, new rulemaking initiatives, and lessons learned in cooperation efforts.

Rulemaking Data

The EU and the U.S. need to address the data the U.S. needs from the EU to support its rulemaking development as well as subsequent compliance and enforcement activities. This is an important issue for the U.S. agencies. The EU may believe it has a better alternative, but the U.S. rulemaking process demands that the U.S. have adequate data to support that conclusion. This is a problem that has to be resolved with the involvement of regulatory and analytical staff. The EU appears to be trying to address the problem and discussions could start off with the steps taken so far.

Confidential and Related Information

The fear of internal or draft documents being leaked and the inability of some agencies to protect confidential information are having an adverse effect on current cooperation efforts. There is a cost in time and money to obtain needed information from other sources. If it is not available elsewhere, it may mean an alternative cannot be justified. The inability or reluctance to share information may make it more difficult to reach the level of cooperation desired. Both sides have to address these problems.

The U.S. needs to explore the possibility of getting legislative authority, for those agencies that do not already have it, to protect confidential data in regulatory cooperation efforts – authority to share data they have and to protect data they receive from another government. The FDA authority noted above could be a model.

As to the leaking of documents or information, it can be very difficult to prevent that. Even some U.S. agencies complain of problems when, during interagency coordination, another U.S. agency may leak their documents. Regardless, the EU and the U.S. should try to address the problem. For example, if the leaks result primarily because of a difference in the way the EU and the U.S. deal in general with their public under their respective processes, educational efforts may help. Agency personnel who want more cooperation may not realize that leaks may make it harder to get the consensus that both sides want.

Rulemaking Supporting Analyses

One of the most significant concerns expressed by U.S. agencies and their affected interests involves the economic and other analyses supporting rulemaking. The EU is already taking steps to address this. However, the depth of the concerns may mean that more is expected than is promised. Both sides should consider creating a joint committee of regulators and economists to develop a consensus plan of action. Because it may be difficult to achieve consensus, the governments should consider using neutral facilitators and/or peer reviewers to assist in the decision making. To the extent the parties cannot reach agreement on what is necessary for a satisfactory analysis, they should be encouraged to identify ways to maximize cooperation and narrow differences without that agreement. There are a variety of approaches that might help address disparities. For example:

- The EU and the U.S. agencies could each prepare their own analysis and seek peer review of both and address the reviewer's comments.
- The agencies could jointly prepare one analysis and update it together as they go through the various stages of any internal and public review of the rulemaking; that may mean extra steps for both when the stages do not overlap closely. If necessary, they could note any areas where they disagree (e.g., on the need for better data) and

seek any required public comment, and try to resolving the differences. A peer review also may help resolve disagreements.

Implementation of Rules

Implementation issues range from guidance to rule amendments to forum shopping. For comparable standard setting or reciprocal recognition approvals to be effective, the EU and the U.S. must ensure that the implementation of the rule does not defeat its intended objectives – essentially eliminating the harmonization or comparability. Again, there is some agreement that the EU is already taking steps to make implementation consistent among the Member States, but more may be necessary to achieve the promise of full regulatory cooperation. From the EU perspective, it might be beneficial for the U.S. to discuss the likelihood of judicial review or Congressional action affecting implementation of an agreed-to action.

Advisory Committees

The EU and the U.S. should explore expanded use of advisory committees for regulatory cooperation. The ability of U.S. agencies to invite their counterpart agencies to be non-voting members has been very helpful. It brings in early, joint participation by both sides in addressing problems and alternative solutions, includes important public participation, and may make consensus solutions more attainable. The EU and the U.S. should also consider using the advisory committees to conduct negotiated rulemakings in appropriate situations. Among other things, the use of a neutral facilitator or mediator in the negotiations should increase the likelihood of achieving consensus. If EU participation in U.S. advisory committees is found to be workable and valuable, the U.S. could seek waivers or legislation to permit Europeans to have voting membership on U.S. advisory committees.

Neutral Facilitators

For discussions of contentious issues, both sides should consider the use of neutral facilitators who are skilled at helping participants in meetings reach agreement by getting them to focus on their interests rather than their positions. (E. g., both parties may want the one available apple and will not settle for half; asking why they want the apple may result in one party saying she is hungry and the other saying he needs the core for an art project.) Focusing on interests can result in the development of better resolutions and could be useful in government-to-government talks as well as public meetings. They could be especially valuable in the early stages of regulatory cooperation to help everyone learn to work well with each other. They would add to the up-front cost to of the process, but they could be well worth it, saving much more in the long-run. Moreover, their use need not be limited to individual rulemakings; they could also be used effectively to help resolve process issues (e.g., use of voluntary consensus standards setting bodies).

