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## TACD BRIEFING PAPER ON MUTUAL RECOGNITION AGREEMENTS (MRA'S)

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### Executive Summary

Since the formation of the World Trade Organization (WTO) in 1995, U.S. and European officials have accelerated transatlantic efforts to develop and apply three important trade promotion devices—harmonization, equivalence, and mutual recognition (MR). Their goal has been to reduce what industry considers to be technical barriers to trade posed by national regulatory requirements. WTO agreements governing trade in food and other products specifically instruct nations to engage in these efforts. Because of their potential to reduce costs to industry, these trade facilitation tools have been promoted heavily by industry groupings such as the Transatlantic Business Dialogue (TABD). TABD is a coalition of major U.S.- and EU-based corporations that dominate transatlantic trade in goods and services.

The three trade promotion mechanisms are closely related but are not interchangeable. Harmonization and equivalence are both methods for bringing about regulatory convergence or uniformity. Harmonization takes two differing standards or procedures and converts them into one. Equivalence allows two differing standards or procedures to remain intact but treats them as if they were the same because in theory they produce the same or similar results.

Mutual recognition, however, is different. Mutual recognition is a vehicle for regulatory cooperation, and it may be based on harmonization, equivalence, or external criteria such as the importing party's standards or international standards. In a mutual recognition agreement, two or more parties agree to recognize and accept each other's conformity assessment results, test reports, certificates, product standards, regulations, markings, quality assurance system standards because they are harmonized or judged to be equivalent, or because they satisfy other agreed-upon external criteria. Thus, mutual recognition can stand alone on the basis of the importing country's standards or it can translate harmonization or equivalence determinations into benefits for trade.

With respect to consumer products, MRAs are agreements between countries to recognize and accept the results of conformity assessments performed by conformity assessment bodies (CABs) of the countries that are parties to the agreement. Conformity assessment is the process by which products are measured against the various technical, safety, purity, and quality standards that governments impose on products. The basis of this mutual recognition is the use of the importing country's tests and standards. Such MRAs allow an exporting country's CABs to use the tests and standards of the importing country in evaluating products, thereby potentially reducing the number of CABs that must evaluate a product destined for multiple markets.

The EU has wrestled with the issues of harmonization, equivalence, and mutual recognition within the context of the common market for many years. Since the formation of the WTO in 1995, the EU has also been at the forefront in promoting MRAs with a number of its major trading partners including the United States. The United States has recently begun to pursue MRAs with other nations and has concluded an MRA on telecommunications equipment as a member of the Asia-Pacific Economic Cooperation (APEC) forum. For the EU, MRAs represent a translation of its internal common market policy, which includes the application of mutual recognition to both conformity assessment procedures and standards, into its external trade policy.

TACD has already expressed its views on the topic of mutual recognition. In its February 2000 paper called *Principles of Harmonization*, TACD stated that MRAs and other trade promotion mechanisms are only ever appropriate if they 1) enhance the well-being of consumers; 2) are not applied in sensitive sectors involving public health, safety, or the environment; 3) are negotiated in open and accountable fora; and 4) are negotiated between countries having equally strong consumer safeguards, including mechanisms for public participation in domestic regulatory decision making and corporate liability structures. These principles guide this paper.

Supporters of MRAs expect them to result in reduced costs and increased market access for industry, as well as freeing up scarce regulatory resources. Consumers are supposed to see these cost savings passed on to them in addition to seeing a wider variety of safer goods appearing earlier in the marketplace. However, it remains to be seen whether these benefits actually do accrue to consumers.

The potential drawbacks of MRAs include the following: 1) transfer of regulatory authority and duties from national regulatory agencies to foreign entities who may operate under different conflict of interest standards and rules of transparency and liability; 2) privatization of public functions; 3) a loss of domestic regulatory control in crucial public health and safety matters; 4) reduced levels of public participation in regulatory decision making; 5) increased opportunities for regulatory evasion by industry; and 6) reductions in the levels of health, safety, and environmental protection.

Finally, while the benefits of MRAs for consumers are uncertain, the cost to taxpayers of implementing MRAs can be substantial. Implementation of just one portion of the U.S.-EC MRA is estimated to cost more than \$10 million on the U.S. side alone.

MRAS 04/01<sup>1</sup> The following points summarize the main conclusions of the report and are intended to help TACD shape its policy with respect to MRAs.

- MRAs are trade facilitation tools that operate in regulatory areas, and their direct benefits accrue primarily to business and to regulators, who argue that they are able to leverage scarce public resources via MRAs. Benefits to consumers are possible but are not at all guaranteed.
- In terms of domestic policymaking, MRAs remove important regulatory discussions and decision making from the public realm and place them behind the opaque screen of foreign affairs. This greatly reduces the opportunities for input from the public, from elected representatives, and even from certain regulators if they are not adequately consulted during MRA negotiations.
- The development of MRAs to date has mirrored the general process of international standard setting in terms of its lack of transparency and opportunities for meaningful public participation. This flaw afflicts the MRAs developed by the European Union, the United States, and APEC.
- MRAs can result in the transfer of regulatory authority from national regulatory agencies, which are to varying degrees transparent and accountable to their citizens, to foreign regulatory agencies and/or private bodies, which are not as transparent or accountable to the citizens of the importing country. Loosening the bonds of oversight and accountability increases the potential for regulatory evasion by industry.
- As conceded by U.S. regulators, mutual recognition does not necessarily produce any upward movement in standards or levels of protection. In fact, MRAs can bind together the standards and regulatory procedures of their parties, thereby stifling innovation and making improvement of regulatory procedures and standards more difficult and less likely.
- As conceded by EU regulators, mutual recognition should never be applied to product approval decisions because doing so would entail impermissible transfers of domestic regulatory authority to foreign regulators or private entities.
- MRAs such as the U.S.-EC MRA's annex on medical devices, which shifts domestic regulatory duties to private entities in another nation, are unacceptable. MRAs should not lead to back door privatization. The U.S.-EC medical device annex is likely to lead to regulatory forum shopping by companies and reduced safety for U.S. consumers.

- MRAs based on equivalence of standards are unacceptable. Equivalency is inappropriate when applied to important health safety and environmental protections and is likely to result in reduced protections for consumers. The pharmaceutical GMP annex of the U.S.-EC MRA is based on equivalence of standards and therefore is not supportable by consumers.
- MRAs are least objectionable when they are limited in application to conformity assessment results on the basis of the importing country's standards and do not involve equivalence, privatization, or standards set in international standard-setting bodies. Ultimate responsibility for the safety and efficacy of all products should rest squarely with the regulators of the importing country and no diminution of their enforcement authority should result.
- Conformity assessment MRAs based on external criteria set by international standard-setting organizations suffer from all the problems that plague the international standard-setting process, which are outlined in the 2000 TACD paper *Principles of Harmonization*. These include reduced transparency and public participation, as well as the problems caused by WTO rules that treat international standards as a ceiling for national standards rather than as a floor.

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## I. INTRODUCTION

Bi-lateral or multi-lateral MRAs are a relatively new trade policy tool that the European Union and the United States have been developing over the course of the last decade as part of their international trade liberalization efforts. The Transatlantic Business Dialogue and other industry groups have championed MRAs. The development of MRAs is consistent with TABD's goal of fostering a "tested once, approved everywhere" policy. This policy is a part of a larger scheme in which national standards would be adjusted to match international standards and conformity

assessment would be privatized as much as possible or performed by the regulated businesses themselves via “supplier’s declarations of conformity.” These policies give rise to serious concerns about the effectiveness of health and safety protections under such a system of regulatory devolution.

