OVERVIEW OF THE U.S. - EU MRA NEGOTIATIONS

Art Wall and Julius P. Knapp
Federal Communications Commission
Equipment Authorization Division
7435 Oakland Mills Road
Columbia, Maryland 21046

ABSTRACT

For the last three years, the United States Government and the European Union have been negotiating a Mutual Recognition Agreement for Conformity Assessment. These negotiations are limited to specific equipment sectors and to conformity assessment. The product sectors that may be included in the Agreement include: Telecommunication Equipment, Pharmaceuticals, Medical Devices, Recreational Crafts and others. The FCC participated in these negotiations for Telecommunications and EMC at the request of the U.S. industry, the Office of the United States Trade Representative and the Department of Commerce, who are leading these negotiations for the USG. The Agreement, which is expected to be signed by both parties in 1997, will allow for these two sectors, U.S. manufacturers and laboratories, to test and approve in the United States certain telecommunications equipment bound for the European market. Conversely, European manufacturers will be allowed to test and approve in Europe similar equipment bound for the U.S. market. This paper will provide an overview of these negotiations from the FCC perspective and outline a number of the steps the U.S. Government and the FCC must take to implement the Agreement.

BACKGROUND

The European Union (EU) consists of fifteen Member States with the possibility of expanding to eighteen or more. It represents the largest single trade market in the world. To facilitate trade between Member States, the EU has adopted a number of broad Directives establishing general product requirements for almost every product marketed in Europe. Current national product approval systems are being replaced by a new European-wide system of approval based on mutual acceptance between Member States. The EU has stipulated that product conformity assessments performed outside of Europe will only be accepted under the terms of an MRA negotiated between governments.

The Office of the United States Trade Representative and the Department of Commerce have led negotiations over the past several years for a mutual recognition agreement (MRA) for

product approvals with the European Union. Representatives of the Federal Communications Commission participated in these negotiations, particularly with regard to the telecommunications equipment and electromagnetic compatibility sectors. (The MRA covers other sectors as well, including electrical safety, pharmaceuticals, medical devices, recreational craft and certain aeronautical equipment. Other federal agencies with responsibilities in these areas also participated in the MRA, including the Occupational Safety and Health Administration, the Food and Drug Administration, and the Federal Aviation Administration.) Representatives of industry in the United States and Europe also provided input to these negotiations. The TransAtlantic Business Dialogue identified the completion of the MRA as a top priority to facilitate increased trade between the United States and Europe. (The TABD is composed of top leaders of industry and government from the United States and Europe. Its purpose is to increase trade and investment opportunities on both sides of the Atlantic. Telecommunications equipment has been one of the main areas of discussion in the TABD. The TABD's TransAtlantic Advisory Committee on Standards, Certification and Regulatory Policy (TACS) has proposed a new transatlantic regulatory model based on the principle "tested once, accepted everywhere in the transatlantic marketplace.") The negotiations are nearing conclusion and the MRA is expected to be finalized in the near future. The issues in the telecommunications equipment and electromagnetic compatibility sectors are resolved except for some minor editorial points.

The MRA would be a bold new step towards enhancing trade and reducing the burden of product compliance in the United States and Europe. Under this agreement, telecommunications equipment and certain electronics products could be tested and approved in the United States to ensure compliance with the technical requirements of the European Union. The equipment could then be shipped directly to any of the fifteen member countries of the European Union. The United States would reciprocate. In other words, the United States has agreed to empower the European Union Member States to test and approve equipment for compliance with United States technical requirements. The equipment could be shipped to the United States directly, with nothing further required from organizations in the United States, including federal agencies.

EU DIRECTIVES

In order to understand the Telecommunications Product Sector, it is necessary to say a few words about the Directives. The EU has adopted a series of directives that establish the essential requirements for a wide variety of equipment including telecommunications equipment. Equipment must comply with the Directives before it is placed on the market in Europe. Equipment must be labelled with a "CE" mark to indicate it complies with all relevant Directives. There are two Directives of particular interest for telecommunications equipment: the Telephone Terminal Equipment Directive 91/263/EEC and the EMC (Electromagnetic Compatibility) Directive 89/336/EEC. (While the Low Voltage Directive is also of interest, it deals with electrical safety and is outside the purview of the FCC.) The key elements of these Directives are summarized below.