Digital Technology

The EU and the U.S. should consider expanding the use of different digital tools to enhance regulatory cooperation. The tools also can decrease costs, increase transparency, and address public concerns. They can be used for a range of matters, such as early notice, joint drafting, public participation, and coordination. For example, DOT agencies and their EU counterparts should consider whether social media tools could be valuable in providing information and education in addition to or in lieu of existing tools. For example, it might provide easier notification when a DOT agency places a document in regulation.gov. Another example is FAA's use, with Canada, of a bi-lateral webinar discussion with stakeholders in the FAA-Canadian cooperative efforts involving unmanned aircraft systems.

Reviews of Existing Rules or Legislation

As noted earlier, the U.S. has requirements for retrospective reviews of rules, including a requirement that they specifically consider rules with “unnecessary differences” with the requirements of other countries. The EU has a Regulatory Fitness and Performance Programme (REFIT) to ensure “that EU legislation remains fit for purpose and delivers the results intended.”⁸² With this emphasis in mind, the EU and the U.S. should consider establishing a special, joint review of their respective rules that focusses on “unnecessary differences.” The counterpart agencies could jointly identify the problem areas. Alternatively, if resources are a problem, the focus could be on particular agencies with good, established relationships and/or the reviews could focus on one major area (e. g., commercial aircraft certification).

Data Collection

The EU and the U.S. should ensure that their agencies keep good data on the costs and benefits of their regulatory cooperation. This should include data on the process (e.g., more or less time needed to do research or analyses) as well as the substance (e.g., more alternatives identified, better data collected, or more or less cost-beneficial rules). The data collected should objectively evaluate the effects on the process and the rules; if positive, it should help address the concerns described in this paper and encourage more cooperation from the participating agencies and other agencies and develop more support from the public. To the extent there are negative findings, it should help identify improvements to the process. The data collected should cover such things as:

- Any savings from joint research.
- Dates for completing key steps in the rulemaking process and explanations for any delays; this information can help determine whether regulatory cooperation is delaying rulemaking and help identify areas where improvements may be possible.

⁸² Id. at 10.

- Data on costs and benefits of rules adopted through cooperative efforts; this could help determine the merits of the underlying rule as well as how those costs and benefits compare to such things as estimates for rules that would have resulted from individual rulemakings.
- The effects of any mutual recognition on costs and benefits of the underlying rules. Any enforcement problems for rules that are jointly developed and any differences in safety benefits in the EU and the U.S.

This need not be overly burdensome. For example, if new software programs are necessary for enhancing the cooperation, every benefit may not have to be analyzed if one or two are sufficient to justify the costs.

Independent Studies of Regulatory Cooperation

The Administrative Conference of the United States (ACUS) is a small U.S. agency that works with a large advisory committee made up of government and public members. Its mission is “to promote improvements in the efficiency, adequacy, and fairness of the procedures by which federal agencies conduct regulatory programs, administer grants and benefits, and perform related governmental functions.”⁸³ It develops recommendations primarily directed to U.S. agencies and Congress that are generally based on scholarly research projects. It also prepares publications and seminars on best procedural practices.

If the EU has an agency such as ACUS or could create a temporary body that could work with ACUS, the EU and the U.S. should recommend that ACUS and the EU body jointly study EU-US initial regulatory cooperation efforts, identify best practices, areas for improvement, and other ideas for joint recommendations. Alternatively, the EU and the U.S. could jointly solicit such studies by non-governmental researchers, such as academics or “think tanks” in the EU and the U.S. Third-party studies rather than reviews by the involved governments might produce more objective analyses. A neutral study might also be more effective in allaying any remaining public concerns.

Conclusion

The significant achievements of the U.S. DOT suggest there has been some, if not significant, reciprocity by its EU counterpart agencies. DOT is also a Department that has not been afraid to be innovative. There are many things that could be done to enhance the processes of cooperation, and transportation regulations may be an area where it is likely to get done.

⁸³ <https://www.acus.gov/>