While the main purpose of MRAs is ostensibly to reduce what business perceives to be regulatory barriers to trade, they also have considerable potential to reduce existing levels of national health, safety, and environmental protection. This briefing paper analyzes MRAs and explains why representatives of civil society should monitor the use of MRAs and ensure that governments take into account the limitations of MRAs. Such oversight can play an important role in propelling governments to adopt trade policies that better serve consumers.

Part II of this paper describes the concepts and functions involved in mutual recognition as a part of the larger context of harmonization and trade liberalization. Part III discusses the legal status and bases for authorization for MRAs in Europe and the United States. Part IV analyzes existing MRAs and explains their structure, operation, and effects. Part V investigates the ramifications of MRAs in general. Finally, Part VI concludes by summarizing the primary concerns and issues related to MRAs.

## II. MUTUAL RECOGNITION: CONCEPTS AND CONTEXT

Mutual recognition agreements exist within the larger context of globalization. As providers of products and services have reached out for new markets, they have encountered barriers in the form of the differences between the standards and procedures imposed by the regulatory authorities of nations. Producers argue that these differences force them to create multiple versions of their products and submit them to duplicative testing, which increases costs and creates inefficiencies for businesses. In response to these perceived barriers, trade advocates have developed three key principles—harmonization, equivalence, and mutual recognition.

### A. Basic Definitions

In order to discuss mutual recognition, harmonization, and equivalence, we must first define our terms. Three important terms are regulations, standards, and procedures. Unfortunately, confusion can result from the differences in meaning accorded to these terms in U.S. and European contexts. In Europe, product specifications with which compliance is voluntary are called “standards,” while specifications with which compliance is mandatory are called “technical regulations.” In the U.S., however, the term “standard” refers to both voluntary specifications, such as can be created by industry groups, and mandatory specifications, which are promulgated by governments. And in the U.S., the term “regulation” includes both mandatory substantive standards and mandatory procedural requirements. The term “procedure” is a general term that can refer to processes related to production or regulation of products, including conformity assessment, which involves the testing of products against substantive standards. This paper follows U.S. patterns of usage.

**Harmonization** involves the adjustment of two or more standards or procedures until they are *the same*. Theoretically, countries may equalize their standards in one of the following three ways: 1) upward harmonization, in which the country with the lower standard strengthens it to match the higher one or the countries together draft a completely new standard at a higher level; 2) downward harmonization, in which the country with the higher standard weakens it to match the lower one or the countries together draft a new standard at a lower level; or 3) what may be called compromise harmonization, in which the two countries negotiate a new standard at an intermediate level. A country may harmonize its standards with those of other countries via bilateral or multilateral agreements, or may harmonize them with standards that are created by international standard-setting organizations such as the International Organization for Standardization (ISO).

**Equivalence**, in contrast, does not necessarily involve the adjustment of any standards. Rather, it involves a determination that two standards or procedures each sufficiently address similar regulatory objectives or achieve similar results even though they are not identical. The distinction between harmonization and equivalence is that “harmonized,” means “the same” while “equivalent” means “close enough.” But how close is close enough? Unlike sameness, equivalence admits differing definitions, even within the same agency. For example, definitions of equivalence in FDA documents vary greatly, ranging from “[resulting in] at least the same level of consumer protection” to “sufficiently comparable.” In some cases, the standard of closeness may be articulated in such definitions as the two mentioned above; in others, the standard must be articulated in the form of a list of criteria against which a system or procedure can be assessed.

From the perspective of health, safety, and environmental protection advocates, equivalence suffers from

considerable flaws. The primary flaw of equivalence stems from the incompatibility of its flexible nature with the inflexible nature of standards in a regulatory context. A mandatory, substantive standard serves as a positive line that divides everything above it from everything below it. Imagine that Country A's product safety standard requires that a textile withstand at least 200-degree C temperatures before catching fire. A textile that burns at 199 degrees will not meet the standard and cannot be marketed. Imagine also that Country B's standard is 180 degrees. Upward harmonization—such as by raising Country B's 180-degree standard to 200 degrees—maintains the integrity of both of the standards.

Equivalence, in contrast, allows two differing standards to coexist and serve as alternatives to each other. And, depending upon how loosely equivalence is defined in a particular situation, the lower of the two standards may be significantly lower, thereby eviscerating the higher standard. If, in the example above, "equivalent" is defined as meaning "within ten percent of each other," then the 180-degree and 200-degree standards may be mutually recognized as equivalent and products that burn at 180 degrees will be able to gain admittance to Country A despite the fact that Country A's standard specifies a 200-degree limit. Country B's standard then becomes an alternative route to Country A's standard, serving as a "back door" to the more stringently regulated market and bypassing its protections. In light of the specificity with which safety, health, and environmental standards must be set in order to have appropriate protective value, the back door effect makes equivalence inherently unsuitable for application to substantive standards.

A second flaw of equivalence is that it deprives consumers and citizens of their right to participate in decisions about the regulation of the products that they consume. Because an equivalence agreement allows products to gain admittance to an importing country by going through the regulatory system of the exporting country, it removes those products from direct regulation and oversight by consumers in the importing country. This displacement of regulatory functions to foreign regulators and private bodies, which are unaccountable to the citizens of the importing country, flies in the face of democratic principles of citizens' access to and involvement in regulatory affairs as enshrined in U.S. laws such as the Administrative Procedure Act (APA), the Freedom of Information Act (FOIA), and the Federal Advisory Committee Act (FACA).

A third flaw of equivalence comes from the flexibility available in the formulation of criteria for equivalence. The efficacy of harmonized standards can be clearly appraised by checking to see whether they are the same. But equivalence is not as easily determined. Whether or not two standards are equivalent depends on the criteria for equivalence that are applied by those making the equivalence determination. If the criteria are not sufficiently specific and rigorous or are not applied stringently, important statutory health, safety, and environmental protections will be undermined and their goals will not be met. Considering the pressures under which regulators must do their jobs, it is not certain that they will always devise appropriate criteria for equivalence and apply them strictly.

A fourth flaw of equivalence is that it tends to make it unlikely that governments will improve the level of protection provided by a standard once it has been judged "equivalent" to a corresponding foreign standard. As noted above, the notion of equivalence allows for some differences between equivalent standards, but there will be a limit to the degree of difference permissible under any definition or criteria. Authorities are not as likely to consider improving a standard if they run the risk of disrupting the equivalence determination upon which a regulatory cooperation arrangement with another country depends. In a context of scarce regulatory resources, the costs of even discussing the matter with foreign regulators may be enough to deter improvement of standards. Thus, equivalence could lock in a certain level of technological development and stifle the technological innovation that often follows standards improvements. It could also have the effect of stifling the application of the precautionary principle.

**Mutual recognition (MR)** as a theoretical concept is the process by which two or more countries agree to recognize some aspect of the other's regulatory regime as being interchangeable with their own. The parties may mutually recognize procedures or substantive standards, or they may agree to accept the results of product testing conducted by the other party's conformity assessment bodies (CABs) against the standards of the importing party. MRAs between governments are only useful in relation to products for which conformity assessment is mandatory. Because conformity assessment is required only for certain types of products, the utility of MRAs is limited to a relatively small portion of the marketplace.

Mutual recognition can be based on harmonization, on equivalence, or on satisfaction of external criteria such as the importing party's standards or international standards. Because true harmonization is often difficult to achieve, MRAs concluded to date appear to have been based on equivalence or external criteria. Nevertheless, mutual recognition would appear to be most effective as a trade-facilitation tool when it is applied in areas where the underlying standards have already been harmonized.

