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INTERNATIONAL LAW

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Volume 15 | Number 1

Article 3

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Winter 1990

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### Recommended Citation

Dan R. Mastromarco, *The European Community Approach to Standardization: A Possible Mechanism for Improved Nonmember State Input*, 15 N.C. J. INT'L L. 47 (1990).

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# The European Community Approach to Standardization: A Possible Mechanism for Improved Nonmember State Input

Dan R. Mastromarco\*

## I. The Importance of EC Standardization

The successful harmonization, implementation, and enforcement of product standards<sup>1</sup> is of paramount importance to the realization of a fully integrated European Community (EC)<sup>2</sup> as contemplated by the Single European Act.<sup>3</sup> The traditional lack of coordination in the development of product standards among the twelve EC Member States<sup>4</sup> and the failure mutually to recognize testing and certification procedures have prevented efficient product

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\* Assistant Chief Counsel for Tax Policy, U.S. Small Business Administration. The views expressed herein are wholly the author's and do not necessarily reflect those of the Small Business Administration. The author would like to thank Pat Cooke, Don Mackay, Walter Leight, and Stephen Cooney for their valuable suggestions.

<sup>1</sup> Product standards are different from certification and testing in that they are generally voluntary, technical specifications that are approved by a standard setting body. Certification attests that a product complies with technical specifications; for some products the manufacturer can declare conformity, but for others certification by a third party is necessary. Most of the standards discussed herein are product standards, but there are also process and production standards involving, for example, good laboratory practice and limits on beef hormones. Harmonization priorities have been assigned to standards for everything from toys, to cosmetics, to machine safety, to tire pressure gauges, to earth moving equipment, to radio interference. See Cooke & Mackay, *The New EC Approach to Harmonization of Standards and Certification*, 109 BUS. AM., Aug. 1, 1988, at 7 [hereinafter Cooke & Mackay].

<sup>2</sup> As one commentator has noted: "For industry and consumers, the most important goal of the European Economic Community is the creation of common technical standards." Jenkins, *Harmonization of Safety Standards*, 4 EUR. TRENDS 53, 53 (1987).

<sup>3</sup> 30 O.J. EUR. COMM. (No. L 169) (1987) (The Single European Act, adopted in February 1986, amended the Treaty of Rome). See generally *The Single Act: A New Frontier for Europe* 1987 BULL. EUR. COMM. (Supp. 1/87) (COM No. 100) (discussing the goals of integration within the EC by 1992 and the Commission's programs toward cohesion). By the end of 1992, the EC intends to complete its internal market and remove substantially all physical, technical, and fiscal barriers to the exchange of goods, services, people, and capital within the Community. The basis for the effort to unify Europe is a 1985 EC White Paper, *Completing the Internal Market*, WHITE PAPER FROM THE COMMISSION OF THE EUROPEAN COMMUNITIES TO THE EUROPEAN COUNCIL (Cat. No. 43-85-894-EN-C) (1985) [hereinafter WHITE PAPER]. See also *EC Promotes Europe's HDTV Standard*, 1 EUROPE-1992: THE REPORT ON THE SINGLE EUROPEAN MARKET 72-73 (1989).

<sup>4</sup> Belgium, Denmark, France, Germany (West), Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, and the United Kingdom comprise the European Community.

marketing throughout the EC, affecting firms both within and without the EC. Some manufacturers have been forced to modify products and retool in order to comply with frequently changing, country-specific requirements.<sup>5</sup> Other firms, especially smaller companies, have been discouraged from expanding into new markets.<sup>6</sup> From the consumers' perspective, the need to have products modified, tested, retested, certified, and recertified for export to markets in neighboring countries causes delay, stifles competition, increases costs, and may reduce product selection.<sup>7</sup>

The concept behind harmonized standards throughout the EC is unassailable and is generally supported by U.S. exporters<sup>8</sup> and EC nationals.<sup>9</sup> Uniform health, safety, and environmental standards,<sup>10</sup> if properly implemented, would benefit most exporters to the EC as well as most Member State industries by eliminating barriers to the efficient flow of goods, and perhaps services, throughout the EC.<sup>11</sup>

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<sup>5</sup> Thompson, *EC92*, NATION'S BUSINESS, June 1989, at 22.

<sup>6</sup> Grant, *The Effects of Product Standardization on Competition: Octane Grading of Petrol in the UK*, in PRODUCT STANDARDIZATION AND COMPETITIVE STRATEGY 284 (H. Gabel ed. 1987) [hereinafter Grant]. See COMM. ON COMMERCE AND INT'L TRADE, OBSTACLES FACED BY SMALL BUSINESS EXPORTERS, S. REP. NO. 249, 97th Cong., 2d Sess. (1982); Comment, *U.S. Government Export Incentives for Small Business*, 22 INT'L LAW. 791 (1988).

<sup>7</sup> Farrell & Saloner, *Competition, Compatibility and Standards: The Economics of Horses, Penguins and Lemmings*, in PRODUCT STANDARDIZATION AND COMPETITIVE STRATEGY 1-19 (H. Gabel ed. 1987) [hereinafter Farrell & Saloner]; Hayes, *Who Sets the Standards?: One Reason for the Trade Deficit*, FORBES, Apr. 17, 1989, at 110 [hereinafter Hayes] (citing the delay of entry into Saudi Arabian port of a shipment of nonconforming goods from Clorox and Westinghouse).

<sup>8</sup> P. CECCHINI, 1992 THE EUROPEAN CHALLENGE: THE BENEFITS OF A SINGLE MARKET, ch. 4 (1988).

<sup>9</sup> *European Consumers: Their Interest, Aspirations and Knowledge on Consumer Affairs* 132 (EC No. CT X/509/76-E) (May 1976) (results and analysis of a sample survey carried out by the EC) [maintained in the office of the N.C.J. INT'L L. & COM. REG.]. This analysis of data from 9,500 individuals from nine Member States indicated that the attitudes of consumers were six to one in favor of the common market. Nearly 70% took the view that integration will enable consumers to have a wider range of products. *Id.*

<sup>10</sup> Standards for health, safety, and the environment are mandated via EC Directives. The Directives establish the framework for these standards which are then worked out in the technical committees of the European regional standard setting bodies. See *infra* notes 45-56 and accompanying text (describing the Directive stage standard setting). Other standards are not mandatory, but are harmonized through the regional, voluntary, standard setting bodies. See *infra* 71-77 and accompanying text.

<sup>11</sup> See Branstad & Waldenstrom, *Europe 1992: Threat or Opportunity*, in SPECIAL REPORT OF BOOZ ALLEN & HAMILTON 5 (1989).

According to the U.S. Department of Commerce the harmonization process, in conjunction with positive changes to promote greater efficiency and economic growth, is projected to increase demand for U.S. goods by \$260 billion. Verity, *U.S. Business Needs to Prepare Now For Europe's Single Internal Market*, 109 BUS. AM., Aug. 1, 1988, at 2 (statement of C. William Verity, U.S. Secretary of Commerce). The EC, as a whole, will constitute a market of 320 million people, with a Gross Domestic Product of \$702 billion. Furthermore, this market is a major consumer of U.S. products; 24% of all U.S. exports were sold to the EC. See *Europe 1992: Economic Integration Plan, Hearings Before the Subcomm. on Europe and the Middle East, and on International Economic Policy and Trade of the House Comm. on Foreign Affairs*, 100th Cong., 1st Sess. 287 (1989) (Hrg. Rep. 23-441) (statement of Manuel Peralta of the American National Standards Institute) [hereinafter Hrg. Rep. 23-441]. U.S. ex-

As one commentator observed, uniform standards may also "contribute to raising the global standard of living by allowing surplus goods from one area to find markets where needed."<sup>12</sup> Establishing uniform standards throughout the EC will facilitate the movement of goods, stimulate competition, and reduce product costs.