Telephone Terminal Directive 91/263/EEC

Purpose. This Directive recognizes that the terminal equipment sector is a vital part of the telecommunications industry, and seeks to harmonize conditions for placing such equipment on the market to create the conditions for an open and unified market. The Directive specifies that terminal equipment shall satisfy the following essential requirements:

- (a) user safety;
- (b) safety of employees of public telecommunications networks and operators;
- (c) electromagnetic compatibility requirements insofar as they are specific to terminal equipment;
- (d) protection of the public telecommunications network from harm;
- (e) effective use of the radio spectrum, where appropriate;
- (f) interworking of terminal equipment with public telecommunications network equipment for the purpose of establishing, modifying, charging for, holding and clearing real or virtual connection;
- (g) interworking of terminal equipment via the public telecommunications network, in justified cases.

Technical Requirements. The TTE Directive relies on the development of European harmonized standards. The standards are initially developed by private sector standards bodies: the European Committee for Standardization (CEN); the European Committee for Electrotechnical Standardization (CENELEC) and the European Telecommunications Standards Institute (ETSI). These organizations develop telecommunications standards on a contract basis for the European Commission.

The standards are converted to Common Technical Regulations (CTRs) by the Telecommunications Regulations Application Committee (TRAC) set up by members of the European Conference of Postal and Telecommunications Administrations (CEPT). To date, CTRs have been developed only for a few technologies, such as GSM, ERMES, DECT, and DCS-1800.

Conformity Assessment Process. Directive 91/263/EEC provides three alternative routes to terminal equipment approval, and they all include both design verification and assessment of production quality:

-EC Type-Examination. Under this procedure, the manufacturer must submit documentation and a product sample, representative of actual production, to a Notified Body. The Notified Body tests the equipment and upon determining that the equipment type meets the provisions of the Directive, issues a certificate. The equipment must be accompanied by a manufacturer's Declaration of Conformity that references the certificate of the Notified Body. The Notified Body must perform audits of production in order to ensure continued compliance of production.

-Production Quality Assurance. Under this procedure, the manufacturer may perform its own tests; however, the quality system must conform to EN 29003. The Notified Body must be involved in the design and production phase. The manufacturer must operate a quality system conforming to EN 29002, which is approved by the Notified Body. This substitutes for product spot checks.

-Full Quality Assurance, which involves the assessment by the Notified Body of the manufacturer's quality assurance for both the design and production.

The choice of options is at the discretion of the manufacturer or its authorized representative.

Notified Bodies. Article 10 of the Directive requires each Member State to notify the Commission the Bodies appointed to carry out the conformity assessment procedures. The Notified Bodies supervise assessment with the technical requirements underlying the Directive. The Notified Bodies can either perform the required tests themselves or can select additional laboratories to perform tests. The Directive states that Notified Bodies must be of a high standard throughout Europe and meet minimum criteria of competence, impartiality and financial and other independence from clients.

The EU maintains and publishes official lists of Notified Bodies and other test laboratories. All Notified Bodies are currently located within the EU, although they may be able to subcontract work to entities outside the EU. A manufacturer seeking approval can select any Notified Body with which to work. Approval granted by that body is effective throughout the EU.

The availability of multiple Notified Bodies in Europe enables the manufacturer to choose one that can complete the tests in the required amount of time and at a competitive price.

The EMC Directive 89/336/EEC

Purpose. The European EMC Directive 89/336/EEC is a horizontal Directive that applies to virtually all electronic equipment. It imposes two essential protection requirements. First, equipment may not cause harmful interference to radio and telecommunications equipment. Second, such equipment must possess sufficient immunity to operate as intended.