The 1998 U.S.-EC MRA is primarily an example of an MRA for conformity assessment. Five out of its six sectors involve the mutual recognition of the results of conformity assessments performed by the exporting party's CABs to the standards of the importing party. However, perhaps its most important sector in terms of trade value is the pharmaceutical GMP annex, which involves the mutual recognition of GMP inspection reports generated by the other party's regulatory agencies. Once the parties have determined that each other's regulatory systems are equivalent, they will be able to accept each other's GMP inspection reports.

Two important points bear reiteration. First, harmonization and equivalence are not the same. Harmonization takes two differing standards or procedures and converts them into one. Equivalence allows two differing standards or procedures to remain intact but treats them as if they were the same because they produce the same results.

Second, harmonization and equivalence differ functionally from mutual recognition. Harmonization and equivalence are methods for bringing about regulatory convergence, while mutual recognition is a vehicle for regulatory cooperation that translates harmonization or equivalence into benefits for trade. According to the European Commission, mutual recognition complements harmonization and equivalence. Harmonization and equivalence allow a producer to use one product configuration for multiple markets, and mutual recognition allows for access to those markets after the product has gained approval in only one market. The potential value of mutual recognition depends upon how it is used and on its basis.

Mutual recognition is very flexible in its applications, and governments have defined and employed mutual recognition in different ways. As the pioneer of mutual recognition, the EU has incorporated mutual recognition into its policy and law to the greatest extent of any government, using it both internally and externally. The interest of U.S. trade officials in using mutual recognition internationally is visible in the growing number of MRAs in which the United States has participated.

## **B. Mutual Recognition in Europe**

The principle of mutual recognition is an integral component of the EU's single market policies and, in particular, of its push toward internal and external regulatory harmonization. However, the EU's internal and external applications of mutual recognition differ significantly.

### *1. Internal Applications of MR*

Internally, Article 28 of the Treaty of Rome blocks EU member states from imposing quantitative restrictions or measures having a similarly restrictive effect on imports. In the 1979 *Cassis De Dijon* case, the *Dassonville* case, and others, the European Court of Justice (ECJ) elaborated on this rule by holding that member states may not forbid the sale on its territory of goods lawfully produced and marketed in another member state even if the goods are produced according to different technical or quality specifications. Under this jurisprudence, mutual recognition involves equivalence of both procedures and standards relating to goods.

As a result, EU member states must recognize each other's standards and procedures as being *equivalent*, and must accept products that conform to any member state's standards and procedures. The affected standards and procedures relate to a wide range of products, services, and professional qualifications. In addition, ECJ decisions require mutual recognition clauses in the national legislation of member states, thereby ensuring implementation of equivalence requirements at the national level.

Even so, the equivalence mandate of Article 28 is not unqualified. Article 30 allows member states to justify prohibitions or other limitations on the marketing of goods on such grounds as "public policy" or "the protection of health and life of humans, animals, and plants," so long as they do not constitute a "means of arbitrary discrimination or a disguised restriction on trade." Many member states have asserted their rights under this article or simply have demonstrated a reluctance in practice to accept the functional equivalence of other national standards and regulations because of a lack of confidence that standards and regulations developed elsewhere adequately uphold their often unique national policy goals. The resulting obstruction of the equivalence process helped push the EU to undertake the massive harmonization initiatives of the 1992 single market program, which includes the harmonization of many consumer product regulations.

The reluctance of EU member states to acquiesce to equivalence has not come from a desire to maintain widely differing standards. In fact, the member states have generally chosen to work towards regulatory convergence by participating in Europe-wide harmonization efforts, and these efforts have produced considerable improvements in levels of health, safety, and environmental protection. Rather, the member states' resistance to equivalence appears

to have been influenced by a recognition that their unique experiences and needs are not necessarily reflected in other states' standards and regulations. In essence, they have recognized that one size does not fit all. Considering that a grouping of similarly developed countries such as the member states of the EU could not successfully apply equivalence to standards, it is unlikely that equivalence will prove to be suitable for broader application on an international level.

The difficulties encountered in applying equivalence-based mutual recognition are apparent not only in the enormous scope of the harmonization undertaken within the EU but also in the Commission's own Communication on Mutual Recognition in the Context of the Follow-up to the Action Plan for the Single Market. This Communication was written in response to the perception—shared in some cases by the Commission—that the principle of mutual recognition is not functioning satisfactorily and is still posing serious problems for economic operators.

## **2. External Applications of MR**

Because the internal rules of the EU require mutual recognition, MRAs as such are unnecessary within the EU and are only used externally. In its Communication of 13 November 1996 on a Community External Trade Policy in the Field of Standards and Conformity Assessment, the European Commission outlined its policy to pursue bilateral agreements with third countries to mutually recognize test reports and conformity certificates. The Commission bases its policy on negotiating directives given by the European Council in 1994 and revised in 1995, which provided a prioritized list of countries with which the Commission should negotiate such agreements. EU policy is also influenced by Article 6.3 of the WTO Agreement on Technical Barriers to Trade (WTO TBT), which encourages members "to be willing to enter into negotiations for the conclusion of agreements for the mutual recognition of results of each other's conformity assessment procedures." Accordingly, the EU has concluded bilateral MRAs with Australia, Canada, Israel, New Zealand, Switzerland, the U.S., and Japan, and has stated an interest in moving to plurilateral and regional MRAs. These agreements involve the mutual recognition of conformity assessment results, but not the mutual recognition of the substantive standards against which conformity is assessed.

Thus, the central difference between the EU's internal and external applications of mutual recognition is that, within the single market, equivalence-based mutual recognition extends beyond systems and procedures and reaches *standards*. In essence, each member country of the EU has agreed that, internally, the various members' standards—although possibly different in form and content—can be deemed to be *functionally equivalent* when they set out to meet the same regulatory objectives. Such an application of equivalence to standards is powerful because it can achieve the same trade-facilitation effects as does harmonization, but without the costs and difficulties inherent in harmonization. This is why equivalence-based MR, in the words of the Commission itself, is a "pragmatic and powerful tool for economic integration." The Commission also states that, in general, harmonization and mutual recognition should be pursued in parallel.

## **3. The "MRA-plus" Concept: Equivalence Applied to Standards**

But the difference between the EU's internal and external applications of equivalence-based mutual recognition may not last. In keeping with its view that the present lack of harmonization of national product regulations and standards is an unacceptable obstacle to the free movement of goods, the Commission has proposed to the U.S. in particular the idea of an "MRA-plus." Under this concept, the core regulations and standards applicable to a specific product group would be analyzed to see to what extent they could be considered to be functionally equivalent. In essence, the Commission is proposing to apply equivalence-based mutual recognition to standards at the international level. However, in light of its lack of success within Europe, it is highly questionable whether equivalence-based mutual recognition can usefully be applied between trading partners who have even less in common than the members of the EU.

The EU's first initiative with respect to the MRA-plus concept has been with the United States in the field of marine safety equipment. Reports drafted at the request of the European Commission and the results of a recent workshop have underlined the difficulties present in such an undertaking. Indeed, it appears that the MRA-plus initiative has in fact resulted not in equivalence agreements but instead in a heightened dialogue between EU and U.S. regulatory authorities on the subject of harmonization of differing regulatory requirements. This development confirms that equivalence is unsuitable for application to standards. Nevertheless, the European Commission appears to hold the opinion that governments can choose between harmonization and equivalence-based mutual recognition—or a combination of the two—depending on the feasibility of each in a particular situation.