Specific benefits of standardization for the producer include a reduction of average costs through scale economies; cost reduction through use of interchangeable parts; a reduction of storage and of logistics costs in international or interfirm trade; a reduction of liability insurance costs in the case of potentially unsafe or unhealthy products; and a facilitation of corporate strategies emphasizing quality control on a permanent basis.<sup>13</sup> The benefits of standardization for the consumer include a reduction in the costs of information with respect to the properties, quality, or compatibility of products and components; a reduction in the cost of learning how to use a product, for example, cameras, computers, and typewriters; network externalities;<sup>14</sup> and an appreciation of some of the benefits that accrue to producers.<sup>15</sup>

Exporters to the EC, however, fear that the standards being promulgated and the certification and testing procedures being adopted<sup>16</sup> will serve to hinder, rather than facilitate access to the EC market.<sup>17</sup> Directives, regulations, and standards intended to harmo-

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ports to the EC were valued at \$75 billion in 1988, accounting for approximately 2 million U.S. jobs. *The European Community's Plan to Integrate Its Economy by 1992: Hearing Before the Subcomm. on International Economic Policy and Trade of the House Comm. on Foreign Affairs*, 101st Cong., 1st Sess. app. at 15 (1989) (Hrg. Rep. No. 23-360) (statement of Glennon Harrison, analyst in International Trade and Finance, Congressional Research Service) [hereinafter Hrg. Rep. 23-360].

<sup>12</sup> J. Ready, *ANSI Standards X.12 and X.400: A Study of the Social Issues Caused by Standardization* 44 (Georgetown Univ. Thesis 5725).

<sup>13</sup> Farrell & Saloner, *supra* note 7, at 6-17.

<sup>14</sup> Network externalities are positive external consumption benefits, *i.e.*, the sense that the utility derived by a consumer from the use of a product increases with the number of other consumers purchasing compatible products.

<sup>15</sup> Farrell & Saloner, *supra* note 7, at 6. "In a perfectly competitive market all cost savings that reduce marginal costs are passed on to buyers . . ." *Id.* at 18 n.4. For specific case studies, see Pelkmans & Beuter, *Standardization and Competitiveness: Private and Public Strategies in the EC Color TV Industry*, in *PRODUCT STANDARDIZATION AND COMPETITIVE STRATEGY* 171 (H. Gabel 1987); Grant, *supra* note 6, at 283; Rohlfs, *A Theory of Interdependent Demand for Communications Service*, 5 *BELL J. ECON.* 16, 16-37 (1974).

<sup>16</sup> The United States hopes to reach an accord with the EC whereby testing and certification for EC-destined products can take place in the United States. *European Single Market: Issues of Concern to U.S. Exporters, Report to the Chairman, Subcomm. on Int'l Trade, of the Senate Comm. on Finance* 21 (GAO No. NSIAD-90-60 European Market) (1990) [hereinafter *European Single Market*]. It is not clear at this time whether all U.S.-made products that require certification will have to be tested by an EC-accredited body. "The EC Commission proposal of July 1989 provides for negotiations with non-EC governments to enable EC 'notified bodies' to accept test data and certificates from non-EC testing bodies." *Id.*

<sup>17</sup> See, *e.g.*, De Smedt, *Common Market, Single Market or Fortress Europe?*, 7 *INT'L FIN. L. REV.* 14, 14-15 (1988); Rosenbaum, *European Standards Panel: Americans Keep Away!*, 15 *ELECTRONICS BUS.*, July 24, 1989, at 95-96. The U.S. Government has also expressed this concern. See U.S. GOV'T INTERAGENCY TASK FORCE ON THE E.C. INTERNAL MARKET, PUB.

nize product requirements may result in the inadvertent exclusion of nonmember state trade with the Community if adopted without meaningful consideration of nonmember viewpoints.<sup>18</sup> Such a process acts to the detriment of all participants in the stream of commerce—EC consumers as well as EC and non-EC exporting industries.<sup>19</sup>

Recognizing the far-reaching effects of EC standardization efforts,<sup>20</sup> nonmember state exporters have been keenly interested in participating in critical stages of the standard-setting process.<sup>21</sup> To date, though, most of these exporters have had limited access to the formal EC standardization process.<sup>22</sup> The EC Commission, which initiates legislation, has thought it inappropriate to grant nonmember industries the opportunity to review and comment during the development of proposed EC Directives.<sup>23</sup> Instead, the Commission

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NO. 1288, COMPLETION OF THE EUROPEAN COMMUNITY INTERNAL MARKET: AN INITIAL ASSESSMENT OF CERTAIN ECONOMIC POLICY ISSUES RAISED BY ASPECTS OF THE EC'S PROGRAM (Dec. 1988).

<sup>18</sup> Hayes, *supra* note 7, at 110 (criticizing the U.S. failure to take advantage of international standard setting organizations).

<sup>19</sup> See Cooke & Mackay, *supra* note 1, at 8.

<sup>20</sup> Hrg. Rep. 23-441, *supra* note 11, at 226-27 (testimony of Steve Lovett, Pres. of Forest Product Industries Association, Apr. 13, 1989).

<sup>21</sup> The desire of industry to participate in the EC standard setting process, whether the standards are mandatory or voluntary, is best exhibited by the record of comments received in Congressional hearings and at U.S. Department of Commerce hearings. See generally Hrg. Rep. 23-441, *supra* note 11 (a compilation of the oral and written statements received). The U.S. Government Interagency Working Group on EC Standards, Testing and Certification Issues received oral comments from 23 witnesses at the Department of Commerce hearings, ranging from statements by Manuel Peralta of the American National Standards Institutes to Doug Thompson of the Toy Manufacturers of America. Another 29 written submissions were reviewed, mostly from specific exporting companies. *Id.* See also U.S. Dept. of Commerce News, Office of the Secretary, Press Release No. G 89-14 (May 31, 1989) (regarding a meeting between U.S. Secretary of Commerce Mosbacher and Martin Bangemann, EC Vice President for Internal Market and Industrial Affairs on May 31, 1989, over the issue of lack of access to EC standards setting boards); CONG. RES. SERV., LIBR. OF CONG., 101ST CONG., 1ST SESS., EUROPEAN COMMUNITY: ISSUES RAISED BY 1992 INTEGRATION, REPORT PREPARED FOR THE SUBCOMM. ON INTERNATIONAL ECONOMIC POLICY AND TRADE OF THE HOUSE COMM. ON FOREIGN AFFAIRS (Comm. Print 1989) (Staff Rep. 98-597).

<sup>22</sup> Effect of Greater Economic Integration Within the European Community of the United States, USITC Pub. No. 2204, 6-8 n.8 (1989).

On the other hand Austria, Finland, Iceland, Norway, Sweden, and Switzerland are the members of the European Free Trade Association (EFTA). EFTA is represented on the technical committees of the Committee for European Standardization (CEN) and the Committee for European Electrotechnical Standardization (CENELEC) and so has had the opportunity to participate in the voluntary standard setting process. *Id.* at 12. See *infra* note 49 and accompanying text. See generally Iloniemi, *The Possibilities for a Moderate Integration Policy*, 61 UNITAS (Finland) 34, 34-40 (1989). CEN and CENELEC are defined as non-governmental European standardization bodies. Cooke & Mackay, *supra* note 1, at 9. CEN and CENELEC represent both EC member countries and EFTA countries as well. See *infra* note 67 and accompanying text.