Technical Requirements. EMC standards are adopted by the EC Commission upon the recommendation of an expert technical committee run by the Committee for European Electrotechnical Standardization (CENELEC). In general, these standards are based on international standards developed by organizations such as the International Committee for Control of Radio Interference (CISPR). The standards become valid after they are published in the *Official Journal of the European Community*.

Conformity Assessment Process. Manufacturers have a choice of two ways in which to demonstrate conformity with the EMC Directive. If standards that apply to the equipment in question have been published in the *Official Journal*, the party responsible for introducing the equipment into the European market can either test the equipment or have it tested by any third-party laboratory, and sign a Declaration of Conformity confirming compliance with the Directive. This is a self-certification process.

At this time standards are in place for most equipment. Two generic standards, EN 50 081-1 and EN 50 082-1 were created to cover generic emissions and immunity requirements, respectively. Therefore, manufacturers are able to take advantage of the self-authorization process for most equipment.

If no relevant standards have been published in the *Official Journal*, approval must be based on tests performed by a "Competent Body." Under this process, the manufacturer must prepare a technical construction file that describes the features of the equipment that are designed to ensure electromagnetic compatibility. To the technical construction file is added a technical report and certificate issued by a competent body showing that based on testing or other analyses, the equipment meets the essential requirements of the EMC directive. The manufacturer may then issue a Declaration of Conformity, referencing the certificate of the Competent Body.

The alternative conformity assessment process may also be used for equipment for which standards exist but cannot, for practical reasons, be tested on a calibrated test site. For example, certain industrial equipment may be too large or require cooling

systems such that it cannot be tested on an open area radiated emissions test site. The alternative may also be used as a basis for certifying a family of similar equipment based on tests on one or a few members of the family. For instance, a Competent Body may issue a certificate that a family of personal computer hard disk drives, each with a different storage capacity, is in conformity with the Directive based on tests of only one or two types. Of course, a manufacturer may choose to have its equipment tested by a Competent Body to further ensure compliance.

Competent Bodies. Each European Member State designates competent bodies within its territory and names them to the European Commission. There are no specific requirements for Competent Bodies, other than that they must have the proper equipment and competence to perform the required testing. However, in most cases the Competent Body has been accredited by an appropriate organization in each Member State. At this time there are more than 80 Competent Bodies designated throughout Europe. Competent Bodies may be designated outside Europe only under the terms of a Mutual Recognition Agreement.

Wireless Equipment & the EMC Directive. One little-noticed aspect of the EMC Directive is that it also applies to wireless equipment. For example, radio receivers must meet standards for spurious emissions and immunity. The Declaration of Conformity for such equipment is not consistent with that for other equipment under this Directive. Such equipment must be approved by a Notified Body, using the procedure described above for telephone terminal equipment. Once the EMC standards are in place, transmitters must be approved by Notified Bodies. transmitters must also meet the spectral requirements and be approved by each Member State.

MRA STATUS AS OF APRIL 1997

After more than three years of negotiations involving U.S., EU and Member States representatives, the text of the Agreement is expected to be reviewed and edited one last time in May of 1997. The MRA will consist of an Umbrella text covering all common elements of the agreement and a number of Sectoral Annexes for each of the product sectors. For the telecommunications and EMC Sectoral Annexes, the text is complete, except for editorial corrections to bring it in line with last minute changes to the Umbrella text. As of April 1997, there were still unresolved issues concerning Pharmaceuticals, Medical Devices and the Umbrella text. Optimistically, we expect these issues to be resolved by June 1997.

For telecommunications equipment, the U.S. and EU have agreed on mutual recognition of product certification after a 24 month transition period during which both the U.S. and the EU make necessary legislative and regulatory changes. From the beginning of the negotiations, the EU has insisted on nothing

less than mutual recognition of product approvals. The transition period is expected to allow for up to two years for changes in regulations and for building confidence in each other's approval system. During the transition period, two workshops will be held -- one in the U.S. and one in Europe -- to learn each other's systems and to discuss details of implementation. If accepted, the MRA will, after a transition period, allow U.S. manufacturers to test and approve covered products going to Europe. Conversely, it will allow European manufacturers to test and approve covered products coming into the U.S. market. Under an MRA, conformity assessment for products going to the European market could be performed at the same time as testing for the domestic market, thereby reducing associated time, costs and uncertainties.