## **C. Mutual Recognition in the United States**

In the United States, the concept of mutual recognition appears to have developed first in regulatory circles as a tool for managing agency resources. As early as the 1960s, the U.S. Food and Drug Administration (FDA) responded to growing demands on its foreign facility inspection resources by concluding nonbinding agreements to cooperate with foreign regulatory agencies. The scope of these agreements—often called memoranda of understanding (MOUs)—ranged from cooperation on inspections and information-sharing to actual mutual recognition of foreign regulatory procedures and mutual acceptance of the results of certain inspections. In 1974, FDA stated a policy of “recogniz[ing] equivalent regulatory control by other nations through bilateral agreements.” In a 1995 Compliance Policy Guide, FDA reiterated its willingness to apply equivalence-based mutual recognition to foreign regulatory systems for food safety.

The U.S. Congress first mentioned mutual recognition in relation to regulatory activities in the Safe Medical Devices Act (SMDA) of 1990. Among other things, SMDA amended the Federal Food, Drug, and Cosmetic Act (FDCA), one of FDA’s main authorizing statutes, to authorize FDA to enter into international agreements involving “the mutual recognition of good manufacturing practice *regulations*” relating to medical devices. Later, in the Food and Drug Administration Modernization Act (FDAMA) of 1997, Congress expanded FDA’s mutual recognition authorization beyond the medical device arena and made it mandatory by requiring FDA to develop “a framework for achieving mutual recognition of good manufacturing practices [GMP] inspections.” This conception of mutual recognition appears involve the application of mutual recognition to regulatory systems and procedures, but not to substantive standards. When FDA responded with a framework plan, it defined mutual recognition agreements as providing for “a reciprocal reliance upon facets of . . . *regulatory systems*,” and noted that “[t]he requirements being met are those of the importing country . . . ,” which does not imply mutual recognition of standards. Both U.S. regulatory officials and U.S. trade officials have often repeated that MRAs do not contemplate equivalence of standards and do not result in U.S. standards being changed.

But this is not completely accurate. As described in Part IV, the U.S. already has applied equivalence to standards in the pharmaceutical GMP annex of the 1998 U.S.-EC MRA. In that agreement, the parties agreed on the equivalence of each other’s “regulatory systems,” which effectively includes standards in the form of GMP requirements. The GMP requirements that are applied during the inspections are those of the *exporting* party. In addition, the obligations of the United States and EU under the WTO Agreements, which require the application of equivalence to standards at the international level, make it possible that the governments will eventually be *forced* to apply equivalence to more standards despite its inherent unsuitability. Business leaders have also been pushing governments to employ equivalence as widely as possible. Thus, the U.S. position on the utility of equivalence-based mutual recognition may converge with the EU’s MRA-plus concept of equivalence of substantive standards.

### III. LEGAL BASES OF AUTHORITY FOR MRAS

#### A. *In the European Union*

As noted above, the EU applies mutual recognition internally through mechanisms other than MRAs. For the EU, MRAs are purely international agreements for use in reducing trade barriers bilaterally and multilaterally between the EU and non-EU-member countries. The following description of EU law accordingly focuses on the legal authorization for international agreements regarding foreign commerce.

Article 3, §1(b) and Article 133, §1 of the Treaty of Rome are the legal basis for an EU-wide “common commercial policy.” Under Article 133, the European Council determines the policy and the Commission negotiates any agreements required to implement it. The Commission may only commence the negotiation of agreements upon receipt of authorization from the Council, and must conduct the negotiations pursuant to the Council’s instructions. The Council ultimately decides whether to approve or reject any agreement. Recently, negotiation authorizations from the Council have taken the form of “directives for negotiation.” These directives define the objectives of the negotiations but leave the methods to be used up to the discretion of the Commission. As a result, they are much more flexible than a more directed mandate.

Once negotiations are underway, the Commission regularly updates Member States and consults them through a committee of the Council called the 133 Committee. The role of the committee is only advisory; the power to take decisions lies solely with the Council and cannot be delegated. Article 300 specifies additional procedural rules that apply to negotiating and concluding agreements. Most of the provisions of Article 300 deal with the relative roles of the Commission and the Council and the interaction between them. While Article 300(3) provides for the formal consultation of the European Parliament in the case of some types of agreements, it exempts agreements contemplated by Article 133, including MRAs. The European Parliament therefore lacks the authority to participate



directly in the MRA process.

The European Council first discussed its objectives regarding international mutual recognition activities in 1992. Priority was given to concluding agreements with the United States, Canada, Japan, Australia, New Zealand, Hong Kong, Israel, Korea, Singapore, Philippines and—upon membership accession to GATT (now the WTO)—China, South Africa, Malaysia, Indonesia, Thailand and Turkey. The Council most recently considered its negotiating priorities and strategy for mutual recognition in March 1995, when it endorsed the Commission's proposals to open additional negotiations or exploratory discussions with Korea, Singapore, Israel and Hungary.

## **B. In the United States**

Under the system of federalism established by the U.S. Constitution, the power to regulate interstate commerce and international trade is mainly reserved to the federal government. At least in the regulatory areas discussed here, a single set of federal standards and regulations apply nationwide, and there are no state-level standards that would be targets for mutual recognition. The United States therefore only applies mutual recognition in an international context.

In contrast to EU law, U.S. law on international agreements is less clearly stated, and has been developed in large part by historical practice and a small number of judicial opinions. Moreover, Congress has not provided specific goals and procedures for MRAs. Executive branch officials, who have made use of their broad powers under trade and regulatory laws, have developed the United States's mutual recognition policies. The inquiry into MRAs from the U.S. perspective requires discussing a number of constitutional and legal issues in sequence.

### *1. MRAs as Executive Agreements (EAs)*

The U.S. Constitution places responsibility for conducting diplomatic affairs in the executive branch. The President—or another duly authorized representative of the United States such as an ambassador or federal agency official—may conclude international agreements in either of two forms: treaties or executive agreements.

In international usage, the term “treaty” includes all international agreements, and generally refers to an agreement that is intended to bind its signatories under international law. In U.S. law, however, the term “treaty” refers to a narrower class of international agreements. Article II, § 2 of the U.S. Constitution explicitly authorizes the President to sign a formal and binding international agreement in the form of a treaty only after gaining the approval of the Senate by a two-thirds vote.

The term “executive agreement” refers to a broad class of non-Senate-approved agreements, including such things as memoranda of understanding (MOUs), memoranda of arrangement (MOAs), letters of acceptance (LOAs), letters of intent (LOIs), and contracts. EAs generally fall into three categories: 1) treaty-based EAs, which are agreements concluded pursuant to specific instructions in a formal treaty; 2) congressional-executive agreements, which are agreements concluded pursuant to specific congressional authorization or after approval by simple majorities in each house; and 3) solely executive agreements, which are concluded under the executive's own independent constitutional authority.

In the case of the U.S.-EC MRA, which is analyzed here as the most important MRA to date, the parties are listed as “[t]he Government of the United States of America and the European Community,” which makes it an international agreement between governments, not just an agency-to-agency agreement. According to U.S. officials, the U.S.-EC MRA is an executive agreement, which does not need to be submitted to the U.S. Senate for approval by a two-thirds vote. For support, FDA officials point to the functional similarity between MRAs and routine MOUs—which undoubtedly are EAs—and suggest that an MRA can be considered to be “a superlative MOU.” Thus, U.S. officials clearly consider MRAs to be EAs, but have not said which of the three EA categories the current MRAs belong to.

### *2. Authorization for MRAs*

Because the primary function of MRAs is to facilitate trade, they can be considered trade agreements that also relate to regulatory issues, and both U.S. trade agencies and regulatory agencies have accordingly participated in their creation. The MRA negotiation process is coordinated by officials of the Office of the U.S. Trade Representative (USTR) and the Department of Commerce (DOC), who negotiated the umbrella agreement of the U.S.-EC MRA. Officials from FDA, the U.S. Coast Guard, the Federal Communications Commission (FCC), and the Occupational Safety and Health Administration (OSHA) contributed in varying degrees to the negotiation of the sectoral annexes

pertaining to each agency. As representatives of the executive branch, all of the above-mentioned agency officials have standing to create EAs in general.