<sup>23</sup> John Farnell, Director of the Division of Standardization and Certification in the EC office of the Directorate-General for Internal Market and Industrial Affairs has said: "It is not in the interests of the Community . . . to open European standard setting for manufactured goods and products to U.S. and other non-EC industry representatives." EC

has generally consulted only with EC industry and Member States in drafting the essential requirements<sup>24</sup> for standards.<sup>25</sup> Non-EC member industries have been excluded from the voting technical committees of the Committee for European Standardization (CEN) and the Committee for European Electrotechnical Standardization (CENELEC), and those industries without a European presence have not been given observer status at committee meetings.<sup>26</sup> In a later stage, when the Directives are forwarded to the voluntary standard setting bodies, nonmember input is again blocked. Non-EC members have been able to provide input only after the standards have been published in final proposed form.<sup>27</sup> At each stage in the process nonmember state industry input is prevented until it is too late for meaningful consideration of their views.

This Article briefly describes the current standard setting procedures within the EC<sup>28</sup> and suggests that the Community should: (1)

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*Official Rejects Role for Outsiders on Standards, But Promised Flexibility*, Daily Executive Rep. (BNA) No. 82, at A-1 (May 1, 1989) (speaking at a press briefing on Apr. 27, 1989, following a U.S. Department of Commerce administrative hearing on the exclusion of U.S. corporate access to European standard setting boards). Farnell indicated that the EC will "resist" recent requests for participation in these processes from U.S. manufacturers and others. *Id.* Farnell further indicated, however, that the EC will allow greater transparency through the publication of monthly reviews of activities of CEN and CENELEC to the American National Standards Institute (ANSI). *Id.* Such statements have confirmed fear over a lack of access to regional standard setting boards.

<sup>24</sup> "Essential requirements" are broadly worded directives that define the frameworks for health, safety, and environmental standards applicable to products or processes. These essential requirements become law throughout the EC community and are developed into more specific technical requirements in the technical committees of the regional standard setting bodies, such as CEN and CENELEC. WHITE PAPER, *supra* note 3, para. 68, at 20.

<sup>25</sup> John Kinn, Staff Vice-President for the Electronics Industry Association, stated:

I can show you a set of correspondence . . . between ourselves and ETSI [European Telecommunications Standards Institute] in which [the electronics industries] have specifically asked to participate in the ETSI committees. And quite frankly, we have another letter back from them specifically stating that they will not do that. We are clearly at a disadvantage and we need to . . . take the steps to try to rectify that situation.

Hrg. Rep. 23-441, *supra* note 11, at 234.

Mr. Lovett, Vice President for the International Trade Council, National Forest Products Association, stated "[Our] [a]ssociations have been excluded from this process. They have requested to attend the CEN meetings. They are not travelling from the United States. They are based and established in Europe. But they have been excluded." *Id.* at 262.

<sup>26</sup> Again, EFTA countries are exceptions in that they have enjoyed limited access. See *supra* note 22 and accompanying text. Also, the ETSI, "an autonomous body set up in 1988 to develop telecommunications standards in Europe, . . . allows nonmember organizations to obtain observer status, conveying the right to speak, but not to vote." *European Single Market*, *supra* note 16, at 17.

<sup>27</sup> Hrg. Rep. 23-441, *supra* note 11, at 295. See *infra* notes 45-56 and accompanying text for a discussion of the standard setting procedure. In sum, after successive drafts, the EC Commission proposes a Directive containing "essential requirements" of a standard which is transmitted simultaneously to the Parliament and the Council for development in an iterative process. When signed by the Council, the Directive is normally accompanied by a mandate to the private sector standard bodies, CEN and CENELEC, to formulate voluntary standards.

<sup>28</sup> See *infra* notes 45-56 and accompanying text.

formalize procedures leading to the development of standards, testing, and certification criteria;<sup>29</sup> and (2) provide for a means of participation in this process by all interested parties.<sup>30</sup> The Article proposes that the EC would benefit by adopting a mechanism, modeled after the U.S. Administrative Procedure Act (APA),<sup>31</sup> to ensure that comments by non-EC member industries are considered. It is beyond the scope of this Article to describe in detail a comprehensive application of the APA to standard setting in the EC. Instead, this Article calls for an open dialogue on the best means to achieve a more efficient standard setting process and suggests that the APA is a valuable model on which to base these decisions.

The APA's notice and comment provisions permit companies, both foreign and domestic, to comment on all rules, including standards, proposed by U.S. Governmental agencies.<sup>32</sup> Much of the rulemaking taking place in government agencies, especially the Environmental Protection Agency, the Federal Communications Commission, the Occupational Safety and Health Administration, the Federal Aviation Administration, the Consumer Products Safety Commission, and the Department of Agriculture involves standard setting. These agencies alone may mandate federal standards. They issue standards in a wide variety of matters, but such standards concern all matters encompassed by the EC Directives standard setting

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<sup>29</sup> See *infra* notes 57-77 and accompanying text.

<sup>30</sup> *Id.*

<sup>31</sup> Pub. L. No. 404, ch. 324, 60 Stat. 237 (1946) amended by Pub. L. No. 89-554, 80 Stat. 378 (1966) (codified as amended at 5 U.S.C. §§ 551-59, 701-06 (1988)). More specifically, the mechanism should be modeled after the notice and comment provisions of §§ 553 and 556. *Id.* See *infra* 78-92 and accompanying text.

<sup>32</sup> *Id.* § 553(c). The APA draws no distinction between foreign based companies and domestic companies in its requirements to consider views and to base a decision upon those views. 5 U.S.C. § 553 (1988). There are numerous instances in which U.S. agencies in the process of setting both voluntary and mandatory standards have considered the views of non-U.S. companies and representatives. Some examples where foreign views were considered in Department of Agriculture rulemaking proceedings are: 51 Fed. Reg. 23,037 (1986) (codified at 7 C.F.R. § 28.402); 51 Fed. Reg. 12,498 (1986) (codified at 7 C.F.R. §§ 925, 944); 51 Fed. Reg. 41,071 (1986) (codified at 7 C.F.R. § 966); 51 Fed. Reg. 17,354 (1986) (codified at 7 C.F.R. § 980); 52 Fed. Reg. 8,865 (1987) (codified at 7 C.F.R. §§ 925, 944); 52 Fed. Reg. 5,307 (1987) (codified at 7 C.F.R. §§ 982, 999); 54 Fed. Reg. 48,735 (1989) (codified at 7 C.F.R. § 810). In addition, non-U.S. companies are represented and vote on some of the technical committees of U.S. standard setting boards. See Hrg. Rpt. No. 23-441, *supra* note 11, at 295-96 (statement of Joe Bhatia, Vice President, Governmental Affairs for Underwriters Laboratories, Inc.). See generally Thorp, *Standards and International Relations*, in NATIONAL STANDARDS IN A MODERN ECONOMY ch. 32 (D. Reck ed. 1958).