The MRA for Telecom equipment and EMC provides information on the scope, coverage and requirements. For access to the United States, the agreement would cover: telecommunications equipment covered by Part 68 of the FCC Rules; telecommunications equipment and electronics products subject to electromagnetic compatibility requirements under Parts 15 and 18 of the Rules; and, all radio transmitters subject to an FCC equipment authorization requirement. For access to Europe, the agreement would cover: telecommunications equipment subject to the Telephone Terminal Equipment (TTE) Directive; analog and digital terminal equipment that is not covered by the TTE Directive; all radio transmitters subject to an equipment authorization by the Member States of the European Union; and, telecommunications equipment and electronics products subject to the Electromagnetic Compatibility (EMC) Directive. For EMC, it should be noted that the Agreement covers more than just telecommunications equipment and computers -- it covers all equipment subject to the EMC Directive and Parts 15 and 18 of FCC Rules. For example, the Agreement also covers ISM equipment, radio receivers, video cassette recorders, etc., which is definitely not telecommunication equipment.

The Agreement calls for the establishment of a Joint Committee for oversight of the Agreement and a Joint Technical Sectoral Committee for Telecommunications and EMC to oversee those two Sectors. Each committee will establish their own operating rules with one vote for each party. Industry representatives will be allowed to participate in the committee at the invite of each party. The JTSC-T/EMC may address any matter related to the effective functioning of the Telecom and EMC Sectors, including:

- providing a forum for discussion of issues that may arise concerning implementation of the Sectoral Annexes;
- advising the other Parties on matters relating to the Sectoral Annexes;
- providing guidance during the transition period.

As you can imagine, there are a number of identifiable steps that need to be taken before the MRA becomes a reality. For example, the FCC must initiate one or more rule makings to change its current equipment authorization programs to empower European Laboratories to approve U.S. bound products. The USG will need to empower U.S. laboratories to approve European bound equipment to meet the European standards. NIST has in fact already taken the first step by releasing a Federal Register Notice requesting interested laboratories and accreditors to identify their interest in testing and approving equipment to EU standards. A number of laboratories already test equipment to EU standards under a contractual relationship with a competent EU laboratory. The Joint Committees, mentioned above, must be established to oversee the implementation of the MRA and to resolve disputes. A system to ensure consistent interpretations of FCC and EU regulations needs to be developed -- another detail for the JTSC-T/EMC. Post market surveillance programs need to be strengthened to ensure a level playing field for U.S. manufacturers.

On the EU side, a number of changes also have to be implemented for this MRA. For example, it is important to understand that the EU conformity assessment system is based on the existence of harmonized standards. While Europe has made great strides in harmonizing their standards, most transmitters and most analog and some digital TTE are not harmonized. Therefore, under the terms of this MRA, the EU must establish a system for the approval of equipment in which the standards are not harmonized. In some cases, Approving Bodies will have to approve equipment to the standards of each of the Member States.

SUMMARY AND CONCLUSION

The above covers most of the important key issues of the MRA between the U.S. and EU for Telecom and EMC. Many of the details will be discussed and resolved during the implementation phases of the Agreement during the two-year transition period. At the time this paper was written, it was not certain that the U.S.-EU agreement would be signed. Assuming it is signed, the copies of the Agreement will be made available through various sources and a detailed discussion of the Agreement will be presented at the Symposium. Even if the Agreement is not signed, many aspects of the MRA are being realized by other means, which also will be discussed at the presentation of this paper.

One final comment that we are obliged to make. All comments and opinions in this paper are those of the authors and do not necessarily represent those of the Commission or its staff.