However, although the executive may have the constitutional authority to negotiate an EA, the EA cannot be valid unless the functions and results of the agreement comport with the laws that control the activities of the federal agencies involved. Thus, federal agencies may not implement provisions for which they have no explicit or implicit statutory authorization.

*a. Trade Agency Authorization*

In 1994, Congress amended the Trade Agreements Act of 1979 to give USTR “responsibility for coordinating United States discussions and negotiations with foreign countries for the purpose of establishing mutual recognition arrangements with respect to standards-related activities.” 19 U.S.C. § 2541. Because the MRAs in question appear to be mutual recognition arrangements with respect to standards-related activities, U.S. officials argue that USTR therefore has ample statutory authority for its coordination of the MRA process.

*b. Regulatory Agency Authorization*

Two of the most important sectoral annexes of the U.S.-EC MRA are the pharmaceutical GMPs annex and the medical devices annex, both of which affect regulatory activities managed by FDA. FDA cites a number of statutory provisions for its authority to conduct MRA negotiations and to take the actions that the agreements contemplate. However, it is questionable whether the cited statutory sections adequately support the activities undertaken by FDA in the MRA process.

Under the Federal Food, Drug, and Cosmetic Act (FDCA), FDA must “participate through appropriate processes with representatives of other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements . . . .” 21 U.S.C. § 393(b)(3). FDA must also

support the Office of the United States Trade Representative, in consultation with the Secretary of Commerce, in meetings with representatives of other countries to discuss methods and approaches to reduce the burden of regulation and harmonize regulatory requirements if the Secretary determines that such harmonization continues consumer protections consistent with the purposes of [the FDCA].

21 U.S.C. § 383(c)(1). More specifically, FDA must

support the Office of the United States Trade Representative, in consultation with the Secretary of Commerce, in efforts to move toward the acceptance of mutual recognition agreements relating to the regulation of drugs, biological products, devices, foods, food additives, and color additives, and the regulation of good manufacturing practices, between the European Union and the United States.

21 U.S.C. § 383(c)(2).

FDA may also

enter into cooperative arrangements with officials of foreign countries to ensure that adequate and effective means are available for purposes of determining, from time to time, whether drugs or devices manufactured, prepared, propagated, compounded, or processed by an establishment described in paragraph (1), if imported or offered for import into the United States, shall be refused admission [into the United States] . . . .

21 U.S.C. 360(i)(3). And FDA is authorized to “enter into agreements with foreign countries to facilitate commerce in [medical] devices between the United States and such countries consistent with the requirements of this chapter . . . .” In such agreements, FDA must “encourage the mutual recognition of good manufacturing practice regulations . . . .” 21 U.S.C. § 383(b). Finally, in the area of pharmaceutical GMPs and medical devices, FDA must

not later than 180 days after November 21, 1997, make public a plan that establishes a framework for achieving mutual recognition of good manufacturing practices inspections.

21 U.S.C. § 383(c)(4). Some have also argued that, in light of the large increases in international trade in pharmaceuticals and medical devices, FDA is authorized indirectly to participate in such mechanisms as MRAs in

order to fulfill its statutory mandate in the FDCA to prevent the importation of that drugs that are adulterated, misbranded, or otherwise in violation of law.

### 3. MRAs: Binding or Not?

An executive agreement such as an MRA may be either self-executing, in which case it becomes domestic law upon its signing, or it may be non-self-executing. An EA may be self-executing if existing U.S. law is adequate to enable the United States to carry out its obligations under the agreement. However, an agreement must be non-self-executing if the Constitution or Congress requires implementing legislation, or if the President intends implementation to take place via further executive action. For example, an agreement that exercises a power or performs a function reserved to Congress—such as creating a new crime or imposing a tax—cannot take effect as domestic law until Congress enacts an appropriate statute. An agreement that requires regulatory action by an agency takes effect upon the enactment of the appropriate rule through the domestic rulemaking process outlined in the Administrative Procedure Act (APA).

However, unlike treaties, not all EAs are binding internationally. EAs concluded by the President or by diplomatic officers have historically been considered to be binding if there was an intent by the signatories to be bound. EAs concluded by nondiplomatic representatives, including most agency-to-agency agreements, were not recognized as binding international agreements until the mid-1970s. In 1976, the U.S. Department of State released a legal memorandum stating that an agency-to-agency agreement may be binding if it has two or more parties, the parties intend that it be binding, the arrangement is sufficiently important and specific, and it is in a form that reflects an intent to make an international agreement.

Although courts have not ruled on whether an EA may in fact bind the U.S. internationally, the scholarly trend has been to equate EAs with treaties and to consider them to be binding. Therefore, a U.S. regulatory agency may choose to cooperate with a foreign agency through nonbinding MOUs or may choose to contract with the foreign agency through a binding international agreement. While FDA appears to have struggled with the question of its authority to enter into binding EAs, the agency published the U.S.-EC MRA in the Federal Register in an effort to make it binding.

### 4. MRAs Within the Hierarchy of U.S. Laws

According to the U.S. Supreme Court in *U.S. v. Belmont* and *U.S. v. Pink*, the Supremacy Clause of the Constitution allows EAs to trump conflicting state laws and policies in the same way that treaties do. However, unlike treaties, not all EAs can supersede preexisting *federal* statutes. Treaty-based EAs and congressional-executive EAs, which have the approval and authority of Congress behind them, may supersede prior inconsistent statutes. However, a solely executive agreement—particularly one made on a matter within the authority of Congress—will not overturn a conflicting statute.

On the reverse, all types of EAs can be superseded by subsequent EAs or treaties, but not all EAs can be overturned by act of Congress. Although the law is not at all settled in this area, commentators suggest that Congress may not be able to overturn EAs on matters within the exclusive power of the President. In summary, implemented EAs have a domestic legal force equal to that of treaties and federal statutes, but in some cases may give way to subsequent statutes. Because it is not clear into which category the U.S.-EC MRA falls, it is accordingly unclear whether or not Congress has the power to reverse or override the MRA.

## IV. ANALYSIS OF EXISTING MRAs RELATED TO CONSUMER ISSUES

As noted above, the European Union uses MRAs only externally. The EU has already concluded MRAs with Australia, Canada, Israel, Japan, New Zealand, Switzerland, and the U.S. For purposes of analysis, the best example is the U.S.-EC MRA, which is discussed below. The United States and its executive branch agencies have signed a number of bilateral MRAs with countries and agencies of countries such as Canada and India, and have concluded multilateral MRAs with organizations such as the Asian Pacific Laboratory Accreditation Cooperation group (APLAC) and (APEC).

### A. The U.S.-EC MRA

Perhaps the most significant MRA to date is the U.S.-EC MRA, which was signed in London on May 18, 1998. This MRA is a modular agreement consisting of an umbrella agreement and sectoral annexes covering the following

six product sectors: telecommunications equipment, electromagnetic compatibility, electrical safety, recreational craft, pharmaceutical good manufacturing practices (GMPs), and medical devices. This modular structure allows for future expansion of the agreement under the control of the trade-oriented umbrella agreement, and it ensures that a substantial part of the operational control of the annexes remains in the hands of trade officials by way of their control of the umbrella agreement.