There are, however, a number of nongovernmental standard setting bodies in the United States composed of industry associations, for which input is only possible by membership. There are over 400 nongovernmental standard setting bodies in the United States according to the National Institute for Standards and Technology (NIST). NAT'L BUREAU OF STANDARDS, PUB. NO. 681, STANDARDS ACTIVITIES OF ORGANIZATIONS IN THE U.S. (1984) (currently being revised). These standard setting bodies have been responsible for the issuance of approximately 30,000 voluntary standards. *European Single Market*, *supra* note 16, at 15.

process for health, safety, and the environment. Development of a formal mechanism to consider the views of non-EC member industries in an organized manner would promote the underlying purpose of the Single European Act,<sup>33</sup> would be consistent with the treatment of foreign-based firms under formal U.S. rulemaking procedures,<sup>34</sup> and would benefit the EC and its trading partners by improving the prospect of foreign trade, reducing incompatibility of goods, and by making the production of goods more efficient.<sup>35</sup>

## II. The EC's "New Approach" to Standard Setting

The EC has resolved to harmonize standards and procedures for testing and certification in order to allow products to circulate freely within the Community by the end of 1992.<sup>36</sup> The movement towards full EC standard harmonization is derived from the general principle that "if a product is lawfully manufactured and marketed in one Member State, there is no reason why it should not be sold freely throughout the Community."<sup>37</sup>

In order to unify standards and adopt procedures for the mutual recognition of testing and certification the EC recently discarded the approach it had followed for more than twenty-five years in favor of a

<sup>33</sup> 30 O.J. EUR. COMM. (No. L 169) (1987). Community law is derived from an "approximation" of the collective legal principles of the member states. Article 3 of the EEC Treaty provides that "the activities of the Community shall include . . . the approximation of the laws of the member States . . ." Treaty of Rome, Mar. 25, 1957, arts. 3, 298 U.N.T.S. 3, at 7.

<sup>34</sup> The comparison between the EC Directives standard setting process and the U.S. process was briefly described in Congressional hearings:

Cong. GEJDENSON. What about the consumer product safety standard? Those aren't mandatory?

Mr. KINN. Those are mandatory.

Cong. GEJDENSON. . . . Do the Europeans have total access to those? Is it a totally transparent process?

Mr. KINN. To the degree that they appear before the Consumer Product Safety Commission—

Cong. GEJDENSON. Treated just like any other American company.

Mr. KINN [continuing]. They would be treated like anyone else . . .

Hrg. Rpt. 23-441, *supra* note 11, at 271 (testimony of John Kinn, Staff Vice President of the Electronic Industries Association).

<sup>35</sup> Consistency in the iterative process of developing standards may lead to consistency in the substance of such standards. At the very least the adoption of a formal mechanism modeled after the APA will allay the fears of nonmember states by creating a public forum for the consideration of their views. It will also permit introduction of a wider range of studies on the effects of certain production and process methods on health, safety, and the environment, and will give participants faith in the process of standard development.

<sup>36</sup> 30 O.J. EUR. COMM. (No. L 169) art. 13, at 7 (1987) (Single European Act). See Lamoriello, *Completing the Internal Market by 1992: The EC's Legislative Program for Business* 109 BUS. AM., Aug. 1, 1988, at 4-5 (discussing the harmonization process and listing priority harmonization areas).

<sup>37</sup> WHITE PAPER, *supra* note 3, para. 58, at 20. For a detailed discussion of the rationale for the harmonization effort and the "new strategy" chosen see paras. 57-80 of the WHITE PAPER. See also Hrg. Rpt. No. 23-360, *supra* note 11, at 44.



“new approach.”<sup>38</sup> In order to progress quickly on unifying standards the “new approach” to standardization adopted two significant changes geared towards greater flexibility and expediency. First, the new procedure provides for qualified majority<sup>39</sup> approval of Directives by EC member countries.<sup>40</sup> The traditional approach, based upon Article 100 of the Treaty of Rome,<sup>41</sup> generally required unanimous approval by Member States for the creation of Directives.<sup>42</sup> Technical standards were written directly into EC legislation.<sup>43</sup> Although unanimity served to safeguard the interests of individual Member States, it contributed to a greater evil—delay in achieving the goals of integration by 1992. Second, for nonessential characteristics of products mutual EC Member State recognition of the adequacy of national standards is required.<sup>44</sup>

#### A. *The European Community Directives Standard Setting Apparatus*

There are two distinct processes at work in the efforts to harmonize standards in the EC. In the first process—the Directive standard setting process—certain standardization priorities for “regulated products” are set by the EC and its members through the Council.<sup>45</sup> The Directives promulgated by the EC under this process are limited to defining “essential requirements” for health, safety, environmental, and in some cases, industrial policy concerns as determined by the Commission,<sup>46</sup> Parliament, and the Council of Ministers.<sup>47</sup> The task of developing technical specifications to implement the Direc-

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<sup>38</sup> WHITE PAPER, *supra* note 3, paras. 60-61, at 17-18. 30 O.J. EUR. COMM. (No. L 169) arts. 6-7, at 5-6 (1987).

<sup>39</sup> Under qualified majority voting principles, different EC member states are given different numbers of votes. Germany, France, Italy, and the United Kingdom each have ten votes; Spain has eight; Belgium, the Netherlands, Greece, and Portugal each have five; Denmark and Ireland each have three; and Luxembourg has two. Fifty-four votes are required for Community action; therefore, the minimum number of member states required to take Community action is seven. Hrg. Rpt. No. 23-441, *supra* note 11, at 289.

<sup>40</sup> WHITE PAPER, *supra* note 3, paras. 67-68, at 20.

<sup>41</sup> Treaty of Rome, *supra* note 33, arts. 100, 298 U.N.T.S. at 54.

<sup>42</sup> See WHITE PAPER, *supra* note 3, para. 61, at 18 (calling for more flexibility in the operation of article 100). Majority vote was permitted, however, for veterinary and phytosanitary controls under Article 43 of the Treaty of Rome. Treaty of Rome, *supra* note 33, art. 43, 298 U.N.T.S. at 32-33.

<sup>43</sup> *European Single Market*, *supra* note 16, at 16.

<sup>44</sup> See WHITE PAPER, *supra* note 3, para. 77, at 22.

<sup>45</sup> Cooke & Mackay, *supra* note 1, at 8.

<sup>46</sup> The seventeen-member Commission, in effect the executive branch of the EC, is entrusted with the interests of the Community as a whole, independent of political or nationalistic concerns. Sitkov, *The European Economic Community: A Sovereign Entity Under its Own Legal Order*, 16 INT'L J. LEGAL INFO. 177, 183 (1988) [hereinafter Sitkov].

<sup>47</sup> The Council of Ministers consists of the Heads of State or Heads of Government from the twelve Member States, and is the principal centralized legislative body of the EC. See Treaty of Rome, *supra* note 33, arts. 145-46, 298 U.N.T.S. at 69. The Council's task is to set the law of the Community by making regulations, guidelines, and decisions. For a general overview of the genesis and function of EC organs, see Sitkov, *supra* note 46, at 177-89.

tives is then usually delegated to certain nongovernmental, regional<sup>48</sup> bodies that are authorized to act by qualified majority vote. Such regional bodies include the *Comité Européen de la Normalisation* (CEN), which deals with mechanical standards, and the *Comité Européen de Normalisation Electrotechnique Standardisation* (CENELEC), which deals with electrical standards. CEN and CENELEC are made up of national standard setting boards.<sup>49</sup> These private, regional standard setting bodies formulate specific technical standards meeting the essential requirements in harmony, if possible, with international standards.

The second process involves the continuing efforts of the private standard setting bodies to unify standards. Where national product regulations already exist, the regional standard bodies are responsible for their harmonization.<sup>50</sup> CEN and CENELEC's policy is to base their work on international standardization organizations, which may be adopted with modification to meet EC criteria.<sup>51</sup> When CEN and CENELEC commence work on a European-wide standard, the national committees cease work until the European standard is finalized. Individual Member States may adopt their own unique standards only if uniform standards are not promulgated for the EC.<sup>52</sup>

These two processes, so vital to the success of the integration of the EC as contemplated by the Single European Act, will eventually culminate in the replacement of all national regulatory standards with uniform standards applicable throughout the EC.<sup>53</sup> This development is a logical extension from the removal of border controls.<sup>54</sup>

The Council of Ministers has acted swiftly, initiating an ambitious program consisting of more than 200 Directives intended to eliminate differing standards.<sup>55</sup> Moreover, a high percentage of in-

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<sup>48</sup> "Regional" encompasses both EFTA and EC countries. See *supra* note 22 and accompanying text.