The primary issue of concern is whether the U.S.-EC MRA involves equivalence of standards and thereby creates the back door effect by which U.S. health and safety standards may be evaded. Five out of the MRA's six sectors—all but the pharmaceutical GMP annex—involve the mutual recognition of the results of conformity assessments performed by the exporting party's CABs to the standards of the importing party. The result is a system of conformity assessment by proxy. Instead of inspecting European manufacturers or products themselves, U.S. regulators will accept the inspection reports generated by European regulatory authorities or their approved private CABs as being sufficient to demonstrate conformity with U.S. standards, and European regulators will accept U.S. reports.

For example, the medical devices annex is designed to allow FDA to accept and endorse quality inspection reports (known as audit reports in the EU) provided by "equivalent" CABs, although FDA will still retain the right to reinspect as it sees fit and to block the marketing of any product, and vice versa. FDA will also accept foreign-generated "initial evaluations" of data submitted for the purpose of obtaining approval of new low- and medium-risk medical devices, but will review those evaluations and will make the actual product approval decisions.

Thus, the standards applied are those of the importing party, and equivalence is only applied to CABs. The annex therefore appears to involve only conformity assessment to external criteria—namely, the importing country's standards—and the parties' standards are not being judged equivalent. But whether the EU CABs will actually apply U.S. standards in a manner equivalent to FDA is questionable. According to a 1996 U.S. General Accounting Office (GAO) report, "[t]he EU's system for regulating medical devices is still evolving, with major aspects of the system not yet fully in place. Drawing a meaningful comparison between the EU and FDA is therefore not possible at this time."

Additionally, conformity assessment for medical devices is performed in Europe by private companies, but is performed in the U.S. mostly by FDA itself. In general, the very different interests, motivations, and goals of private companies as compared with public regulatory agencies would suggest that equivalence would be unlikely. And while employees of both FDA and EU CABs are both subject to conflict of interest rules, GAO found that "the rules that govern FDA reviewers are more comprehensive than those that apply to [European CABs]." Even if only on this point alone, EU CABs should not be considered to be equivalent to FDA.

It also is not clear that the criteria to be used in determining the equivalence of CABs are appropriate or adequate. With regard to U.S. criteria for evaluating EU CABs, Appendix 1 of the medical devices annex provides a uselessly broad list of U.S. laws and regulations, without specifying which particular ones are relevant. The Appendix also refers to a public notice regarding a pilot program for private device review in the U.S. But in that notice, FDA states that the criteria contained in the notice are incomplete and that they differ from its own internal conflict-of-interest standards. Such criteria are not adequate for determining equivalence.

The pharmaceutical GMPs annex is even more problematic. Once the parties have determined that each other's "regulatory systems" are equivalent, the annex requires each party to accept the other party's GMP inspection reports and therefore the other party's GMPs, which essentially are production standards. The annex, which states that the parties "will carry out the inspections against their own requirements," therefore unacceptably applies equivalence to standards.

Although the MRA does not classify GMPs as standards, it is clear that they are standards. One author describes GMPs as "practices and procedures for manufacturing, processing, and packing drugs and drug products to ensure their identity, quality, and purity." However, an FDA publication describes GMPs as being standards for production methods, and GMPs certainly do appear to function as standards—albeit standards for manufacturers rather than for products. FDA requires producers to adhere to GMPs because GMPs are likely to lead to better quality control during the production process and therefore to safer, more pure, and more efficacious products. For example, a GMP may establish a maximum level of permissible contamination of a drug product by cleaning solution residues in processing machinery, and a manufacturer must undertake adequate measures to ensure that the limit is not exceeded. As standards, GMPs are not appropriate subjects for equivalence.

Even if GMPs were appropriate subjects for equivalence, the U.S. and EU GMPs differ sufficiently that they should not be considered equivalent. As shown in the definitions listed in Article 1 of the pharmaceutical GMP annex,

U.S. GMPs set out requirements as to the safety, identity, strength, quality, and purity of drug products, while EU GMPs focus only on quality. The absence of safety as a crucial attribute makes the EU and U.S. GMPs clearly nonequivalent.

As in the case of the medical devices annex, the criteria provided in the pharmaceutical GMP annex for determining equivalence of regulatory authorities are far from adequate. Most of the criteria listed are very simple and nonspecific, and they do not provide sufficiently meaningful guidance to regulators trying to evaluate the equivalency of their systems.. For example, the criteria for an equivalent regulatory system include the “[a]bility to enforce requirements and to remove products found in violation of such requirements from the market.” Just because an agency has the ability to perform these tasks does not mean that it actually does so in all appropriate situations, or is successful in doing so. Only an evaluation of an agency’s track record or performance would provide the needed information. The appendix also mentions the “[e]ffective use of surveillance systems” but does not specify how to assess whether or not the agency’s use is in fact “effective.” Overall, these criteria give far too much discretion to regulators who, apply these broad criteria behind closed doors in an attempt to evaluate the equivalency of their systems. No public notice is required for equivalence determinations, no opportunities for public input or participation is provided, and review of an equivalence determination is not available.

Notwithstanding the application of equivalence to GMPs in the pharmaceutical annex, Article 4(3) of the umbrella agreement states that the MRA “shall not be construed to entail mutual acceptance of standards or technical regulations of the Parties and, unless otherwise specified in a Sectoral Annex, shall not entail the mutual recognition of the equivalence of standards or technical regulations.” Article 4(3) would thus appear to preclude the back door effect but for the fact that it includes the qualifying phrase “unless otherwise specified in a Sectoral Annex.” Therefore, as EU officials have confirmed, “the EU-US MRA allows the parties to conclude sectoral annexes which could be based on recognition of equivalence of standards and technical regulations,” and in the case of the pharmaceutical GMP annex, they have done so.

Another issue of concern with the 1998 U.S.-EC MRA is that its umbrella agreement gives the Joint Committee (JC)—the bilateral governing body for the operation of the MRA—the power to settle disputes, amend annexes, and add new annexes. In fact, as noted in an interagency MOU between USTR and FDA, trade officials from USTR “normally shall speak for and vote on behalf of the United States in the Joint Committee.” Problems could arise if the trade officials who generally serve on the Joint Committee take steps to facilitate trade over the objections of regulators, who are governed by strong public health and worker safety statutes. In response to this flaw, FDA required that USTR sign the MOU, which states that controlling decisions in “matter[s] pertaining to FDA’s statutory or regulatory authority” will be taken by FDA officials only. In this way, FDA hopes to ensure that regulators’ decisions will not be overridden by USTR. However, other regulatory agencies involved in the 1998 U.S.-EC MRA did not develop such MOUs. As a result, some existing and future annexes may be subject to amendment to further facilitate trade at the expense of public health and safety protections.

## **B. The APEC Telecommunications MRA**

In November 1995, the leaders of the member states of APEC, which includes the United States and seventeen other countries around the Pacific Rim, adopted the Osaka Action Agenda. The Agenda states that the APEC economies would develop and begin to implement on an elective basis a model MRA on conformity assessment of telecommunications equipment. In May 1998 in Kuching, Malaysia, the member nations of APEC concluded the MRA and opened it up to be joined by the various member states.

According to the MRA text itself, its main purpose is to streamline the conformity assessment procedures for a wide range of telecommunications and telecommunications- related equipment and to thereby facilitate trade among the parties. It provides for the mutual recognition of conformity assessment bodies (CABs) and the mutual acceptance of the results of testing and equipment certification procedures undertaken by those CABs in assessing conformity of equipment to the importing parties’ standards. The agreement states that it does not involve the mutual recognition of parties’ standards or of the equivalence of those standards.

As such, the APEC MRA is a classic example of a conformity assessment MRA. The mutual recognition of conformity assessment results is based on acceptance of CABs as measured against general criteria including the adequacy of a CAB’s technical competence, its practical capabilities, and its knowledge of the relevant standards to be applied in its assessments. CABs are also to be evaluated against more specific criteria found in a number of ISO/IEC Guides relating to conformity assessment such as the International Organization on Standardization (ISO)/International Electrotechnical Commission (IEC) Guide 58: Calibration and Testing Laboratory Accreditation Systems - General Requirements for Operation and Recognition. The APEC MRA is therefore a mutual recognition

agreement based on external criteria rather than on equivalence.

Such an MRA does not pose the same dangers that an equivalence-based MRA can pose, but it is not free of problems. The first problem arises out of the question of the adequacy of the external criteria chosen as the basis for mutual recognition. If the criteria do not require levels of efficacy and dependability commensurate with the levels required by the country with the most developed regulatory system, then that country may find its standards being applied by foreign CABs that would not be approved as CABs if they were located within that country. In such a case, producers would be able to “forum shop” or seek out the loosest CABs in the hope of receiving more lenient conformity assessments for their products.

A second problem is that MRAs based on external criteria set by international standard-setting organizations unacceptably distance the standard-setting process from the public arena, in which consumers and their representatives can more easily participate. In the case of the APEC MRA, the parties mutually recognize each other's CABs in part because they conform to standards set by ISO/IEC. Such organizations do not necessarily operate according to the principles of openness and public participation that are central to the regulatory process in the United States and the EU. When standard-setting is moved from governments to closed-door international standards organizations, citizens lose much of their influence on the formulation of the regulations that protect them. This unacceptably blocks citizens' oversight over their own health and safety protections and diminishes the accountability and responsiveness of regulatory processes. Additionally, under WTO rules, international standards serve as a ceiling rather than as a floor for national standards. The WTO inappropriately elevates international standards to the status of presumptively “trade-legal” standards and provides for the challenge of national standards that are more stringent than the international standards, but does not allow for the challenge of lower standards. These rules are likely to put downward pressure on domestic standards that currently provide for higher levels of consumer, public health and environmental protection than international standards.

## V. EFFECTS OF MRAS IN GENERAL

### A. *Theoretical Benefits to Consumers*

MRAs theoretically can produce a number of benefits, which fall into two main categories: direct benefits and indirect benefits. While some of the indirect benefits may accrue to consumers, it seems clear that the main benefits of MRAs—the direct benefits—go to industry and to regulators. Those benefits generally come in the form of reduced costs to industry and reduced workloads for regulators.

According to FDA, MRAs “eliminate unnecessary regulatory burdens on industry” by minimizing duplicative testing and reducing paperwork requirements. By allowing for testing and certification to take place in a product's country of origin instead of in multiple destination countries, MRAs reduce the risks, costs, and time involved in selling products in distant foreign markets. In fact, it is argued that requiring businesses to deal with conformity assessment bodies in other countries may dissuade some of them from even entering those markets, thereby reducing consumer choice. The European Commission suggests that MRAs can help businesses better understand and access foreign regulatory systems by allowing businesses to deal with local regulators with whom they can communicate more easily.

Regulators also expect MRAs to provide benefits in the form of 1) increased regulatory efficiency and effectiveness through “leveraging” of scarce resources; 2) long-term regulatory cooperation and convergence; and 3) the development of more transparent and internationally compatible regulatory practices in different countries. In addition, the further delegation of regulatory functions from a single public agency to multiple private entities is seen as reducing the possibility that regulatory practices will support protectionism or permit unauthorized technology transfers.

What then are the benefits to consumers? The U.S. and EU argue that the direct benefits mentioned above will also indirectly benefit consumers in that the cost savings to businesses and regulators will be passed on to consumers and will lead to a wider selection of products that are more dependably safe, less expensive, and of higher quality. But it is questionable how much of the cost savings, if any, are truly passed on to the consumer. FDA also asserts that the “leveraging” of regulatory resources permitted by MRAs will lead to more effective surveillance of products, especially imports, and thus to a higher overall level of protection of public health and safety. If the protective functions delegated to foreign regulators and private testing entities are in fact carried out as well as they are by national regulators, then FDA's assertion may be valid. However, if they are not, then public health and safety will be adversely affected by the implementation of MRAs.

## B. Costs and Drawbacks

The first major drawback of MRAs is that they will pose considerable risks to public health and safety if they do not function perfectly in the real world. If the regulatory systems of the parties to an MRA do not have the same authority, skills, and resources, adequate enforcement of regulatory requirements may not take place and the MRA will result in the creation of large loopholes in the protective structure of at least one of the parties.

A second drawback is that MRAs shift regulatory control to foreign regulators or CABS, which removes regulatory functions and discretion from national regulatory agencies and the citizens to which they are accountable. Certainly, domestic regulatory agencies are much more likely than foreign agencies or private companies to have consumer health and safety as their primary interest. If regulatory authorities in an exporting country do not adequately ensure product safety or quality, the consumers in the importing country will have little recourse. In fact, consumers will have difficulty even knowing who to blame for defective or unhealthy products that might slip by. Moreover, producers will have the option of selling products in markets without scrutiny by—or accountability to—the regulators and protectors of the citizens of that market. Considering the mobility of production in this globalizing era, the danger of regulatory evasion is made even greater by MRAs.

Third, MRAs are likely to lead to regulatory convergence or harmonization. Although regulatory convergence to the highest standards is desirable, there is a danger that harmonization may happen outside of a context that guarantees public participation. TACD's concerns with harmonization are elucidated in the 2000 TACD paper *Principles of Harmonization*.

Finally, although regulators are quick to point to the efficiencies that MRAs should create, they have not been as forthcoming about the costs of implementing MRAs. MRAs require evaluations of the equivalence of regulatory systems or the competence of CABS before the delegation of responsibilities can take place, and these evaluations require considerable resources and time.

For example, the U.S.-EC MRA requires that FDA assess the equivalence of each of the fifteen European regulatory systems for pharmaceutical GMPs by the end of its three-year transition phase ending November 30, 2001. The U.S. General Accounting Office (GAO) reports that FDA will need to devote at least \$10 million and over 125 employees to this evaluation stage of the MRA process alone. FDA does not have these resources, and has admitted that it can finish evaluating only one of the fifteen EU member states—the United Kingdom—by the deadline. FDA has pleaded a lack of adequate resources and a lack of cooperation by EU regulators as factors. In addition, key cost issues such as who is going to translate the potentially hundreds of inspection reports are still unresolved. Thus, it is unclear whether the “resource efficiencies” that an MRA is supposed to create do in fact outweigh their implementation costs.

## C. Transparency & Public Participation Issues

### 1. In the EU

EU treaty arrangements leave the European Parliament (EP) largely sidelined in the MRA process. In the early 1990s, the Commission presented to the EP its rationale behind its mutual recognition strategy in its Commission Communication on Community External Trade Policy in the Field of Standards and Conformity Assessment, but the EP did not formally respond. The EP provided no input into the discussions surrounding the negotiating directives given to the Commission that have served as a basis for concluding the U.S.-EC MRA and other MRAs.

But the EP's lack of involvement is not due solely to a lack of interest on its part. The European Parliament noted in its “Report on Transatlantic Trade and Economic Issues (A4-0403/97) – Resolution” that it lacked information on mutual recognition. According to the EP, MRAs “should be carefully monitored and made transparent; regular progress reports on this process should be submitted by the Commission to the European Parliament.”

Opportunities for the involvement of stakeholders such as consumers and public health officials are of course also limited. The European Commission has recently made an effort to try to associate stakeholder interests with the MRA process, but only in 2000 has the public gained some access to Council documents on MRAs. Much more remains to be done in the area of public participation.