<sup>49</sup> See *supra* note 22. These boards are generally funded by their respective governments and promulgate what have been described as "quasi-governmental" standards. See Hrg. Rpt. No. 23-441, *supra* note 11, at 269.

<sup>50</sup> See WHITE PAPER, *supra* note 3, paras. 71-80, at 20-21.

<sup>51</sup> Two examples of international standard setting bodies are the International Electrotechnical Commission (IEC) and the International Standards Organization (ISO). See U.S. Dept. of Commerce News, International Trade Administration, Press Release No. ITA 89-68 (Oct. 6, 1989) (joint press release communique in which U.S.-EC officials reaffirmed their commitment to the work of international standardization bodies).

<sup>52</sup> See WHITE PAPER, *supra* note 3, para. 4, at 4. "The Treaty [of Rome] clearly envisages from the outset the creation of a single integrated internal market free of restriction on the movement of goods . . ." *Id.* Existing European standardization bodies have been recently restructured into a coherent group with a clear framework for mutual consultation and decision-making.

<sup>53</sup> *Id.* para. 69, at 20.

<sup>54</sup> *Id.* para. 11, at 6. See *supra* note 3 and accompanying text.

<sup>55</sup> See P. COOKE, A SUMMARY OF THE NEW EUROPEAN APPROACH TO STANDARDS DEVELOPMENT (Nat'l Bureau of Standards Pub. No. NBSIR 88-3793, 1988). "High priority" areas have included gaseous emissions, diesel particulates, helicopter exhaust noise, food

ternational standards adopted as national standards by EC member state standard setting institutes have facilitated harmonization.<sup>56</sup>

*B. The European Community Notification and Comment Provisions*

The "new approach" to standardization contemplates several notification and comment requirements to ensure that affected groups within the EC are aware of proposals to set standards and have the opportunity to influence those proposals. According to the Commission's 1985 White Paper "it is essential that in all programmes designed to achieve a unified internal market, the interests of all sections likely to be affected, e.g. both sides of industry, commerce and consumers are taken into account."<sup>57</sup> Accordingly, the Commission has taken steps to ensure that EC consumer interests, as well as EC industry interests, are considered.<sup>58</sup> In fact, Member States now must notify the Commission in advance of all draft regulations concerning technical specifications that they intend to introduce in their own territory.<sup>59</sup>

Despite the provisions for EC Member State input, however, non-EC member input has been limited at each critical stage of standard development: (1) when the Commission first drafts the frameworks for the Directives, and (2) when CEN and CENELEC develop technical specifications. Although European Free Trade Association (EFTA) countries can formally participate in the standard setting process,<sup>60</sup> other non-EC member participation is at best informal and indirect.<sup>61</sup> The most effective informal participants in this process are multinational companies or those with affiliates or subsidiaries in the EC. To understand the difficulty nonmember state industries have in gaining access to the standardization process

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law, pharmaceuticals and high technology medicines, chemical products, construction and construction equipment, tower cranes, cosmetics, and even good laboratory practices for nonchemical tests.

<sup>56</sup> *European Single Market*, *supra* note 16, at 17. "ISO and IEC standards now comprise 43% of Danish standards, 37% of French standards, 22% of Dutch standards, 16% of British standards, and 5% of German standards." *Id.*

<sup>57</sup> WHITE PAPER, *supra* note 3, para. 72, at 21.

<sup>58</sup> As discussed *supra* note 22, the EC considers EFTA interests even where other non-EC members are excluded.

<sup>59</sup> This provides for pre-approval by the Commission and the other member states. See 26 O.J. EUR. COMM. (No. L 109) art. 18, at 8 (1983) (Directive 83/189/EEC). If the Commission and the other Member States determine that the draft regulations contain any elements likely to create barriers to trade, they may start remedial action under Articles 30 and 100 of the Treaty of Rome. See WHITE PAPER, *supra* note 3, para. 75, at 21.

<sup>60</sup> For information on the relationship between EFTA and the EC, see EEC AND EFTA: MORE THAN JUST GOOD FRIENDS? (J. Jamar & H. Wallace eds. 1988) (proceedings of the symposium organized by the College of Europe in Bruges on 30 June and 2 July 1988).

<sup>61</sup> Telephone interview with Donald Mackay, Former Chief, Office of Standards Code and Information, National Institute of Standards and Technology (Mar. 7, 1990) [hereinafter Mackay Interview].

it is necessary to examine the process from the formulation of frameworks for essential requirements to the implementation of technical specifications.

The standardization process is obtuse and many of the procedures are unwritten. The process begins when the Commission develops a proposed draft<sup>62</sup> for "essential requirements" in a proposed EC Directive. This Directive typically is revised through successive drafts. At each stage in the drafting process the Commission may seek the advice of individual EC industries or industry associations. Nonmember industry input at this critical stage, however, depends upon the industry's awareness of the proposed items and the access of the individual participants to the process. Multinational corporations and non-EC companies with a base in Europe, therefore, have an advantage. In practice, however, the process of developing draft frameworks is closed to the general public and comment is not solicited.<sup>63</sup>

When the framework for a Directive is in final form the Commission transmits the document to the EC Parliament and EC Council. At this stage, the proposal becomes generally available for review as a public document. The Parliament, currently made up of 518 members apportioned among the Member States, is not a legislative body, but it is empowered to consider the proposed framework and comment on the legislation.<sup>64</sup> Parliament then transmits the proposal, with its recommendations, to the Council of Ministers. The Council may either finalize the proposal as a Directive, or return it to Parliament for further consideration. The Council must coordinate the general economic policies of the Member States and make the decisions necessary to carry out the Treaty provisions.<sup>65</sup> Both the Council and Parliament may receive comments about the proposal from interested parties but no formal mechanism ensures their consideration.

The Directive, when approved by the Council, binds member and non-EC member states to the framework of "essential requirements" for the product or process at issue. These "essential requirements" are then adopted by each of the Member States in its individual legislative process. Following Council approval, the framework also passes to the relevant private standard setting body, such as CENELEC or CEN, for the required development of specific,

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<sup>62</sup> *Id.* The Commission may develop a more specific standard at this stage, however, which is normally considered a regulation.

<sup>63</sup> Hrg. Rep. No. 23-441, *supra* note 11, at 22 (statement of Kyle Pitsor, manager of International Affairs, National Electrical Manufacturers Association). See also Cooke & Mackay, *supra* note 1, at 8.

<sup>64</sup> Sitkov, *supra* note 46, at 181. Members of Parliament sit in political, rather than national groups. *Id.*

<sup>65</sup> *Id.* at 182.

voluntary standards.<sup>66</sup> Eventually products must be marketed in accordance with the essential requirements as contained in the Directive. Although it is theoretically possible to demonstrate conformity with the essential requirements themselves, the easiest way to demonstrate compliance is to conform with the technical specifications of the regional bodies.

CEN and CENELEC are private sector organizations composed of the standardization institutes of each Member State.<sup>67</sup> The institutes, in turn, are either official governmental entities or private sector entities with official governmental recognition. An example of the latter is the British Standards Institution.<sup>68</sup> Each member institute has a maximum representation of three delegates to the technical committees of CEN and CENELEC. These three representatives to the technical committees normally include industry representatives, government officials, academicians, consumer advocates, or some combination of these.<sup>69</sup> The functions of CEN and CENELEC are also heavily subsidized by the Member States.

From a legal standpoint, non-EC member industries have the same opportunity for notice and comment as Member State industries when the Directive passes through the Commission, the Parliament, and the Council. Because there is no formal mechanism for notice and comment regarding the framework, both member and

<sup>66</sup> WHITE PAPER, *supra* note 3, para. 68, at 19-20. The preparation and coordination of the Council's work is carried out by the Committee of Permanent Representatives, composed of national civil servants and ambassadors from Member States. See Sitkov, *supra* note 46, at 182.

<sup>67</sup> The members of CENELEC are: Austria (*Osterreichisches Elektrotechnisches Komitee (OKK)*), *Osterreichischen Verband fur Elektrotechnik (OVE)*); Belgium (*Comité Electrotechnique Belge (CEB)*); Switzerland (*Electrotechnique Suisse (CES)*); Germany (*Deutsche Elektrotechnische Kommission im DIN und VDE (DKE)*); Denmark (*Dansk Electroteknisk Komite (DEK)*); Spain (*Comite Espanol del CENELEC (Asociación Electrotécnica y Electronica Espanola (AEE))*); Finland (*Finnish Electrotechnical Standards Assn. (SESKO)*); France (*Union Technique de l'Electricité (UTE)*); Greece (*Hellenic Organization for Standardization (ELOT)*); Ireland (*Electro-Technical Council of Ireland (ETCI)*); Iceland (*The Icelandic Council for Standardization, Technological Institute of Iceland*); Italy (*Comitato Elettrotecnico Italiano (CEI)*); Luxemburg (*Service de l'Energie de l'Etat*); the Netherlands (*Nederlands Electrotechnisch Comité (NEC)*); Norway (*Norsk Electroteknisk Komite (NEK)*); Portugal (*Portuguese Institute for Quality*); Sweden (*Swedish Electrotechnical Commission (SEK)*); and the United Kingdom (*British Electro-technical Committee, British Standards Institute*).

The eighteen members of CEN are: Spain (*Asociación Espanola de Normalizacion y certificación (AENOR)*); France (*Association Francaise de Normalisation (AFNOR)*); United Kingdom (*British Standards Institution (BSI)*); West Germany (*Deutsches Institut für Normung (DIN)*); Denmark (*Dansk Standardiseringsrad (DS)*); Greece (*Ellmikis Prganismos Typopiiseos (ELOT)*); Belgium (*Institut Belge de Normalisation (IBN)*); Portugal (*Instituto Portugues da Qualidade (IPQ)*); Luxembourg (*Inspection du Travail et des Mines (ITM)*); the Netherlands (*Nederlands Normalisatie-Instituut (NNI)*); Ireland (*National Standards Authority of Ireland (NSAI)*); Norway (*Norges Standardiseringsforbund (NSF)*); Austria (*Osterreichisches Normungsinstitut (ON)*); Finland (*Suomen Standardisoimisliitto (SFS)*); Sweden (*Suomen Standardiseringskommissionen i Sverige (SIS)*); Switzerland (*Schweizerische Normen-Vereinigung (SNV)*); Iceland (*Technological Institute of Iceland (STRI)*); Italy (*Ente Nazionale Italiano di Unificazione (UNI)*).

<sup>68</sup> Mackay Interview, *supra* note 61.

<sup>69</sup> *Id.*

nonmember concerns must be informally voiced through industry representatives. From a practical standpoint, however, non-EC member industries are placed at a severe disadvantage. EC industries have direct access either to the elected officials in Parliament or to the appointed officials of the Commission, and thus their interests may be represented there despite the non-nationalistic roles of these groups. As a result, they are better informed of the progress of the proceedings and the content of proposed drafts. They are also better situated to comment on those drafts and to have their comments considered. Furthermore, although there is an opportunity for non-EC members to comment at both the Parliamentary and Council stages of the proceedings, the interests of Member State industries will likely receive primary consideration. The Ministers are not generally receptive to frameworks for essential requirements that do not favor each of their own nation's economic interests.<sup>70</sup>

### C. *The European Community "Voluntary" Standards*

The development by CEN and CENELEC of technical specifications to conform with the essential requirements is perhaps the most important stage in the promulgation of standards. The consideration of detailed technical specifications at this stage is comparable to the promulgation of proposed regulations by U.S. governmental agencies, except that the standards developed by CEN and CENELEC are voluntary.<sup>71</sup> Consideration of non-EC member inter-

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<sup>70</sup> "EC policymakers, like their U.S. counterparts, face internal pressure to protect domestic industry from foreign competition. The extent to which these policymakers succumb to this internal pressure will test the EC's commitment to establishing a rational, nonprotectionist European economy." Hrg. Rpt. No. 23-360, *supra* note 11, app. at 13.

<sup>71</sup> The standards are voluntary only because it is possible to satisfy the essential requirements directly. The notification aspects under the GATT Standards Code may be applicable to the Directive-standards system. The GATT Code would not mandate notification from these nongovernmental, voluntary standard setting bodies, regardless of whether these standards are harmonized. Statement by Walter Leight, Acting Deputy Director, Office of Standards Services, Standards Code and Information, National Institute of Standards and Technology, U.S. Dept. of Commerce, Dec. 4, 1989 [copy maintained in the office of N.C.J. INT'L L. & COM. REG.]. The standards promulgated by CEN and CENELEC are given more weight than voluntary standards and are looked upon as regulations. In hearings before the Subcommittee on Europe and the Middle East, and on International Economic Policy and Trade the following exchange took place:

Cong. GEJDENSON: If CEN/CENELEC writes standards . . . not similar to American standards . . . will not the European industry risk being shut out of the U.S. market?

Mr. KINN: No. . . . [O]ur standards are predominantly voluntary. Their standards become quasi-regulatory.

Cong. GEJDENSON: So in our case the standards are simply guidelines . . . ?

Mr. KINN: In the U.S., that is the way it is. Unless a regulatory body of the U.S. Government takes that standard over and makes it mandatory.

. . . .  
The standards they adopt . . . are . . . looked upon by everyone as a regulation, not as a standard, and they follow them. We do not do that in the United States.

ests, however, is also limited at this stage. As noted, CEN and CENELEC are private organizations advised by technical committees. EC Member States may have direct input to CEN and CENELEC through their standardization institutes or through industry representation on the technical committees.

The proceedings conducted by CEN and CENELEC are essentially closed and nonmember industries have traditionally been uninformed of both the content of the proposals and the stage of their review.<sup>72</sup> U.S. efforts to increase the transparency of standard development within CEN and CENELEC have met with some minor success. The American National Standards Institute has obtained agreement from the executive board of CEN and CENELEC to publish a monthly review of their activity.<sup>73</sup>

These concessions have served to make the process more transparent. This has helped to alert nonmember industry to coming changes so that they can timely adjust to those changes. However, nonmember industry has limited and indirect input in developing these changes. The EC has defended their "members only" standard setting process by stating that the EC does not have a seat at the table for discussion of U.S. trade policy, such as the trade policy under the 1988 Trade Act.<sup>74</sup> The EC also argues that the negotiated settlement, whereby U.S. firms would receive the working papers used by CEN and CENELEC before the draft standard is issued to the public, will alleviate any problems otherwise caused by the failure to allow U.S. firms to participate directly in the process of standard setting. In addition, the EC cites nonmember state participation in the international standard setting organizations such as the International Standards Organization (ISO) and the International Electrotechnical Commission (IEC), in which EC Member States also participate, as evidence of nonmember state input. This response by the EC, however, misses the point. EC industry has always had seats at the table of hundreds of organizations throughout the United States and in non-EC countries that set voluntary product standards. EC industry has also been free to comment on nonvoluntary standards promulgated by U.S. agencies.<sup>75</sup> Furthermore, although the agreement to advise U.S. businesses of the stage in the proceeding and to disclose working papers represents an improvement in the system, there are no guarantees that this information will be pro-

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Hrg. Rep. 23-441, *supra* note 11, at 269.