### 2. In the U.S.

On the U.S. side, the MRA development process has been similarly characterized by an almost complete lack of public participation. U.S. trade and regulatory agencies began discussing harmonization tools such as MRAs as early as 1989, and began formal MRA talks with the EU in April 1994. During this crucial period of policy formation, the agencies took substantial input and direction from representatives of business through advisory committees and the Transatlantic Business Dialogue (TABD), which benefited from having its own dedicated liaison within the Department of Commerce.

But the agencies gave no public notices that communicated the importance of the issues and failed to allow any meaningful public input into the development process. Although actual MRA negotiations had begun in mid-1994, FDA did not hold any public meetings on the MRA process until March 1995, failed to provide an opportunity for public comment on MRA-related standards harmonization until July 1995, and did not open a public docket on MRAs until mid-1996. And although the U.S. and EU concluded the MRA negotiations in June 1997, FDA took until April 1998 to release its proposed rule regarding MRA implementation, which provided for a public comment period of only thirty days. Only three days after that comment period closed, and without responding to any issues raised in the comments, FDA notified USTR that it approved of the MRA. Four days later, the U.S. and the EU signed the MRA. FDA did not promulgate its final rule until November 6, 1998—over four months after the signing of the MRA.

U.S. trade and regulatory officials also failed to adequately inform Congress about the MRA process and its ramifications. Working under a perceived mandate found in the vague and generalized wording of a handful of statutory sections, agency officials negotiated and implemented substantial changes in U.S. regulatory systems without any oversight by or input from Congress. When congressional committees finally convened a series of hearings on MRAs, it was late in 1998—over a year after the negotiations had been concluded.

In addition, the structure of the MRA itself means that public participation in the operation of the MRA is practically nonexistent. Major agency actions such as determinations of equivalency regarding foreign regulatory systems and procedures will take place without any public notice or opportunity for public comment, and related documents in some cases will never be available to the public. Under the U.S.-EC MRA, operational decisions affecting the trade of regulated products worth hundreds of millions of dollars will be made within closed committees, to which there will be no public access either during the committees' work or after the fact.

## VI. CONCLUSIONS

While MRAs theoretically may have beneficial uses, the analysis above shows that they are subject to numerous unacceptable flaws in their current form. The following is a summary of the most important points to remember about MRAs:

- MRAs are trade facilitation tools that operate in regulatory areas, and their direct benefits accrue primarily to business and to regulators, who argue that they are able to leverage scarce public resources via MRAs. Benefits to consumers are possible but are not at all guaranteed.
- In terms of domestic policymaking, MRAs remove important regulatory discussions and decision making from the public realm and place them behind the opaque screen of foreign affairs. This greatly reduces the opportunities for input from the public, from elected representatives, and even from certain regulators if they are not adequately consulted during MRA negotiations.
- The development of MRAs to date has mirrored the general process of international standard setting in terms of its lack of transparency and opportunities for meaningful public participation. This flaw afflicts the MRAs developed by the European Union, the United States, and APEC.
- MRAs can result in the transfer of regulatory authority from national regulatory agencies, which are to varying degrees transparent and accountable to their citizens, to foreign regulatory agencies and/or private bodies, which are not as transparent or accountable to the citizens of the importing country. Loosening the bonds of oversight and accountability increases the potential for regulatory evasion by industry.
- As conceded by U.S. regulators, mutual recognition does not necessarily produce any upward movement in standards or levels of protection. In fact, MRAs can bind together the standards and regulatory procedures of their parties, thereby stifling innovation and making improvement of regulatory procedures and standards more difficult and less likely.



- As conceded by EU regulators, mutual recognition should never be applied to product approval decisions because doing so would entail impermissible transfers of domestic regulatory authority to foreign regulators or private entities.
- MRAs such as the U.S.-EC MRA annex on medical devices, which shifts domestic regulatory duties to private entities in another nation, are unacceptable. MRAs should not lead to back door privatization. The U.S.-EC medical device annex is likely to lead to regulatory forum shopping by companies and reduced safety for U.S. consumers.
- MRAs based on equivalence of standards are unacceptable. Equivalency is inappropriate when applied to important health safety and environmental protections and is likely to result in reduced protections for consumers. The pharmaceutical GMP annex of the U.S.-EC MRA is based on equivalence of standards and therefore is not supportable by consumers.
- MRAs are least objectionable when they are limited in application to conformity assessment results on the basis of the importing country's standards and do not involve equivalence, privatization, or standards set in international standard setting bodies. Ultimate responsibility for the safety and efficacy of all products should rest squarely with the regulators of the importing country and no diminution of their enforcement authority should result.
- Conformity assessment MRAs based on external criteria set by international standard-setting organizations suffer from all the problems that plague the international standard-setting process, which are outlined in the 2000 TACD paper *Principles of Harmonization*. These include reduced transparency and public participation, as well as the problems caused by WTO rules that treat international standards as a ceiling for national standards rather than as a floor.

# TRANSATLANTIC CONSUMER DIALOGUE

## Policy Recommendations regarding Mutual Recognition Agreements (MRAs)

March 2001

As noted in the TACD Briefing Paper, MRAs suffer from considerable intrinsic and practical flaws. In particular, the 1998 U.S.-EC MRA, which deals with sensitive public health sectors and entails both privatization and equivalency, is not supportable by consumers. MRAs that are least objectionable are those that do not affect public health and safety, do not involve equivalence determinations or privatization, and utilize the standards of the importing party. Yet even with these narrowly drawn agreements, TACD recommends that governments employ non-binding alternatives to MRAs, including memoranda of understanding (MOUs) or cooperative agreements, and that governments involve the public in every aspect of the decision making and post-implementation analysis.

If governments nevertheless continue to employ MRAs, TACD asserts that certain important qualifications must be imposed upon their use.

TACD calls upon governments to do the following:

- 1) Conclude MRAs only if they achieve a clearly defined benefit to the public, not just benefits to the private sector
- 2) Refrain from negotiating MRAs in sensitive public health, food safety and environmental sectors
- 3) Refrain from incorporating product approval or certification into MRAs
- 4) Refrain from negotiating MRAs between regulatory systems that are significantly different
- 5) Refrain from negotiating MRAs that result in privatization or the transfer of regulatory functions to private entities
- 6) Avoid all application of equivalence in MRAs
- 7) Ensure that MRAs do not impede the application of the Precautionary Principle and ensure that domestic regulators lose none of their rights or abilities to enforce domestic regulations or directly respond to emergencies threatening public health and safety
- 8) MRAs that meet the standards of the importing party are preferable to MRAs meeting equivalent standards or standard developed in international standard setting institutions
- 9) Eliminate overarching “umbrella agreements” from MRAs. Full responsibility and authority for negotiating, and managing MRAs or cooperative agreements should rest in the hands of the regulatory agencies responsible for implementing them
- 10) Ensure that the procedural safeguards of the countries involved in an MRA are equally strong, meaning that there is a democratic process that assures consumer input and redress, government enforcement and a comprehensive liability regime
- 11) Provide for adequate openness and transparency in all MRA-related activities, including public notice, document availability, and public access to meetings and public participation in decision making
- 12) Ensure that the evaluation of conformity assessment bodies is made according to clear and rigorous criteria that have been formulated with substantive public input
- 13) Ensure that nations retain the right to accept or reject a conformity assessment body or a foreign regulatory authority and that in all instances the burden of proof rests with the party claiming conformity with criteria
- 14) Any regulatory changes that may be needed to implement an MRA or any regulatory convergence that may take

place as a result of an MRA should be publicly noticed, incorporate public comment and concerns, and result in the adoption of the highest possible standards

15) Prepare a full environmental impact statement for any proposed MRA that could affect the environment

16) Publish an assessment of the functioning of each MRA two years after its implementation