<sup>72</sup> Hrg. Rep. 23-441, *supra* note 11, at 295.

<sup>73</sup> See *EC Official Rejects Role for Outsiders on Standards, But Promised Flexibility*, Daily Exec. Rep. (BNA) No. 82, at A-1 (May 1, 1989). U.S. Dept. of Commerce News, International Trade Administration, Press Release No. ITA 89-68 (Oct. 6, 1989).

<sup>74</sup> Hrg. Rep. 23-360, *supra* note 11, app. at 30.

<sup>75</sup> *Id.* See *supra* note 51.

vided in a complete and timely fashion.<sup>76</sup> Moreover, working papers are not an adequate substitute for discussions of the positions of the various interests and the chance to offer comments on the proper standard to the participants while the standard is in its formative stage. Without the ability to examine the information on which the final decision for a standard is based, non-EC companies can have little influence, and will be effectively excluded from the standard setting process.<sup>77</sup> Although CEN and CENELEC have agreed to use international standards where they exist, the European influence on the development of these standards must be considered. The EC and EFTA countries control eighteen votes at the national level. Other countries, such as the United States, have only one vote.

### III. The U.S. Administrative Procedure Act in Application to Standard Setting Bodies

Since 1946 the Administrative Procedure Act (APA)<sup>78</sup> has specified the formal procedure that U.S. agencies must follow when issuing rules, whether they be legislative or adjudicatory.<sup>79</sup> The APA requires that agencies engaged in standard setting or rulemaking: (1) provide the public with notice of the proposed rulemaking;<sup>80</sup> (2) solicit and consider comments on the proposed rule by interested parties,<sup>81</sup> and (3) issue a "concise general statement of their basis

<sup>76</sup> A delay in notifying U.S. companies can create a significant competitive edge. Hrg. Rep. No. 23-441, *supra* note 11, at 265 (statement of Mr. Kinn, Staff Vice President, Electronic Industries Association).

<sup>77</sup> Hrg. Rep. 23-360, *supra* note 11, app. at 28. For an account of the difficulties a firm may experience as a result of differing product standards, see *Getting Your Bear to Market or Breaking the "Bear-iers" to Product Approval Under the New Toy Safety Directive* (Annex II, U.S. Chamber of Commerce) [copy maintained in the office of N.C.J. INT'L L. & COM. REG.].

<sup>78</sup> Pub. L. No. 404, ch. 324, 60 Stat. 237 (1946) amended by Pub. L. No. 89-554, 80 Stat. 378 (1966) (codified as amended at 5 U.S.C. §§ 551-59, 701-06 (1988)).

<sup>79</sup> See 5 U.S.C. §§ 553-54 (1988). The APA has evolved considerably from legislative amendment and judicial construction. Some legislative changes include: Pub. L. No. 90-23, § 2, 81 Stat. 56 (1967); Pub. L. No. 90-83, § 1(1)(B), 81 Stat. 195 (1967); Pub. L. No. 93-579, § 4, 88 Stat. 1905 (1974); and Pub. L. No. 94-409, § 3(b), 90 Stat. 1246 (1976).

<sup>80</sup> 5 U.S.C. § 553(b) (1988). With respect to the notice requirements, the Act provides:

(b) General notice of proposed rulemaking shall be published in the Federal Register, unless persons subject thereto . . . have actual notice thereof . . . . The notice shall include -

(1) a statement of the time, place and nature of public rulemaking proceedings;

(2) reference to the legal authority under which the rule is proposed; and

(3) either the terms or substance of the proposed rule or a description of the subject and issues involved.

*Id.*

<sup>81</sup> *Id.* § 553(c). The Act provides that, "[a]fter notice required . . . the agency shall give interested persons an opportunity to participate in the rulemaking through submission of written data, views, or argument . . ." *Id.*



and purpose"<sup>82</sup> justifying the rule in light of comments received.<sup>83</sup> The publication requirements do not apply to interpretative rules or policy statements.<sup>84</sup> They also do not apply when notice is impracticable, unnecessary, or contrary to the public interest.<sup>85</sup>

The APA is bolstered by a 1978 Executive Order requiring that agencies adopt procedures to conform existing and future regulations to the APA: "To achieve these objectives, regulations shall be developed through a process which ensures that . . . opportunity exists for early participation and comment by . . . businesses, organizations and other members of the public . . . [so that] meaningful alternatives are considered and analyzed before the regulation is issued . . ." <sup>86</sup> The most common form of rulemaking under the APA is informal and is governed by Section 553.<sup>87</sup> Formal rulemaking is less common but provides for notice and comment.<sup>88</sup>

The purpose of the APA notice requirement is not to allow parties to insist that a rule be fashioned in a particular way, but rather to assure fairness and mature consideration of rules of general application and to give affected members of the public an opportunity to comment.<sup>89</sup> Solicitation of comments allowing public participation in the rulemaking process is fundamental to the APA. Moreover, it serves as an efficient channel through which experts in the field can provide information that may have been overlooked by the agency.<sup>90</sup> Through this forum experts can discover abstruse effects of proposed rules, demonstrate a need for alternatives, and propose less burdensome or more appropriate alternatives.<sup>91</sup> In sum, notice and comment rulemaking results in more informed decisionmaking in matters of substantial impact.<sup>92</sup>

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<sup>82</sup> 5 U.S.C. § 553(c) (1988). See also *National Petroleum Refiners Ass'n v. Federal Trade Comm'n*, 392 F.Supp. 1052, 1053 (D.C. Cir. 1974) (requiring the government to consider the relevant matters presented).

<sup>83</sup> *Rockway v. U.S. Department of Agriculture*, 514 F.2d 809, 814 (D.C. Cir. 1975).

<sup>84</sup> 5 U.S.C. § 553(b)(3)(A)-(B) (1988).

<sup>85</sup> *Id.*

<sup>86</sup> Exec. Order No. 12,044, 43 Fed. Reg. 12,661 (1978). For a discussion of the procedure by which U.S. agencies must consider the effects of their rules on small entities, see Freedman, Singer & Swain, *The Regulatory Flexibility Act: Orienting Federal Regulation to Small Business*, 93 DICK. L. REV. 439 (1989).

<sup>87</sup> 5 U.S.C. § 553.

<sup>88</sup> *Id.* §§ 553, 556.

<sup>89</sup> *American Standard Inc. v. United States*, 602 F.2d 256, 267 (Ct. Cl. 1979). See also *Pacific Coast European Conference v. United States*, 350 F.2d 197, 205-06 (9th Cir.), cert. denied, 382 U.S. 958 (1965).

<sup>90</sup> An example of a recent voluntary U.S. government standard developed with the input of industry is United States Standards for Grades of Canned Pineapples, 55 Fed. Reg. 3,029 (1990).

<sup>91</sup> *Dow Chemical U.S.A. v. Consumer Product Safety Comm'n*, 459 F. Supp. 378, 391 (W.D. La. 1978).

<sup>92</sup> *Standard Oil Co. v. Department of Energy*, 596 F.2d 1029, 1058 (Temp. Emer. Court App. 1978). See Gellhorn & Robinson, *Perspective on Administrative Law*, 75 COLUM. L. REV. 771 (1975).

A. *Public Accountability: The Essential Requirement of Basis and Findings*

It is clear from the legislative history of the APA that the U.S. Congress recognized a need for relating rules to a factual basis: "The agency must analyze and consider all relevant material presented. The required statement of the basis and purpose of rules issued should not only relate to the data so presented but with reasonable fullness explain the factual basis and objectives of the rule."<sup>93</sup> Demonstrable evidence that the agency has in fact considered comments of the public is necessary not only to justify the agency's decision in the eyes of the public, but also to force the agency to consider suggestions systematically.

Since the APA's adoption, the judicial and legislative branches have expanded the requirement that the agency disclose the "general basis and purpose" of a rule or standard far beyond what appears on the face of the APA.<sup>94</sup> For example, in *Automotive Parts and Accessories Association v. Boyd*,<sup>95</sup> the court found that the "concise general statement of basis and purpose" must enable the public to "see what major issues of policy were ventilated by the . . . proceedings . . . and why the agency reacted to them as it did."<sup>96</sup> A more significant expansion occurred in *Kennecott Copper Corp. v. Environmental Protection Agency (EPA)*.<sup>97</sup> The court in *Kennecott* found that in the interest of "expeditious disposition of changes to standards [the Administrator of the EPA] is required to supply an implementing statement that will enlighten the court as to the basis on which he reached the . . . standard."<sup>98</sup> Even if the rules turn on choices of policy, on assessment of risks, or on predictions dealing with matters on the frontiers of scientific knowledge, the courts have interpreted the APA to demand "adequate reasons and explanations."<sup>99</sup> In short, the APA contemplates that rules will be made through a constructive dialogue between agency experts and concerned members of the public.<sup>100</sup>

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<sup>93</sup> S. Doc. No. 248, 79th Cong., 2nd Sess. 201, 259 (1946).

<sup>94</sup> See 1 K. DAVIS, ADMINISTRATIVE LAW TREATISE § 6:12, at 496 (1972).

<sup>95</sup> 407 F.2d 330 (D.C. Cir. 1968) (concerning federal automotive safety standards).

<sup>96</sup> *Id.* at 338.

<sup>97</sup> 462 F.2d 846 (D.C. Cir. 1972) (involving a rule promulgated by the EPA limiting sulfur oxide output to 60 micrograms per meter).

<sup>98</sup> *Id.* at 850.

<sup>99</sup> *Amoco Oil Co. v. U.S. Environmental Protection Agency*, 501 F.2d 722, 741 (D.C. Cir. 1974).

<sup>100</sup> Wright, *The Courts and the Rulemaking Process: The Limits of Judicial Review*, 59 CORN. L. REV. 375, 381 (1974). See *contra* *Vermont Yankee Nuclear Power Corp. v. National Resources Defense Council, Inc.*, 435 U.S. 519, 523-25 (1978). "Even apart from the Administrative Procedure Act this Court has . . . emphasized that the formation of [review] procedures [are] basically to be left within the discretion of the agencies to which Congress ha[s] confided the responsibility for substantive judgment." *Id.* at 524.

*B. Application to EC Standard Setting*

The methods and procedures embodied in the APA are in striking contrast to those employed in EC standard setting. The APA does not give U.S.-based companies more consideration or greater access than foreign-based companies for purposes of considering comments. It invites and considers comments by all interested parties during the development of standards while there is still adequate time for meaningful consideration.

The APA has governed the issuance of thousands of pages of regulations dealing with issues ranging from the deceptive labeling and advertising of adhesive compositions,<sup>101</sup> to standards relating to pesticides,<sup>102</sup> livestock,<sup>103</sup> sleeping bag sizes,<sup>104</sup> fresh fruit, vegetables, and other food products.<sup>105</sup> In 1989 the APA served as the mechanism for the promulgation of more than one thousand proposed rules. The APA has been successful as a methodical approach to standard setting, resulting in rules that are better constructed to effect intent with minimal burden.

The APA has direct application to the EC standard setting process in that it provides a useful model for the consideration of comments. The APA also is a valuable tool because of the considerable body of case law interpreting the statute.<sup>106</sup> Through the development of a written procedure following the primary guidelines of the APA—the requirement of notice, solicitation of comment, and disclosure of basis and findings—EC and non-EC industries would benefit from rules issued as a result of informed decisionmaking. The APA would be especially helpful at the CEN or CENELEC stage, when the details of standards are determined. This stage in the process is equivalent to standard setting at the U.S. agency level. It also is the stage where the political decision of what type of standards should be set is replaced with the implementation of regulations effecting that political intent.

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<sup>101</sup> 16 C.F.R. § 235 (1989).

<sup>102</sup> 40 C.F.R. § 155 (1989).

<sup>103</sup> 7 C.F.R. § 53 (1989).

<sup>104</sup> 16 C.F.R. § 400 (1989).

<sup>105</sup> 7 C.F.R. § 51 (1989).

<sup>106</sup> A plethora of cases highlight U.S. agency requirements to consider the views of interested parties when setting standards. *See, e.g.*, *National Nutritional Foods Ass'n v. Federal Drug Administration*, 504 F.2d 761 (2d Cir. 1974); *Chrysler Corp. v. Department of Transportation*, 472 F.2d 659 (6th Cir. 1972); *Corn Products Co. v. Department of Health, Education & Welfare*, 427 F.2d 511 (3d Cir. 1970); *Marshall v. Pittsburgh-Des Moines Steel Co.*, 584 F.2d 638 (3d Cir. 1978); *Laminators Safety Glass Ass'n v. Consumer Product Safety Comm'n*, 578 F.2d 406 (D.C. Cir. 1978); *Riegel Textile Corp. v. Celanese Corp.*, 649 F.2d 894 (2d Cir. 1981); *National Knitwear Mfrs. Ass'n v. Consumer Product Safety Comm'n*, 666 F.2d 81 (4th Cir. 1981).

#### IV. Conclusion

More open participation in the EC standard setting process would be beneficial not only for U.S. interests, but also for the promotion of trade between the EC and nonmember states. The same goals that have guided European efforts to unify standards support efforts to extend those standards to nonmember nations. Input on standard setting will ensure greater coordination between EC and non-EC products, will facilitate joint ventures, will eliminate needless duplicate testing for goods destined for global distribution, and will discourage dumping of nonconforming products. Moreover, it will permit the EC to draw upon a broader pool of environmental studies, health and safety studies, and methods of practice, so that standards are more efficiently and effectively designed.

Application of the principles embodied in the U.S. Administrative Procedure Act, most notably the notice and comment requirements, could help achieve this result. Applying the APA procedures to CEN and CENELEC would permit non-EC member companies and their representatives to provide formal input on the standard under consideration. The weight accorded this input would not depend on physical presence in the EC or on political access, but upon the merits of the issues raised. Furthermore, by adopting an APA-type approach, the EC will consider the views of all participants, avoiding the perception of arbitrarily designed rules.

The purpose of this Article was to describe the standard setting process in the EC in order to reveal the need for greater openness and more effective participation by non-EC member state industries. The benefits from harmonized standards are clear, yet the process by which the standards are set can be improved by building into the procedure a method whereby participation by interested parties outside the European Community is solicited and considered.

The underlying economic principle of the Treaty of Rome and the Single European Act is that uniformity of otherwise diverse national requirements, especially standards, ensures free transferability of goods and services. This assists suppliers and consumers alike by creating a more efficient system for the production and marketing of goods. This principle can be better served if applied without prejudice to the global economy.

